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I

(Legislative acts)

REGULATIONS

REGULATION (EU, Euratom) 2016/2030 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 26 October 2016****amending Regulation (EU, Euratom) No 883/2013, as regards the secretariat of the Supervisory Committee of the European Anti-Fraud Office (OLAF)**

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 325 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a 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 Court of Auditors ⁽¹⁾,Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In accordance with Article 15(1) of Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ⁽³⁾, the Supervisory Committee of the European Anti-Fraud Office ('the Office') is tasked with regularly monitoring the implementation by the Office of its investigative function, in order to reinforce the Office's independence.
- (2) The framework for the implementation of the budgetary appropriations relating to the members of the Supervisory Committee should be set up in a way that avoids any appearance of a possible interference of the Office in their duties. Regulation (EU, Euratom) No 883/2013 should be adapted in order to allow for such a framework, while guaranteeing the same transparency of the appropriations for the operation of the Supervisory Committee as before.
- (3) In order to ensure that the Supervisory Committee functions effectively and efficiently, its secretariat should be provided directly by the Commission, independently from the Office, and the Commission should provide the secretariat with appropriate means to fulfil its function. In order to safeguard the Supervisory Committee's independence, the Commission should refrain from interfering with the monitoring functions of the Supervisory Committee.

⁽¹⁾ OJ C 150, 27.4.2016, p. 1.

⁽²⁾ Position of the European Parliament of 6 July 2016 (not yet published in the Official Journal) and Council decision of 20 September 2016.

⁽³⁾ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

- (4) Where the Office appoints a Data Protection Officer in accordance with Article 10(4) of Regulation (EU, Euratom) No 883/2013, that Data Protection Officer should continue to be competent for the processing of data by the secretariat of the Supervisory Committee.
- (5) Confidentiality obligations for the staff of the secretariat of the Supervisory Committee should continue to apply.
- (6) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽¹⁾ and on 18 March 2016 decided not to issue any opinion,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU, Euratom) No 883/2013 is amended as follows:

- (1) Article 10 is amended as follows:

- (a) in paragraph 4, the following subparagraph is added:

‘The Data Protection Officer shall be competent for the processing of data by the Office and by the secretariat of the Supervisory Committee.’;

- (b) in paragraph 5, the second subparagraph is replaced by the following:

‘In accordance with the Staff Regulations, the staff of the Office and the staff of the secretariat of the Supervisory Committee shall refrain from any unauthorised disclosure of information received in the exercise of their functions, unless that information has already been lawfully made public or is accessible to the public, and shall continue to be bound by that obligation after leaving the service.

The members of the Supervisory Committee shall be bound by the same obligation of professional secrecy in the exercise of their functions, and shall continue to be bound by that obligation after the end of their mandate.’.

- (2) In Article 15, paragraph 8 is replaced by the following:

‘8. The Supervisory Committee shall appoint its chair. It shall adopt its own rules of procedure, which shall, before adoption, be submitted to the European Parliament, the Council, the Commission and the European Data Protection Supervisor for information. Meetings of the Supervisory Committee shall be convened on the initiative of its chair or the Director-General. It shall hold at least 10 meetings per year. The Supervisory Committee shall take its decisions by a majority of its component members. Its secretariat shall be provided by the Commission, independently from the Office, and in close cooperation with the Supervisory Committee. Before the appointment of any staff to the secretariat, the Supervisory Committee shall be consulted and its views shall be taken into account. The secretariat shall act on the instructions of the Supervisory Committee and independently from the Commission. Without prejudice to its control over the budget of the Supervisory Committee and its secretariat, the Commission shall not interfere with the monitoring functions of the Supervisory Committee.

Officials assigned to the secretariat of the Supervisory Committee shall neither seek nor take instructions from any government or any institution, body, office or agency relating to the exercise of the monitoring functions of the Supervisory Committee.’.

⁽¹⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(3) Article 18 is replaced by the following:

'Article 18

Financing

The total appropriations for the Office shall be entered under a specific budget line within the section of the general budget of the European Union relating to the Commission and shall be set out in detail in an Annex to that section. The appropriations for the Supervisory Committee and its secretariat shall be entered into the section of the general budget of the European Union relating to the Commission.

The establishment plan of the Office shall be annexed to the establishment plan of the Commission. The establishment plan of the Commission shall include the secretariat of the Supervisory Committee.'

Article 2

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

It shall apply from 1 January 2017.

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

Done at Strasbourg, 26 October 2016.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
I. LESAY

**REGULATION (EU) 2016/2031 OF THE EUROPEAN PARLIAMENT OF THE COUNCIL
of 26 October 2016**

on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC

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(2) 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 ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Directive 2000/29/EC ⁽³⁾ sets out a plant health regime.
- (2) On 21 November 2008, the Council invited the Commission to proceed to an evaluation of that plant health regime.
- (3) In the light of the outcome of that evaluation and the experience gained from the application of Directive 2000/29/EC, that Directive should be replaced. In order to ensure uniform application of the new rules, the act replacing that Directive should take the form of a Regulation.
- (4) Plant health is very important for plant production, forests, natural and planted areas, natural ecosystems, ecosystem services and biodiversity in the Union. Plant health is threatened by species injurious to plants and plant products which now present a greater risk of being introduced into the Union territory owing to globalisation of trade and climate change. In order to fight that threat, it is necessary to adopt measures concerning the determination of the phytosanitary risks posed by those pests and the reduction of those risks to an acceptable level.
- (5) The need for such measures has long been recognised. They have formed the subject of international agreements and international conventions, including the International Plant Protection Convention (IPPC) of 6 December 1951 concluded at the United Nations Food and Agricultural Organisation (FAO) and its new, revised text approved by the FAO Conference in November 1997 at its 29th session. The Union and all its Member States are contracting parties to the IPPC.
- (6) It has become apparent that for the determination of the scope of this Regulation it is important to take into account bio-geographical factors to avoid the introduction into and spread within the territory of the European Union of pests not present in that territory. Consequently, Ceuta, Melilla and, with the exception of Madeira and the Azores, the outermost regions of Member States referred to in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU) should be excluded from the territorial scope of this Regulation. References to third countries should be read as references also to those excluded territories.

⁽¹⁾ OJ C 170, 5.6.2014, p. 104.

⁽²⁾ Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 18 July 2016 (not yet published in the Official Journal). Position of the European Parliament of 26 October 2016 (not yet published in the Official Journal).

⁽³⁾ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

- (7) Directive 2000/29/EC sets out rules concerning official controls to be carried out by the competent authorities as regards protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. It requires the Member States to carry out adequate and efficient control measures. Such adequate and efficient official controls measures should also be continued in the future. As part of the 'Smarter Rules for Safer Food' package, this Regulation should only provide for a limited number of provisions on official controls since those rules should be provided for in the framework of the horizontal legislation on official controls.
- (8) Criteria should be set out for the identification of pests for which the adoption of measures is necessary to prevent their introduction into and spread within the entire Union territory. Such pests are referred to as 'Union quarantine pests'. Criteria should also be set out for the identification of pests for which it is necessary to adopt measures of control only as regards one or more parts of that territory. Such pests are referred to as 'protected zone quarantine pests'. Where those pests are plants, the implementation of this Regulation should focus in particular on plants which are parasitic to other plants, when they are most injurious to plant health.
- (9) In order to allow efforts for the control of Union quarantine pests to concentrate on those pests whose potential economic, environmental or social impact is the most severe for the Union territory a restricted list of such pests ('priority pests') should be established.
- (10) In order to ensure that effective and timely action is taken where a Union quarantine pest is found to be present or suspected of being present, notification obligations should apply to the Member States, professional operators and the public.
- (11) Where those notification obligations imply that personal data of natural or legal persons should be disclosed to the competent authorities, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter on Fundamental Rights of the European Union ('the Charter'). However such a limitation would be necessary and proportionate to the achievement of the public interest objective of this Regulation.
- (12) A professional operator or other person suspecting or becoming aware of the presence of a Union quarantine pest in a plant, plant product or other object which is or was under its control should be under an obligation to notify the competent authority of that suspicion or awareness, to take all measures that may be appropriate as regards the elimination of the pest and the withdrawal or recall of the plants, plant products or other objects concerned, and to provide to the competent authority, other persons in the trade chain and the public with information.
- (13) Member States should take all necessary phytosanitary measures to eradicate Union quarantine pests, when found to be present in their territories. It is appropriate to set out measures which may be taken by Member States in such a case. It is also appropriate to set out the principles which the Member States should follow when deciding which measures should be taken. Those measures should include the establishment of demarcated areas, consisting of an infested zone and a buffer zone and, when applicable, the determination of actions which should be taken by a professional operator or other person in order to eliminate the quarantine pest or in order to prevent the spread of that pest.
- (14) In certain cases, Member States should impose measures for the eradication of quarantine pests on plants in private premises, because eradication of pests can only be successful if all sources of infestation are removed. For that purpose, the competent authorities of Member States should have legal access to those premises. This may constitute a limitation of Article 7 (Respect for Private and Family Life) and Article 17 (Right to Property) of the Charter. That limitation should be necessary and proportionate to the achievement of the public interest objective of this Regulation.
- (15) Prevention and early detection of the presence of pests is extremely important for timely and effective eradication. Member States should therefore carry out surveys for the presence of Union quarantine pests in the areas where those pests were not known to be present. In view of the number of Union quarantine pests and the time and resources required to carry out those surveys, Member States should establish multiannual survey programmes.

- (16) The Commission should be empowered to adopt measures where there is a suspected or confirmed presence of specific Union quarantine pests, in particular concerning their eradication and containment and the establishment of demarcated areas, surveys, contingency plans, simulation exercises and action plans.
- (17) Where a Union quarantine pest has become established in a demarcated area and cannot be eradicated, the Commission should adopt Union measures as regards the containment of that pest in that area.
- (18) In order to ensure swift and effective action against pests which are not Union quarantine pests, but which Member States consider may fulfil the conditions for inclusion in the list of Union quarantine pests, provision should be made for measures to be taken by Member States in the event that they become aware of the presence of such a pest. Similar provisions should be set out for the Commission.
- (19) Under certain conditions Member States should be allowed to adopt more stringent measures than those required by Union legislation.
- (20) Special provisions should apply to priority pests as regards, in particular, the provision of information to the public, surveys, contingency plans, simulation exercises, action plans for eradication and co-financing of measures by the Union.
- (21) Quarantine pests which are present in the Union territory but which are absent from specific parts of that territory designated as 'protected zones', and whose presence would have an unacceptable economic, social or environmental impact only within those protected zones, should be specifically identified and listed as 'protected zone quarantine pests'. The introduction into, movement within, and release into the respective protected zones of protected zone quarantine pests should be prohibited.
- (22) Rules should be established concerning the recognition, modification or revocation of recognition of protected zones, survey obligations for protected zones, action to be taken in the event that protected zone quarantine pests are found to be present in the respective protected zones, as well as the establishment of temporary protected zones. Strict rules should apply for the amendment of the extent, and for the revocation of recognition, of protected zones where a protected zone quarantine pest is found to be present within the respective protected zone.
- (23) A pest, which is not a Union quarantine pest, should be referred to as a 'Union regulated non-quarantine pest' if that pest is mainly transmitted through specific plants for planting, its presence on those plants for planting has an unacceptable economic impact as regards the intended use of those plants and it is listed as a Union regulated non-quarantine pest. In order to limit the presence of such pests, their introduction into, or movement within, the Union territory on the plants for planting concerned should be prohibited where those pests are present at an incidence above a certain threshold.
- (24) Certain plants, plant products and other objects pose an unacceptable risk due to their likelihood of hosting a Union quarantine pest. For some of those, acceptable risk-mitigation measures are available, while not for others. Depending on the availability of acceptable risk-mitigation measures, their introduction into, or movement within, the Union territory should be either prohibited or subject to special requirements. Those plants, plant products and other objects should be listed.
- (25) In addition to the measures taken to manage the unacceptable risk of the plants, plant products and other objects thereof, this Regulation should provide risk-based and preventive measures to protect the Union territory from pests that a plant, plant product or other object originating from a third country might introduce, on the basis of a preliminary assessment of that high risk. That preliminary assessment should take into account specific criteria appropriate for the plant, plant product or other object concerned. For that purpose scientific opinions or studies of the IPPC, the European and Mediterranean Plant Protection Organisation (EPPO), the European Food Safety Authority (EFSA) or Member State authorities should be taken into account. On the basis of that preliminary assessment, a list of those high-risk plants, plant products or other objects should be established and their introduction into the Union territory should be prohibited, pending a risk assessment carried out in accordance with IPPC standards. Those plants, plant products or other objects should not include those whose introduction in the Union territory is prohibited or subject to special and equivalent requirements, on the basis of a pest risk analysis, or which are subject to the temporary prohibitions set out in this Regulation.

- (26) Provision should be made for derogations from the prohibitions or special requirements as regards the introduction of plants, plant products and other objects into the Union territory. The Commission should be empowered to recognise certain measures of third countries as equivalent to the requirements for the movement within the Union territory of plants, plant products and other objects concerned.
- (27) Those prohibitions or requirements should neither apply to small quantities of certain plants, plant products and other objects, other than plants for planting, for non-commercial and non-professional purposes, nor, in certain cases, to the introduction into, and movement within, frontier zones of plants, plant products and other objects.
- (28) It is appropriate to provide for exemptions from the prohibition of introduction into, and movement within, the Union territory of pests, plants, plant products and other objects which are subject to those prohibitions and which are intended for certain purposes such as official testing, scientific or educational purposes, trials, varietal selection or breeding. Proper safeguards should be set and information should be provided to those concerned.
- (29) Plants moving into the Union from third countries and moving through postal services are in many cases non-compliant with the phytosanitary requirements of the Union. In order to raise awareness, specific rules concerning the information to be provided to travellers and clients of postal services should be set out.
- (30) A derogation from the Union rules for the introduction into, and movement within, the Union territory should be provided for plants, plant products and other objects in phytosanitary transit, subject to specific conditions.
- (31) The international trade of plants, plant products and other objects with which there is limited phytosanitary experience can potentially involve unacceptable risks of the establishment of quarantine pests which are not yet listed as Union quarantine pests and for which no measures have been adopted pursuant to this Regulation. In order to ensure swift and effective action against those newly identified or suspected pest risks associated with plants, plant products and other objects which are not subject to permanent requirements or prohibitions, but may qualify for such permanent measures, the Commission should have the possibility to adopt temporary measures in accordance with the precautionary principle and identify those plants, plant products and other objects taking into account objective and established elements.
- (32) It is necessary to set out prohibitions and special requirements, similar to those set out for the Union territory, in respect of the introduction into, and movement within, protected zones of plants, plant products and other objects that would pose a risk of an unacceptable level due to their likelihood of hosting the respective protected zone quarantine pest.
- (33) General requirements should be adopted concerning vehicles, machinery and packaging material used for plants, plant products and other objects to ensure that they are free from quarantine pests.
- (34) Member States should designate confinement facilities and quarantine stations. Requirements concerning the designation, authorisation, operation and supervision of those confinement facilities and quarantine stations and concerning the release of plants, plant products or other objects from those facilities or stations should be set out. Where those requirements include the maintenance of lists of staff and visitors entering the facilities and stations, this may constitute a limitation of Article 8 (Protection of Personal Data) of the Charter. However that limitation would be necessary and proportionate to the achievement of the public interest objective of this Regulation.
- (35) The Commission should keep a publicly available, updated list of all notifications it has received concerning emerging pests in third countries which may pose a risk to plant health in the Union territory.
- (36) In order to ensure effective implementation of this Regulation, certain professional operators subject to obligations under this Regulation should be registered in registers set up by the Member States. Requirements for registration, as well as exemptions from those requirements, should be set out.
- (37) In order to facilitate the detection of the source of an infestation by a quarantine pest, it is appropriate to require professional operators to keep records in respect of the plants, plant products and other objects supplied to them by professional operators and supplied by them to other professional operators. In view of the latency periods of some quarantine pests, and the time required for the detection of the source of infestation, records should be kept for at least three years.

- (38) Professional operators should also have in place systems and procedures to allow identification of the movements of plants, plant products and other objects within and between their own premises.
- (39) A phytosanitary certificate should be required for the introduction from third countries into the Union territory, and into protected zones, of certain plants, plant products and other objects. Those plants, plant products and other objects should be listed in the interest of transparency.
- (40) Phytosanitary certificates should also be required for the introduction of other plants from third countries into the Union territory. This is important in order to ensure an appropriate level of phytosanitary safety as well as effective overview of the import of those plants into the Union and the risks thereof. Those plants should, however, not be subject to the provisions on official controls at border control posts laid down in the relevant Union legislation.
- (41) Those phytosanitary certificates should comply with the requirements of the IPPC and should attest compliance with the requirements and measures established pursuant to this Regulation. In order to ensure the credibility of the phytosanitary certificates, rules should be established concerning the conditions of their validity and invalidation.
- (42) The movement within the Union territory, and into and within protected zones, of certain plants, plant products and other objects should only be permitted if accompanied by a plant passport, attesting compliance with the requirements and measures established pursuant to the provisions of this Regulation. Those plants, plant products and other objects should be listed in the interest of transparency.
- (43) Plant passports should not be required for plants, plant products and other objects supplied directly to final users, including home gardeners. However, certain exceptions should be set out.
- (44) In order to ensure the credibility of the plant passports, rules should be established concerning their content and form.
- (45) Plant passports should generally be issued by the authorised professional operator. It should be possible for competent authorities to decide to issue plant passports.
- (46) Rules should be set out for the issuance of plant passports, the examinations required for issuance, the attaching of plant passports, the authorisation and supervision of professional operators issuing plant passports, the obligations of authorised operators and the withdrawal of that authorisation.
- (47) In order to reduce the burden of authorised operators, examinations for issuing plant passports should, where appropriate, be combined with the examinations required under Council Directives 66/401/EEC ⁽¹⁾, 66/402/EEC ⁽²⁾, 68/193/EEC ⁽³⁾, 2002/54/EC ⁽⁴⁾, 2002/55/EC ⁽⁵⁾, 2002/56/EC ⁽⁶⁾, 2002/57/EC ⁽⁷⁾, 2008/72/EC ⁽⁸⁾ and 2008/90/EC ⁽⁹⁾.
- (48) Authorised operators should possess the necessary knowledge concerning pests.
- (49) Certain authorised operators may wish to establish a pest risk management plan, ensuring and demonstrating a high level of competence and awareness as regards pest risks as regards critical points in their professional activities and justifying special control arrangements with the competent authorities. Union rules should be established concerning the contents of those plans.

⁽¹⁾ Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ L 25, 11.7.1966, p. 2298/66).

⁽²⁾ Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ L 25, 11.7.1966, p. 2309/66).

⁽³⁾ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁽⁴⁾ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁽⁵⁾ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁽⁶⁾ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

⁽⁷⁾ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

⁽⁸⁾ Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

⁽⁹⁾ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

- (50) It is appropriate to provide for the replacement of plant passports and of phytosanitary certificates.
- (51) In cases of non-compliance with the Union rules, plant passports should be removed, invalidated and, for reasons of traceability, kept.
- (52) International Standard for Phytosanitary Measures No 15 *Regulation of Wood Packaging Material in International Trade* (ISPM15) requires wood packaging material to be marked with a specific mark, applied by duly authorised and supervised professional operators. This Regulation should set out requirements concerning the treatment, marking and repairing of wood packaging material in line with that standard. This Regulation should also set out rules for the authorisation and supervision of professional operators in the Union territory applying that mark.
- (53) Where so required by a third country, the respective plants, plant products or other objects should be moved from the Union territory to that third country with a phytosanitary certificate for export or re-export. In respect of the relevant provisions of the IPPC, those certificates should be issued by the competent authorities, respecting the contents of the model certificates for export and re-export set out by the IPPC. Protection should be offered to third countries against Union quarantine pests because of their acknowledged harmful nature, except where a Union quarantine pest is officially known to be present in the third country concerned and not under official control, or where it can be reasonably assumed that that Union quarantine pest does not meet the criteria to qualify as a quarantine pest for the third country concerned.
- (54) Where a plant, plant product or other object is moved through more than one Member States before it is exported to a third country, it is important that the Member State in which the plants, plant product or other objects were produced or processed exchanges information with the Member State which issues the phytosanitary certificate for export. That exchange of information is important in order to enable compliance with the requirements of the third country to be attested. Therefore, a harmonised 'pre-export certificate' should be established in order to ensure that the exchange of that information takes place in a uniform manner.
- (55) The Commission should establish an electronic system for the notifications required in accordance with this Regulation.
- (56) In order to take into account the most severe economic, social or environmental impact on the Union territory of certain Union quarantine pests, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of listing priority pests.
- (57) In order to ensure that the exceptions for Union quarantine pests and for plants, plant products and other objects originating from third countries or territories which are prohibited from being introduced into the Union territory, used for official testing, scientific or educational purposes, trials, varietal selection or breeding are implemented in a manner that does not pose any pest risk to the Union territory or parts of it, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the exchange of information between Member States and the Commission as regards the introduction into, movement within, and holding, multiplication and use in, the Union territory of the pests and plants, plant products and other objects concerned, the procedure and conditions for granting the corresponding authorisation, and the monitoring of compliance as well as the actions to be taken in the event of non-compliance.
- (58) In order to ensure the correct application of the derogations from the obligation to carry out annual surveys of demarcated areas, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of further specifying the pests concerned by those derogations and conditions for the application of those derogations.
- (59) In order to ensure that protected zones are established and function in a reliable manner, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of detailed rules for the surveys to be carried out for purposes of the recognition of protected zones and for the preparation and the content of surveys on protected zone quarantine pests.
- (60) In order to ensure a proportionate and restricted application of the exemptions concerning the movement of plants, plant products or other objects into or within frontier zones, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning the maximum width of

third country frontier zones and Member State frontier zones, the maximum distance of the movement of the plants, plant products and other objects concerned within the third country frontier zones and Member State frontier zones and the procedures concerning the authorisation of the introduction into, and movement within, the Member State frontier zones of plants, plant products and other objects.

- (61) In order to ensure that the registration of professional operators is proportionate to the objective of controlling pest risk, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out further categories of professional operators to be exempted from the obligation to register, particular requirements for the registration of certain categories of professional operators and the maximum figures for small quantities that the professional operators may supply to final users in order to be exempted from the obligation to register.
- (62) In order to ensure the credibility of phytosanitary certificates of third countries which are not contracting parties to the IPPC, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules supplementing the conditions for acceptance of phytosanitary certificates from those third countries.
- (63) In order to minimise the pest risks of plants, plant products or other objects moved within the Union territory, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the cases where, for particular plants, plant products or other objects, the exemption from the requirement to issue plant passports only applies for small quantities.
- (64) In order to ensure the reliability of examinations of plants, plant products and other objects carried out for the issuance of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules on visual examination, sampling and testing and the frequency and timing of the examinations.
- (65) In order to enhance the credibility of plant passports, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out criteria to be fulfilled by the professional operators in order for them to be authorised to issue plant passports and procedures ensuring that those criteria are met.
- (66) In order to ensure correct marking of wood packaging material and to take into account the development of international standards, and in particular of ISPM15, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending and supplementing the requirements concerning wood packaging material, including its introduction into the Union territory, and of specifying the requirements for authorisation of registered operators to apply the mark of wood packaging material in the Union territory.
- (67) In order to take into account the development of international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules concerning attestations for plants, plant products and other objects, other than wood packaging material, which would require the application of a specific attestation of compliance with the rules of this Regulation.
- (68) In order to ensure the utility and reliability of official attestations, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules setting out the contents of official attestations, the authorisation and supervision of professional operators issuing those attestations, as well as the elements of the export, re-export and pre-export certificate.
- (69) In order to adapt to the development of scientific and technical knowledge and of international standards, in particular the standards of the IPPC and the EPPO, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of rules amending the Annexes to this Regulation.
- (70) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽¹⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁽¹⁾ OJ L 123, 12.5.2016, p. 1.

- (71) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to listing Union quarantine pests; setting out the format of reports on surveys, as well as instructions on how to fill in that format; establishing the format of the multiannual survey programmes and related practical arrangements; setting out measures against specific Union quarantine pests; and adopting measures for a limited time as regards the risks posed by pests not listed as Union quarantine pests.
- (72) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to establishing a list of protected zones and of the respective protected zone quarantine pests; and amending the extent of, or revoking the recognition of, protected zones.
- (73) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to listing of Union regulated non-quarantine pests and the plants for planting concerned; and setting out measures to prevent the presence of Union regulated non-quarantine pests on the respective plants for planting.
- (74) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to: listing the plants, plant products and other objects which are prohibited from being introduced into the Union territory, and the third countries concerned; listing the plants, plant products and other objects subject to special requirements, and the special requirements concerned for their introduction into, and movement within, the Union territory; the provisional listing of the high-risk plants, plant products and other objects whose introduction into the Union territory is to be prohibited, and the third countries concerned; the procedure for risk assessment in connection with that listing; setting out, for third countries, requirements that are equivalent to the requirements for movement within the Union territory of plants, plant products or other objects; setting out arrangements for the presentation and use of posters and brochures concerning the introduction of plants, plant products and other objects into the Union territory; setting out specific conditions or measures concerning the introduction of particular plants, plant products and other objects into frontier zones of Member States; adoption of temporary measures concerning plants, plant products and other objects likely to pose newly identified pest risks or other suspected phytosanitary risks; adopting decisions on temporary measures taken by Member States concerning imminent danger; listing of plants, plant products and other objects which are prohibited from being introduced into certain protected zones; listing the plants, plant products and other objects subject to special requirements, and the special requirements concerned for their introduction into, and movement within, certain protected zones; and laying down rules concerning the requirements for quarantine stations and confinement facilities, and the release of plants, plant products and other objects from those stations and facilities.
- (75) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to setting out shorter or longer minimum periods for keeping the records concerning traceability by the professional operators, and requirements as to the accessibility of those records.
- (76) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to: listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into the Union territory; listing of the plants, plant products and other objects, and the respective third countries of origin or dispatch, for which a phytosanitary certificate is to be required for their introduction into certain protected zones from those third countries; listing of the plants, plant products and other objects, the third countries concerned, and the maximum quantity subject to be exempted from the requirement for a phytosanitary certificate when introduced in the Union territory; and setting out technical arrangements concerning the invalidation of the electronic phytosanitary certificates.
- (77) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to listing of the plants, plant products and other objects, for which a plant passport is to be required for their movement within the Union territory; listing of the plants, plant products and other objects for which a plant passport is to be required for their introduction, and movement within, certain protected zones; and specifying the protected zone pests, plants, plant products or other objects for which a plant passport for protected zones is required in the case of direct supply to a final user.

- (78) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to setting out the format specifications of the plant passport; identifying types and species of plants for planting for which exemptions from the indication of traceability code in the format of the plant passport should not apply; and setting out technical arrangements for the issuance of electronic plant passports.
- (79) In order to ensure uniform conditions for the implementation of this Regulation implementing powers should be conferred on the Commission with respect to setting out specific arrangements concerning the material, treatment and marking as regards repairing of wood packaging material; laying down the format specifications of attestations other than the mark of wood packaging material; laying down the procedures for the issuance of the pre-export certificate; and laying down specific rules concerning the submission of notifications.
- (80) The implementing powers conferred on the Commission should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (81) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to measures to be adopted against specific Union quarantine pests or pests not listed as Union quarantine pests, to the prohibition of introduction of certain plants, plant products and other objects into the Union territory or a protected zone or to subjecting such introduction to specific requirements and to temporary measures concerning plants, plant products and other objects likely to pose newly identified pest risks or other suspected phytosanitary risks, imperative grounds of urgency so require.
- (82) Council Directives 74/647/EEC ⁽²⁾ and 2006/91/EC ⁽³⁾ set out measures on the control of carnation leaf-rollers and San José Scale. Following the entry into force of those Directives, the pests concerned have become widespread throughout the Union territory, and their containment is thus no longer feasible. Those Directives should therefore be repealed.
- (83) Council Directives 69/464/EEC ⁽⁴⁾, 93/85/EEC ⁽⁵⁾, 98/57/EC ⁽⁶⁾ and 2007/33/EC ⁽⁷⁾ should be repealed, as new measures on the pests which they concern should be adopted in accordance with this Regulation. In view of the time and resources required to adopt those new measures, those Directives should be repealed with effect from 1 January 2022.
- (84) Regulation (EU) No 652/2014 of the European Parliament and of the Council ⁽⁸⁾ provides that grants for measures against pests are to concern certain pests listed in the Annexes to Directive 2000/29/EC, and certain pests not listed in those Annexes but subject to temporary Union measures adopted with regard to them. In addition to the provisions of that Regulation, this Regulation establishes the category of priority pests and it is essential that certain measures taken by the Member States as regards, in particular, priority pests are to be eligible for Union grants, including compensation paid to professional operators for the value of plants, plant products and other objects subject to destruction pursuant to the eradication measures set out in this Regulation. Regulation (EU) No 652/2014 should therefore be amended.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²⁾ Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers (OJ L 352, 28.12.1974, p. 41).

⁽³⁾ Council Directive 2006/91/EC of 7 November 2006 on control of San José Scale (OJ L 312, 11.11.2006, p. 42).

⁽⁴⁾ Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease (OJ L 323, 24.12.1969, p. 1).

⁽⁵⁾ Council Directive 93/85/EEC of 4 October 1993 on control of Potato Ring Rot (OJ L 259, 18.10.1993, p. 1).

⁽⁶⁾ Council Directive 98/57/EC of 20 July 1998 on control of *Ralstonia solanacearum* (Smith) Yabuuchi et al. (OJ L 235, 21.8.1998, p. 1).

⁽⁷⁾ Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC (OJ L 156, 16.6.2007, p. 12).

⁽⁸⁾ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

- (85) Technical amendments should also be made in Regulations (EU) No 228/2013 ⁽¹⁾ and (EU) No 1143/2014 ⁽²⁾ of the European Parliament and of the Council.
- (86) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to protective measures against pests of plants, cannot be sufficiently achieved by the Member States but can rather, by reason of its effect, complexity, and trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective.
- (87) For small and medium-sized enterprises (SMEs), this Regulation does not create a disproportionate administrative burden or economic impact. Under this Regulation, based on consultation with stakeholders, the special situation of SMEs has been taken into account where possible. A potential universal exemption for micro-enterprises, which make up the majority of companies, has not been considered, in view of the public policy objective of protecting plant health.
- (88) This Regulation takes into account the IPPC, the Agreement on the Application of Sanitary and Phytosanitary Measures and the guidelines set out under them.
- (89) In accordance with the principle of 'smart' regulation, the implementation of this Regulation should be coordinated with that of Regulation (EU) No 1143/2014 in order to ensure that Union plant health legislation applies fully and in its entirety.
- (90) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and notably respect for private and family life, the right to property, the protection of personal data, freedom to conduct business and the freedom of art and science. This Regulation should be applied by the Member States in accordance with those rights and principles,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

Subject matter, scope and definitions

Article 1

Subject matter and scope

1. This Regulation establishes 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 ('pests') and measures to reduce those risks to an acceptable level.
2. Where there is evidence that non-parasitic plants, other than those regulated under Article 4(1) of Regulation (EU) No 1143/2014, pose phytosanitary risks which would have a severe economic, social and environmental impact on the Union territory, those non-parasitic plants may be considered as pests for the purposes of this Regulation.
3. For the purposes of this Regulation, references to third countries shall be read as references to third countries, Ceuta, Melilla and to the territories that are referred to in Article 355(1) TFEU, with the exception of Madeira and the Azores.

For the purposes of this Regulation, references to the Union territory shall be read as references to the Union territory without Ceuta, Melilla and the territories that are referred to in Article 355(1) TFEU, other than Madeira and the Azores.

⁽¹⁾ Regulation (EU) No 228/2013 of the European Parliament and the Council of the 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).

⁽²⁾ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35).

*Article 2***Definitions**

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

- (1) 'plants' means living plants and the following living parts of plants:
 - (a) seeds, in the botanical sense, other than those not intended for planting;
 - (b) fruits, in the botanical sense;
 - (c) vegetables;
 - (d) tubers, corms, bulbs, rhizomes, roots, rootstocks, stolons;
 - (e) shoots, stems, runners;
 - (f) cut flowers;
 - (g) branches with or without foliage;
 - (h) cut trees retaining foliage;
 - (i) leaves, foliage;
 - (j) plant tissue cultures, including cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material;
 - (k) live pollen and spores;
 - (l) buds, budwood, cuttings, scions, grafts;

- (2) 'plant products' means unmanufactured material of plant origin and those manufactured products that, by their nature or that of their processing, may create a risk of the spread of quarantine pests.

Except where otherwise provided in the implementing acts adopted pursuant to Articles 28, 30 and 41, wood shall only be considered as a plant product if it fulfils one or more of the following criteria:

- (a) it retains all or part of its natural round surface, with or without bark;
 - (b) it has not retained its natural round surface due to sawing, cutting or cleaving;
 - (c) it is in the form of chips, particles, sawdust, wood waste, shavings or scrap, and has not undergone processing involving the use of glue, heat or pressure or a combination thereof to produce pellet, briquettes, plywood or particle board;
 - (d) it is, or is intended to be, used as packaging material, whether or not it is actually in use for transport of goods;
- (3) 'planting' means any operation for the placing of plants in a growing medium, or by grafting or similar operations, to ensure their subsequent growth, reproduction or propagation;
- (4) 'plants for planting' means plants intended to remain planted, to be planted or to be replanted;
- (5) 'other object' means any material or object, other than plants or plant products, capable of harbouring or spreading pests, including soil or growing medium;
- (6) 'competent authority' means the central authority or authorities of a Member State, or, where applicable, of a third country, responsible for the organisation of official controls and of other official activities, or any other authority to which that responsibility has been conferred, in accordance with Union legislation on official controls;
- (7) 'lot' means a number of units of a single commodity, identifiable by its homogeneity of composition, origin and other relevant elements, forming part of a consignment;
- (8) 'trade unit' means the smallest commercial or other useable unit applicable to the marketing stage concerned, which may be the subset or the whole of a lot;

- (9) 'professional operator' means any person, governed by public or private law, involved professionally in, and legally responsible for, one or more of the following activities concerning plants, plant products and other objects:
- (a) planting;
 - (b) breeding;
 - (c) production, including growing, multiplying and maintaining;
 - (d) introduction into, and movement within and out of, the Union territory;
 - (e) making available on the market;
 - (f) storage, collection, dispatching and processing;
- (10) 'registered operator' means a professional operator registered in accordance with Article 65;
- (11) 'authorised operator' means a registered operator authorised by the competent authority to issue plant passports in accordance with Article 89, to apply a mark in accordance with Article 98, or to issue attestations in accordance with Article 99;
- (12) 'final user' means any person acting for purposes which are outside that person's trade, business or profession who acquires plants or plant products for personal use;
- (13) 'test' means an official examination, other than visual, to determine if pests are present or to identify pests;
- (14) 'treatment' means a procedure, whether official or non-official, for the killing, inactivation or removal of pests, or for rendering those pests infertile, or for the devitalisation of plants or plant products;
- (15) 'incidence' means the proportion or number of units in which a pest is present in a sample, consignment, field or other defined population;
- (16) 'establishment' means the perpetuation, for the foreseeable future, of a pest within an area after entry;
- (17) 'eradication' means the application of phytosanitary measures to eliminate a pest from an area;
- (18) 'containment' means the application of phytosanitary measures in and around an infested area to prevent the spread of a pest;
- (19) 'quarantine station' means any official station for holding pests, plants, plant products or other objects in quarantine;
- (20) 'confinement facility' means any facility, other than quarantine stations, where pests, plants, plant products or other objects are kept under confinement conditions;
- (21) 'traceability code' means a letter, numerical or alphanumerical code that identifies a consignment, lot or trade unit, used for traceability purposes, including codes referring to a lot, batch, series, date of production or professional operator documents;
- (22) 'phytosanitary measure' means any official measure having the purpose to prevent the introduction or spread of quarantine pests or to limit the economic impact of regulated non-quarantine pests.

CHAPTER II

Quarantine pests

Section 1

Quarantine pests

Article 3

Definition of quarantine pests

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

- (a) its identity is established, within the meaning of point (1) of Section 1 of Annex I;

- (b) it is not present in the territory, within the meaning of point (2)(a) of Section 1 of Annex I, or, if present, is not widely distributed within that territory, within the meaning of points (2)(b) and (c) of Section 1 of Annex I;
- (c) it is capable of entering into, becoming established in and spreading within the territory, or, if present in the territory, but not widely distributed, is capable of entering into, becoming established in and spreading within those parts of that territory where it is absent, within the meaning of point (3) of Section 1 of Annex I;
- (d) its entry, establishment and spread would, within the meaning of point (4) of Section 1 of Annex I, have an unacceptable economic, environmental or social impact on that territory, or, if present but not widely distributed, for those parts of the territory where it is absent; and
- (e) feasible and effective measures are available to prevent the entry into, establishment in or spread of that pest within, that territory and to mitigate the risks and impact thereof.

Section 2

Union quarantine pests

Article 4

Definition of Union quarantine pests

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

Article 5

Prohibition of introduction, movement, holding, multiplication or release of Union quarantine pests

1. A Union quarantine pest shall not be introduced into, moved within, or held, multiplied or released in, the Union territory.
2. The Commission shall, by means of an implementing act, establish a list of pests which fulfil the conditions listed in Article 3 in respect of the Union territory ('list of Union quarantine pests').

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

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

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

3. Where the results of an assessment show that a pest not included in the list of Union quarantine pests fulfils the conditions listed in Article 3 in respect of the Union territory, or that a pest included in the list of Union quarantine pests no longer fulfils one or more of those conditions, the Commission shall, by means of implementing acts, amend the implementing act referred to in paragraph 2 of this Article accordingly by adding the pest concerned to, or removing it from, that list.

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

The Commission may, by means of implementing acts, replace the implementing act referred to in paragraph 2 of this Article for the purpose of consolidating amendments.

4. The implementing acts referred to in paragraphs 2 and 3 shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Article 6***Priority pests**

1. Union quarantine pests are 'priority pests' if they fulfil all of the following conditions:
 - (a) they fulfil, as regards the Union territory, one or more of the conditions set out in point (2) of Section 1 of Annex I;
 - (b) their potential economic, environmental or social impact is the most severe in respect of the Union territory as set out in Section 2 of Annex I;
 - (c) they are listed in accordance with paragraph 2 of this Article.
2. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by establishing a list of the priority pests ('list of priority pests').

Where the results of an assessment show that a Union quarantine pest fulfils the conditions referred to in paragraph 1 of this Article, or that a pest no longer fulfils one or more of those conditions, the Commission is empowered to adopt delegated acts in accordance with Article 105 amending the list referred to in the first subparagraph accordingly by adding the pest concerned to, or removing it from, that list.

The Commission shall make that assessment available to the Member States without delay.

Where, in the case of a serious pest risk, imperative grounds of urgency so require, the procedure provided for in Article 106 shall apply to delegated acts adopted pursuant to this Article.

*Article 7***Amendment of Section 1 of Annex I**

The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Section 1 of Annex I in order to adapt it to the development of scientific and technical knowledge and of relevant international standards.

*Article 8***Union quarantine pests used for official testing, scientific or educational purposes, trials, varietal selections or breeding**

1. By way of derogation from Article 5(1), Member States may, on application, temporarily authorise the introduction into, the movement within, and the holding and multiplication in, their territory of Union quarantine pests or pests subject to the measures adopted pursuant to Article 30(1) for official testing, scientific or educational purposes, trials, varietal selections, or breeding.

An authorisation shall be granted for the activity concerned only if adequate restrictions are imposed to ensure that the introduction, movement, holding, multiplication or use of the pest concerned does not result in its establishment or spread within the Union territory, taking into account the identity, biology and means of dispersal of the pest, the activity envisaged, the interaction with the environment and other relevant factors relating to the risk posed by that pest.

2. Authorisations granted pursuant to paragraph 1 shall include all of the following conditions:
 - (a) the pest is to be kept in a location and under conditions which:
 - (i) the competent authorities consider to be appropriate; and
 - (ii) are referred to in the authorisation;
 - (b) the activity involving the pest is to be carried out in a quarantine station or a confinement facility designated by the competent authority in accordance with Article 60 and referred to in the authorisation;

- (c) the activity involving the pest is to be carried out by personnel:
 - (i) whose scientific and technical competence is considered to be appropriate by the competent authority; and
 - (ii) who are referred to in the authorisation;
- (d) the pest is to be accompanied by the authorisation when introduced into, moved within, or held or multiplied in, the Union territory.

3. Authorisations granted pursuant to paragraph 1 shall be limited as to the quantity of the pest that can be introduced, moved, held, multiplied or used and the length of time that are adequate for the activity concerned. Authorisations shall not exceed the capacity of the designated quarantine station or confinement facility.

Authorisations shall include the restrictions necessary to adequately eliminate the risk of establishment and spread of the respective Union quarantine pest or pest subject to the measures adopted pursuant to Article 30(1).

4. The competent authority shall monitor compliance with the conditions referred to in paragraph 2 and the limitation and the restrictions referred to in paragraph 3 and take the necessary action in the event of non-compliance. Where appropriate, that action shall be the revocation of the authorisation referred to in paragraph 1.

5. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by laying down detailed rules concerning:

- (a) the exchange of information between Member States and the Commission concerning the introduction into, movement within, and holding, multiplication and use in, the Union territory of the pests concerned;
- (b) the procedure and conditions for granting the authorisation referred to in paragraph 1; and
- (c) the monitoring of compliance and the actions to be taken in the event of non-compliance, as referred to in paragraph 4.

Article 9

Notification of an imminent danger

1. Where a Member State has evidence that there is an imminent danger of the entry of a Union quarantine pest into the Union territory or into a part of it where that pest is not yet present, the Member State shall immediately notify the Commission and the other Member States of that evidence in writing.

2. Paragraph 1 shall also apply to a pest that is not included in the list of Union quarantine pests, where:

- (a) the pest is subject to the measures adopted pursuant to Article 30(1); or
- (b) the Member State concerned considers that the pest may fulfil the conditions for inclusion in the list of Union quarantine pests.

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

Article 10

Official confirmation by the competent authorities of the presence of a Union quarantine pest

Where a competent authority suspects or has received evidence concerning the presence of a Union quarantine pest, or a pest subject to measures adopted pursuant to Article 30(1), in a part of the territory of its Member State where that pest was previously not known to be present, or in a consignment of plants, plant products or other objects introduced into, intended to be introduced into, or moved within, the Union territory, it shall immediately take the measures necessary to confirm whether that pest is present ('to officially confirm').

That official confirmation shall be based on a diagnosis from an official laboratory designated by the competent authority in accordance with conditions and requirements set out in Union legislation on official controls.

Pending the official confirmation of the presence of the pest, the Member State concerned shall, where appropriate, take phytosanitary measures to eliminate the risk of spread of the pest.

The suspicion or evidence referred to in the first paragraph of this Article may be based on any information received pursuant to Articles 14 and 15, or any other source.

Article 11

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

A Member State shall notify the Commission and the other Member States where its competent authority officially confirms any of the following situations:

- (a) the presence in its territory of a Union quarantine pest not known to be present there;
- (b) the presence of a Union quarantine pest in a part of its territory where it was previously not present;
- (c) the presence in its territory of a Union quarantine pest in a consignment of plants, plant products or other objects introduced into, intended to be introduced into, or moved within, the Union territory.

Notification under the first paragraph shall be made by the single authority, as referred to in Union legislation on official controls, of the Member State concerned and through the electronic notification system referred to in Article 103.

Article 12

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

1. Where one of the situations referred to in Article 11 is officially confirmed, the competent authority shall ensure that professional operators whose plants, plant products or other objects may be affected are informed of the presence of the Union quarantine pest without delay.
2. The Commission shall establish and keep up to date a publicly available list of all notifications it has received concerning emerging pests in third countries which may pose a risk to plant health in the Union territory.

That list may be part of the electronic system referred to in Article 103.

Article 13

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

Where one of the situations referred to in points (a) and (b) of the first paragraph of Article 11 is officially confirmed as regards a priority pest, the competent authority shall inform the public about the measures it has taken or intends to take and about any measures to be taken by relevant categories of professional operators or other persons.

Article 14

Measures to be taken immediately by professional operators

1. Where a professional operator suspects or becomes aware that a Union quarantine pest or a pest subject to measures adopted pursuant to Article 30(1) is present in plants, plant products or other objects which are under that operator's control, it shall immediately notify the competent authority thereof, in order for that competent authority to take actions in accordance with Article 10. Where appropriate, the professional operator shall also immediately take precautionary measures to prevent the establishment and spread of that pest.
2. The competent authority may decide that the notification referred to in paragraph 1 is not required where a specific pest is known to occur in an area. In such a case, it shall inform the professional operators concerned of that decision.

3. Where a professional operator receives an official confirmation concerning the presence of a Union quarantine pest in plants, plant products or other objects which are under that operator's control, it shall consult the competent authority regarding the action to be taken and shall proceed, as applicable, with the actions referred to in paragraphs 4 to 7.

4. The professional operator shall immediately take the necessary measures to prevent the spread of that pest. Where the competent authority has provided instructions concerning those measures, the professional operator shall act in accordance with those instructions.

5. Where so instructed by the competent authority, the professional operator shall take the necessary measures to eliminate the pest from the plants, plant products or other objects concerned and from that operator's premises, land, soil, water or other infested elements which are under its control.

6. Unless otherwise instructed by the competent authority, the professional operator shall, without delay, withdraw from the market the plants, plant products and other objects which are under that operator's control and in which the pest could be present.

Where those plants, plant products or other objects have left the control of the professional operator, the professional operator shall, unless otherwise instructed by the competent authority, immediately:

- (a) inform the persons in the trade chain to whom those plants, plant products and other objects have been supplied of the presence of the pest;
- (b) provide those persons with guidelines on the necessary measures to be taken during shipment of the respective plants, plant products and other objects to reduce the risk of spread or escape of the pests concerned; and
- (c) recall those plants, plant products or other objects.

7. Where paragraph 1, 3, 4, 5 or 6 of this Article applies, the professional operator shall, on request, provide to the competent authority all information which is relevant for the members of the public. Without prejudice to Article 13, if action is necessary with regard to the plants, plant products or other objects in which the respective pest may be present, the competent authority shall inform the public as soon as possible of that fact.

Article 15

Measures to be taken by persons other than professional operators

1. Where any person other than a professional operator becomes aware of the presence of a Union quarantine pest or has reason to suspect such a presence, that person shall immediately notify the competent authority. Where that notification is not made in writing, the competent authority shall officially record it. If so requested by the competent authority, that person shall provide that authority with the information which is in its possession concerning that presence.

2. The competent authority may decide that the notification referred to in paragraph 1 is not required where a specific pest is known to be present in an area.

3. The person who made the notification referred to in paragraph 1 shall consult the competent authority on the action to be taken and shall, in accordance with the instructions of the competent authority, take the measures necessary to prevent the spread of that pest and to eliminate it from the plants, plant products or other objects concerned and, where applicable, from that person's premises.

Article 16

Derogations to notification obligations

The notification obligations referred to in Articles 14 and 15 shall not apply where:

- (a) a Union quarantine pest is found to be present in the infested zone of a demarcated area established for the containment of that pest, as referred to in Article 18(2);
- (b) a Union quarantine pest is found to be present in the infested zone of a demarcated area and subject to eradication measures requiring eight years or more, during the period of those first eight years.

*Article 17***Eradication of Union quarantine pests**

1. Where one of the situations referred to in points (a) and (b) of the first paragraph of Article 11 is officially confirmed, the competent authority shall immediately take all necessary phytosanitary measures to eradicate the relevant Union quarantine pest from the area concerned. Those measures shall be taken in accordance with Annex II.

That obligation to eradicate shall not apply where an implementing act concerning that pest, adopted pursuant to Article 28(2), provides otherwise.

2. The competent authority shall without delay investigate the source of the presence of the Union quarantine pest concerned, in particular where that presence may be related to movements of plants, plant products or other objects, and the possibility that the pest concerned has been spread to further plants, plant products or other objects by those movements.

3. Where the measures referred to in paragraph 1 concern the introduction into, or movement within, the Union territory of plants, plant products and other objects, the Member State concerned shall immediately notify those measures to the Commission and the other Member States.

4. The measures referred to in paragraph 1 and the investigations referred to in paragraph 2 shall be taken irrespective of whether the pest is present on public or private premises.

*Article 18***Establishment of demarcated areas**

1. Where one of the situations referred to in points (a) and (b) of the first paragraph of Article 11 is officially confirmed, the competent authority shall immediately establish one or more areas where the eradication measures referred to in Article 17(1) are to be taken ('demarcated area').

The demarcated area shall consist of an infested zone and a buffer zone.

2. The infested zone shall, as applicable, contain:

- (a) all plants known to be infested by the pest concerned;
- (b) all plants showing signs or symptoms indicating possible infestation by that pest;
- (c) all other plants liable to have been or become contaminated or infested by that pest, including plants liable to be infested due to their susceptibility to that pest and their close proximity to infested plants or common source of production, if known, with infested plants, or plants grown from them;
- (d) land, soil, water courses or other elements infested, or liable to be infested, by the pest concerned.

3. The buffer zone shall be adjacent to the infested zone and shall surround it.

Its extent shall be appropriate in view of the risk of the pest concerned spreading out of the infested zone naturally or by human activities in the infested zone and its surroundings, and shall be decided in accordance with the principles set out in Section 2 of Annex II.

However, where any risk of the pest spreading out of the infested zone is eliminated or reduced to an acceptable level through natural or artificial barriers, no buffer zone shall be required to be established.

4. By way of derogation from paragraph 1, where upon initial examination the competent authority concludes, in view of the nature of the pest, the plant, plant product or other object concerned and the site where it was found, that the pest concerned can be eliminated immediately, the competent authority may decide not to establish a demarcated area.

In that case, it shall carry out a survey to determine whether any further plants or plant products have been infested. On the basis of that survey, the competent authority shall determine whether there is a need to establish a demarcated area.

5. Where, in accordance with paragraphs 2 and 3, a demarcated area is to extend into the territory of another Member State, the Member State where the pest concerned was found to be present shall immediately contact the Member State into whose territory the demarcated area is to extend in order to allow that Member State to take all appropriate actions, as referred to in paragraphs 1 to 4.

6. Member States shall notify the Commission and the other Member States, by 30 April of each year, of the number and locations of the demarcated areas established, the pests concerned, and the respective measures taken during the preceding calendar year.

This paragraph shall apply without prejudice to any obligation to notify demarcated areas laid down in the implementing acts referred to in Article 104.

Article 19

Surveys and modifications of demarcated areas and lifting of restrictions

1. Competent authorities shall at least annually, at appropriate times, carry out a survey of each demarcated area as regards the development of the presence of the pest concerned.

Those surveys shall be carried out in accordance with Article 22(2).

2. Where, whether or not as a result of a survey as referred to in paragraph 1, a competent authority finds a presence of the pest concerned in the buffer zone, the Member State concerned shall immediately notify the Commission and the other Member States thereof.

3. Competent authorities shall modify the boundaries of infested zones, buffer zones and demarcated areas, where appropriate, in view of the results of the surveys referred to in paragraph 1.

4. Competent authorities may abolish a demarcated area and terminate the respective eradication measures where the pest-free status of that area has been verified. This will be the case where the following two conditions are fulfilled:

- (a) the survey referred to in paragraph 1 shows that the area has been found to be free from the pest concerned; and
- (b) the pest concerned has not been found to be present in that demarcated area for a sufficiently long period.

5. When deciding on the modifications referred to in paragraph 3 or the abolition of the demarcated area referred to in paragraph 4, the competent authority concerned shall take into account at least the following factors:

- (a) the biology of the pest and the vector concerned;
- (b) the presence of host plants;
- (c) the ecoclimatic conditions; and
- (d) the likelihood of the eradication measures having been successful.

6. By way of derogation from paragraph 1 of this Article, annual surveys shall not be required to be carried out in the infested zone of demarcated areas established for:

- (a) pests subject to eradication measures requiring eight years or more;
- (b) pests subject to the containment measures referred to in Article 28(2).

7. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by further specifying the pests referred to in point (a) of paragraph 6 of this Article and in point (b) of Article 16 and conditions for the application of those derogations.

*Article 20***Reports on measures taken in accordance with Articles 17, 18 and 19**

1. Where measures are taken by a Member State in an area adjacent to the border with another Member State, a report on the measures taken in accordance with Articles 17, 18 and 19 shall be submitted to that other Member State.
2. Where so requested by the Commission or by any other Member State, a Member State shall submit a report on specific measures taken in accordance with Articles 17, 18 and 19.

*Article 21***Amendment of Annex II**

The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Annex II in order to adapt it to the development of scientific and technical knowledge and of relevant international standards.

*Article 22***Surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pests**

1. Member States shall carry out risk-based surveys, over specific periods of time, checking at least for:
 - (a) the presence of any Union quarantine pest; and
 - (b) signs or symptoms of any pest subject to the measures referred to in Article 29 or to measures adopted pursuant to Article 30(1).

Those surveys shall take place in all areas where the pest concerned was not known to be present.

Those surveys shall not be required to be carried out for pests for which it is unequivocally concluded that they cannot become established or spread in the Member State concerned due to its ecoclimatic conditions or to the absence of the host species.

2. The design of the surveys referred to in paragraph 1 shall be based on the risk that the pest occurs in the area covered by each survey. They shall consist, at least, of visual examinations by the competent authority and, where appropriate, the collection of samples and performance of tests. Those surveys shall be carried out in all appropriate locations and shall include, where appropriate, premises, vehicles, machinery and packaging used by professional operators and other persons. They shall be based on sound scientific and technical principles and shall be carried out at appropriate times with regard to the possibility to detect the pest concerned.

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

3. Member States shall report to the Commission and the other Member States, by 30 April of each year, the results of the surveys referred to in paragraph 1 which were carried out in the preceding calendar year. Those reports shall include information on where the surveys were conducted, the timing of the surveys, the pests and the plants, plant products or other objects concerned, the number of inspections and samples taken, and the finding of each pest concerned.

The Commission may, by means of implementing acts, set out the format of those reports, as well as instructions on how to fill it in. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Article 23***Multiannual survey programmes and collection of information**

1. Member States shall establish multiannual survey programmes setting out the content of the surveys to be carried out pursuant to Article 22. Those programmes shall provide for the collection and recording of the scientific and technical evidence and other information referred to in the second subparagraph of Article 22(2).

The multiannual survey programmes shall include the following elements in conformity with Article 22(2):

- (a) the specific objective of each survey;
- (b) the scope of each survey as regards the area concerned and the time scale covered, as well as the pests, plants and commodities targeted;
- (c) the survey methodology and quality management including a description of the procedures for visual examination, sampling and testing and their technical justification;
- (d) the timing, frequency and numbers of scheduled visual examinations, samples and tests; and
- (e) the methods of recording and reporting the information collected.

The multiannual survey programmes shall be for a period of five to seven years.

2. Member States shall, on request, notify their multiannual survey programmes upon their establishment to the Commission and the other Member States.

3. The Commission may adopt implementing acts establishing the format of the multiannual survey programmes and the practical arrangements for the application of the elements set out in paragraph 1 to specific pest risks.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

Article 24

Surveys of priority pests

1. For each priority pest, Member States shall carry out a survey annually, as set out in Article 22(1) and (2). Those surveys shall include a sufficiently high number of visual examinations, sampling and testing, as appropriate for each priority pest, to ensure, as far as it is possible given the respective biology of each priority pest and the ecoclimatic conditions, with a high degree of confidence, the timely detection of those pests.

The surveys shall not be required to be carried out for pests for which it is unequivocally concluded that they cannot become established or spread in the Member State concerned due to its ecoclimatic conditions or to the absence of the host species.

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

Article 25

Contingency plans for priority pests

1. Each Member State shall draw up and keep up to date for each priority pest which is capable of entering into and becoming established in its territory, or a part thereof, a separate plan containing information concerning the decision-making processes, procedures and protocols to be followed, and the minimum resources to be made available and the procedures to make available further resources in the event of an officially confirmed or suspected presence of that pest ('the contingency plan').

Member States shall, at an appropriate stage, consult all relevant stakeholders in the process of drawing up and keeping up to date the contingency plans.

No contingency plans shall be required to be drawn up for pests for which it is unequivocally concluded that they cannot become established or spread in the Member State concerned due to its ecoclimatic conditions or to the absence of the host species.

2. Each contingency plan shall include the following:

- (a) the roles and responsibilities of the bodies involved in the execution of the plan in the event of an officially confirmed or suspected presence of the priority pest concerned, as well as the chain of command and procedures for the coordination of actions to be taken by competent authorities, other public authorities, delegated bodies or natural persons involved, laboratories and professional operators, including the coordination with neighbouring Member States and neighbouring third countries, where appropriate;
- (b) access of competent authorities to premises of professional operators, other relevant operators and natural persons;

- (c) access of competent authorities, where necessary, to laboratories, equipment, personnel, external expertise and resources necessary for the rapid and effective eradication or, where appropriate, containment of the priority pest concerned;
- (d) measures to be taken concerning the provision of information to the Commission, the other Member States, the professional operators concerned and the public as regards the presence of the priority pest concerned and the measures taken against it in the event that the presence of the pest concerned is officially confirmed or suspected;
- (e) arrangements for recording findings of the presence of the priority pest concerned;
- (f) the available assessments as set out in Article 6(2) and any assessment of the Member State as regards the risk of the priority pest concerned for its territory;
- (g) the risk management measures to be taken as regards the priority pest concerned, in accordance with Section 1 of Annex II, and the procedures to be followed;
- (h) principles for the geographical demarcation of demarcated areas;
- (i) protocols describing the methods of visual examinations, sampling and laboratory testing; and
- (j) principles concerning the training of personnel of the competent authorities and, where appropriate, the bodies, public authorities, laboratories, professional operators and other persons referred to in point (a).

Where appropriate, the items referred to in points (d) to (j) of the first subparagraph shall take the form of instruction manuals.

3. Contingency plans may be combined for multiple priority pests with similar biology and range of host species. In those cases, the contingency plan shall consist of a general part common to all priority pests covered by it and of specific parts for each priority pest concerned.

4. Within four years from the date of establishment of the list of priority pests, Member States shall establish a contingency plan for the priority pests included in that list.

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

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

5. Member States shall, on request, communicate their contingency plans to the Commission and to the other Member States, and shall inform all relevant professional operators through publication on the internet.

Article 26

Simulation exercises for priority pests

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

Those exercises shall take place with regard to all priority pests concerned within a reasonable period of time and with the involvement of the relevant stakeholders.

Those exercises shall not be required where the Member State concerned has recently taken measures for the eradication of the pest or pests concerned.

2. Simulation exercises concerning priority pests whose presence in one Member State could have an impact on neighbouring Member States may be carried out together by those Member States on the basis of their respective contingency plans.

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

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

*Article 27***Action plans for priority pests**

1. Where the presence of a priority pest is officially confirmed in the territory of a Member State pursuant to Article 10, the competent authority shall immediately adopt a plan (the 'action plan') setting out the measures for the eradication of that pest, as provided for in Articles 17, 18 and 19, or its containment, as provided for in Article 28(2), as well as a time schedule for the application of those measures.

The action plan shall include a description of the design and organisation of the surveys to be carried out and set out the number of visual examinations, samples to be taken and laboratory tests to be carried out, as well as the methodology to be applied for the examination, sampling and testing.

The action plan shall be based on the relevant contingency plan and shall be immediately communicated by the competent authority to the professional operators concerned.

2. Each Member State shall, on request, notify the Commission and the other Member States of the action plans it has adopted.

*Article 28***Union measures for specific Union quarantine pests**

1. The Commission may, by means of implementing acts, set out measures against specific Union quarantine pests. Those measures shall implement, specifically for each of the pests concerned, one or more of the following provisions:

- (a) Article 10 concerning measures to be taken in the event of suspicion and official confirmation by competent authorities of the presence of that Union quarantine pest;
- (b) Article 14 concerning measures to be taken immediately by professional operators;
- (c) Article 15 concerning measures to be taken by persons other than professional operators;
- (d) Article 17 concerning eradication of Union quarantine pests;
- (e) Article 18 concerning establishment of demarcated areas;
- (f) Article 19 concerning surveys and modifications of demarcated areas and lifting of restrictions;
- (g) Article 22 concerning surveys on Union quarantine pests and pests provisionally qualifying as Union quarantine pests;
- (h) Article 24 concerning surveys for priority pests, as regards the number of visual examinations, samples and tests for particular priority pests;
- (i) Article 25 concerning contingency plans for priority pests;
- (j) Article 26 concerning simulation exercises for priority pests;
- (k) Article 27 concerning action plans for priority pests.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

2. By way of derogation from Article 17, where it is concluded, on the basis of the surveys referred to in Article 19 or other evidence, that the eradication of the Union quarantine pest concerned in a demarcated area is not possible, the Commission shall adopt implementing acts referred to in paragraph 1 of this Article which set out measures with the purpose of containment.

For the purpose of reaching that conclusion, the Commission shall, without delay, take the necessary actions following the submission of the relevant evidence by the Member State concerned or any other source.

3. Where the Commission concludes that prevention measures in areas outside demarcated areas are necessary to protect the part of the Union territory where the Union quarantine pest concerned is not present, it may adopt implementing acts referred to in paragraph 1 setting out such measures.
4. The measures referred to in paragraphs 1, 2 and 3 shall be taken in accordance with Annex II, taking into account the specific risks of the Union quarantine pests concerned, the specific ecoclimatic conditions and risks as regards the Member States concerned and the need to implement the necessary risk-mitigation measures in a harmonised manner at Union level.
5. Until a measure has been adopted by the Commission, the Member State may maintain any measures that it has taken.
6. On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 107(3). Those acts shall be adopted in accordance with Annex II, taking into account the specific risks of the Union quarantine pests concerned, the specific ecoclimatic conditions and risks as regards the Member States concerned and the need to implement the necessary risk-mitigation measures in a harmonised manner at Union level.
7. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States of any cases of non-compliance with the measures adopted pursuant to this Article which create a risk of spread of Union quarantine pests.

Article 29

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

1. Where the presence of a pest that is not included in the list of Union quarantine pests is officially confirmed in the territory of a Member State, and the Member State considers that that pest may fulfil the conditions for inclusion in the list of Union quarantine pests, it shall immediately assess whether the pest fulfils the criteria set out in Subsection 1 of Section 3 of Annex I. If it concludes that those criteria are fulfilled, it shall immediately take eradication measures in accordance with Annex II. Articles 17 to 20 shall apply.

Where it is concluded, on the basis of the surveys referred to in Article 19 or other evidence, that the eradication of a pest in a demarcated area is not possible, Article 28(2) shall apply *mutatis mutandis*.

Where the presence of a pest fulfilling the criteria referred to in the first subparagraph is officially confirmed in a consignment of plants, plant products or other objects introduced into, or moved within, the territory of a Member State, that Member State shall take the necessary measures to prevent the entry of that pest into, and its establishment and spread in, the Union territory.

Where a Member State suspects the presence in its territory of a pest fulfilling the criteria referred to in the first subparagraph, Article 10 shall apply *mutatis mutandis*.

Pending the official confirmation of the presence of that pest, the Member State shall, where appropriate, take phytosanitary measures to mitigate the risk of it spreading.

2. After taking the measures referred to in paragraph 1, the Member State shall assess whether the pest concerned fulfils the criteria for quarantine pests set out in Section 1 of Annex I.
3. The Member State concerned shall notify the Commission and the other Member States of the presence of the pest referred to in paragraph 1. It shall also inform the Commission and the other Member States of the assessment referred to in that paragraph, the measures taken and the evidence justifying those measures.

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

Notifications of the presence of that pest shall be submitted through the electronic notification system referred to in Article 103.

*Article 30***Union measures concerning pests not listed as Union quarantine pests**

1. Where the Commission receives a notification as referred to in the first subparagraph of Article 29(3), or has other evidence concerning the presence in, or imminent danger of entry into, or spread within, the Union territory of a pest which is not included in the list of Union quarantine pests and it considers that that pest may fulfil the conditions for inclusion in that list, it shall immediately assess whether, as regards the Union territory, that pest fulfils the criteria set out in Subsection 2 of Section 3 of Annex I.

Where the Commission concludes that those criteria are fulfilled, it shall immediately, by means of implementing acts, adopt measures for a limited time as regards the risks posed by that pest. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

Those measures shall, where appropriate, implement, specifically for each of the pests concerned, one or more of the provisions referred to in points (a) to (g) of the first subparagraph of Article 28(1).

2. After adopting the measures referred to in paragraph 1, the Commission shall assess whether the pest concerned fulfils, as regards the Union territory, the criteria for quarantine pests set out in Section 1 of Annex I.

3. Where it is concluded, on the basis of surveys referred to in Articles 19 and 22 or other evidence, that the eradication of the pest concerned in a demarcated area is not possible, the implementing acts referred to in the second subparagraph of paragraph 1 of this Article may set out measures with the purpose of containment.

4. Where it is concluded that prevention measures in areas outside demarcated areas are necessary to protect the part of the Union territory where the pest concerned is not present, the implementing acts referred to in paragraph 1 may set out such measures.

5. The measures referred to in paragraphs 1, 3 and 4 shall be adopted in accordance with Annex II, taking into account the specific risks of the pests concerned and the need to implement the necessary risk-mitigation measures in a harmonised manner at Union level.

6. Until measures have been adopted by the Commission, the Member State concerned may maintain the measures that it has taken pursuant to Article 29.

7. On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 107(3). Those acts shall be adopted in accordance with Annex II, taking into account the specific risks of the pests concerned and the need to implement the necessary risk-mitigation measures in a harmonised manner at Union level.

8. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States of any cases of non-compliance with the measures adopted pursuant to this Article which create a risk of spread of the pests referred to in paragraph 1 of this Article.

*Article 31***More stringent requirements adopted by Member States**

1. Member States may apply within their territories more stringent measures than those adopted pursuant to Article 28(1), (2) and (3) and Article 30(1), (3) and (4), if justified by the objective of phytosanitary protection and in accordance with the principles set out in Section 2 of Annex II.

Those more stringent measures shall not impose, or result in, any prohibitions or restrictions on the introduction into, or movement within and through, the Union territory of plants, plant products and other objects, other than those imposed by Articles 40 to 58 and 71 to 102.

2. Member States shall immediately notify the Commission and the other Member States of measures taken by them in accordance with paragraph 1.

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

Section 3

Protected zone quarantine pests

Article 32

Recognition of protected zones

1. Where a quarantine pest is present in the Union territory but not in the territory of a Member State or a part thereof, and is not a Union quarantine pest, the Commission may, upon application of that Member State pursuant to paragraph 4, recognise such territory or part thereof as a protected zone in accordance with paragraph 3 as regards that quarantine pest ('protected zone quarantine pest').

2. A protected zone quarantine pest shall not be introduced into, moved within, or held, multiplied or released in, the respective protected zone.

Article 8 shall apply *mutatis mutandis* to the introduction into, movement within, and holding and multiplication in, protected zones of protected zone quarantine pests.

3. The Commission shall, by means of an implementing act, establish a list of protected zones and the respective protected zone quarantine pests. That list shall include the protected zones recognised in accordance with the first subparagraph of point (h) of Article 2(1) of Directive 2000/29/EC, the respective pests listed in Part B of Annex I and Part B of Annex II to Directive 2000/29/EC, and codes specifically attributed to those pests.

The Commission may, by means of implementing acts amending the implementing act referred to in the first subparagraph, recognise additional protected zones where the conditions provided for in paragraph 1 of this Article are fulfilled.

The Commission may, by means of implementing acts, replace the implementing act referred to in the first subparagraph of this paragraph for the purpose of consolidating amendments.

The implementing acts referred to in this paragraph shall be adopted in accordance with the examination procedure referred to in Article 107(2).

4. With the application referred to in paragraph 1, the Member State concerned shall submit:

- (a) a description of the boundaries of the proposed protected zone, including maps;
- (b) the results of surveys showing that, during at least the three years preceding the application, the quarantine pest concerned was not present in the territory concerned; and
- (c) evidence that the quarantine pest concerned fulfils the conditions set out in Article 3 with respect to the proposed protected zone.

5. The surveys referred to in point (b) of paragraph 4 shall be carried out at appropriate times and be of appropriate intensity with regard to the possibility of detecting the presence of the quarantine pest concerned. They shall be based on sound scientific and technical principles, and take into account the relevant international standards.

The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by laying down detailed rules for those surveys. Those acts shall be adopted in accordance with the development of scientific and technical knowledge and the applicable international standards.

6. The Commission may recognise temporary protected zones. For that purpose, the conditions set out in paragraphs 1 and 4 and the first subparagraph of paragraph 5 shall apply *mutatis mutandis*. By way of derogation from the requirement referred to in point (b) of paragraph 4, a survey shall have been carried out over a period of at least one year preceding the application.

The recognition of a temporary protected zone shall last no longer than three years after recognition, and shall expire automatically after three years.

7. Member States shall notify the Commission and the other Member States and inform, via publication on the official website of the competent authority, the professional operators of the boundaries of the protected zones in their territory, including by means of maps.

*Article 33***General obligations concerning protected zones**

1. With regard to a protected zone, the obligations set out in Articles 9 to 19 shall apply *mutatis mutandis* to the respective protected zone quarantine pest.

2. A plant, plant product or other object originating in a demarcated area established in a protected zone for the protected zone quarantine pest concerned shall not be moved from that demarcated area into the remaining part of that protected zone or into any other protected zone established for that protected zone quarantine pest.

By way of derogation from the first subparagraph, that plant, plant product or other object may be moved out of that demarcated area through and out of the protected zone concerned only if it is packed and moved in such a way that there is no risk of spreading that protected zone quarantine pest within that protected zone.

3. The demarcated areas established within a protected zone and the eradication measures taken in those areas pursuant to Articles 17, 18 and 19 shall be immediately notified to the Commission and the other Member States.

*Article 34***Surveys on protected zone quarantine pests**

1. The competent authority shall carry out annual surveys of each protected zone as regards the presence of the protected zone quarantine pest concerned. Article 22(2) shall apply *mutatis mutandis* to those surveys.

The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by laying down detailed rules for the preparation and the content of those surveys.

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 were carried out in the preceding calendar year.

*Article 35***Amendment of extent and revocation of recognition of protected zones**

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

Where that amendment concerns the extension of a protected zone, Article 32 shall apply *mutatis mutandis*.

2. On application by the Member State referred to in paragraph 1, the Commission shall revoke the recognition of a protected zone or reduce its extent.

3. The Commission shall revoke the recognition of a protected zone if the surveys referred to in Article 34 have not been carried out in accordance with that Article.

4. The Commission shall revoke the recognition of a protected zone if the respective protected zone quarantine pest has been found to be present in that zone and one of the following conditions is fulfilled:

- (a) no demarcated area has been established, in accordance with Article 33(1), within three months of the official confirmation of the presence of that pest;
- (b) the eradication measures taken in a demarcated area pursuant to Article 33(1) have not been successful within 24 months of the official confirmation of the presence of that pest, or within a period longer than 24 months where the biology of the pest so justifies and that period is set out in the implementing act adopted pursuant to Article 32(3);
- (c) information available to the Commission demonstrates, with regard to the application of measures pursuant, by virtue of Article 33(1), to Articles 17, 18 and 19, gross negligence in reaction to the presence of that pest in the concerned protected zone.

5. The Commission shall revoke the recognition of a protected zone or reduce its extent, pursuant to paragraph 2, 3 or 4 of this Article, by means of an implementing act amending the implementing act referred to in Article 32(3). That implementing act shall be adopted in accordance with the examination procedure referred to in Article 107(2).

CHAPTER III

Union regulated non-quarantine pests

Article 36

Definition of Union regulated non-quarantine pests

A pest is a 'Union regulated non-quarantine pest' if it fulfils all of the following conditions and it is included in the list referred to in Article 37:

- (a) its identity is established in accordance with point (1) of Section 4 of Annex I;
- (b) it is present in the Union territory;
- (c) it is not a Union quarantine pest or a pest subject to measures adopted pursuant to Article 30(1);
- (d) it is transmitted mainly through specific plants for planting, in accordance with point (2) of Section 4 of Annex I;
- (e) its presence on those plants for planting has an unacceptable economic impact, as regards the intended use of those plants for planting, in accordance with point (3) of Section 4 of Annex I;
- (f) feasible and effective measures are available to prevent its presence on the plants for planting concerned.

Article 37

Prohibition of the introduction and movement of Union regulated non-quarantine pests on plants for planting

1. Professional operators shall not introduce a Union regulated non-quarantine pest into, or move that pest within, the Union territory on the plants for planting through which it is transmitted, as specified in the list referred to in paragraph 2.

The prohibition laid down in the first subparagraph shall not apply in the following cases:

- (a) movement of plants for planting within, or between, the premises of the professional operator concerned;
- (b) movement of plants for planting necessary for their disinfection.

2. The Commission shall, by means of an implementing act, establish a list setting out the Union regulated non-quarantine pests and the specific plants for planting, as referred to in point (d) of Article 36, where appropriate with the categories referred to in paragraph 7 of this Article and thresholds referred to in paragraph 8 of this Article.

3. The list referred to in paragraph 2 shall include the pests and the respective plants for planting set out in the following provisions:

- (a) Section II of Part A of Annex II to Directive 2000/29/EC;
- (b) points (3) and (6) of Annex I and point (3) of Annex II to Directive 66/402/EEC;
- (c) Annex I to Directive 68/193/EEC;
- (d) the acts adopted pursuant to Article 5(5) of Council Directive 98/56/EC ⁽¹⁾;
- (e) Annex II to Directive 2002/55/EC;
- (f) Annex I and point B of Annex II to Directive 2002/56/EC, and the acts adopted pursuant to point (c) of Article 18 of that Directive;
- (g) point (4) of Annex I and point (5) of Annex II to Directive 2002/57/EC;

⁽¹⁾ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

- (h) the acts adopted pursuant to Article 4 of Directive 2008/72/EC; and
- (i) the acts adopted pursuant to Article 4 of Directive 2008/90/EC.

Pests listed in Annex I and in Section I of Part A and in Part B of Annex II of Directive 2000/29/EC and listed as a Union quarantine pest pursuant to Article 5(2) of this Regulation, as well as pests subject to measures adopted pursuant to Article 30(1) of this Regulation, shall not be included in that list.

4. The Commission shall, by means of an implementing act, where appropriate, set out measures to prevent the presence of Union regulated non-quarantine pests on the plants for planting concerned, as referred to in point (f) of Article 36 of this Regulation. Those measures shall, where appropriate, concern the introduction into, and the movement within, the Union of those plants. Those measures shall be adopted in accordance with the principles set out in Section 2 of Annex II to this Regulation. Those measures shall apply without prejudice to the measures adopted pursuant to Directives 66/401/EEC, 66/402/EEC, 68/193/EEC and 98/56/EC, Council Directive 1999/105/EC⁽¹⁾, and Directives 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC.

5. The Commission shall, by means of implementing acts, amend the implementing acts referred to in paragraphs 2 and 4 of this Article where the results of an assessment show that:

- (a) a pest not listed in the implementing act referred to in paragraph 2 of this Article fulfils the conditions referred to in Article 36;
- (b) a pest listed in the implementing act referred to in paragraph 2 of this Article no longer fulfils one or more of the conditions referred to in Article 36;
- (c) amendments to that list are necessary as regards categories referred to in paragraph 7 of this Article or thresholds referred to in paragraph 8 of this Article; or
- (d) amendments to measures adopted pursuant to paragraph 4 of this Article are necessary.

The Commission shall make that assessment available to the Member States without delay.

The Commission may, by means of implementing acts, replace the implementing acts referred to in paragraphs 2 and 4 of this Article for the purpose of consolidating amendments.

6. The implementing acts referred to in paragraphs 2, 4 and 5 shall be adopted in accordance with the examination procedure referred to in Article 107(2).

7. Where point (e) of Article 36 is only fulfilled for one or more of the pre-basic, basic, or certified material, seed or seed potatoes, or standard or CAC material or seed, as referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, the list referred to in paragraph 2 of this Article shall set out those categories stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies to those categories.

8. Where point (e) of Article 36 is only fulfilled if the pest concerned is present at an incidence above a certain threshold higher than zero, the list referred to in paragraph 2 of this Article shall set out that threshold stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies above that threshold.

Such a threshold shall only be set if both of the following points are fulfilled:

- (a) it is possible for professional operators to ensure that the incidence of that Union regulated non-quarantine pest on those plants for planting does not exceed that threshold;
- (b) it is possible to verify whether that threshold is not exceeded in lots of those plants for planting.

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

9. Article 31 shall apply *mutatis mutandis* to the measures to be taken by the Member States concerning regulated non-quarantine pests and the respective plants for planting.

⁽¹⁾ Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

*Article 38***Amendment of Section 4 of Annex I**

The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Section 4 of Annex I in order to adapt it to the development of scientific and technical knowledge and of relevant international standards.

*Article 39***Union regulated non-quarantine pests used for scientific or educational purposes, trials, varietal selection, breeding or exhibitions**

The prohibition provided for in Article 37 shall not apply to Union regulated non-quarantine pests which are present on plants for planting used for scientific or educational purposes, trials, varietal selection, breeding or exhibitions.

*CHAPTER IV****Measures concerning plants, plant products and other objects****Section 1***Measures relating to the entire Union territory***Article 40***Prohibition of the introduction of plants, plant products and other objects into the Union territory**

1. Certain plants, plant products or other objects shall not be introduced into the Union territory if they originate from all or certain third countries or territories.
2. The Commission shall, by means of implementing acts, adopt a list containing the plants, plant products and other objects referred to in paragraph 1 which are prohibited from being introduced into the territory of the Union, together with the third countries, groups of third countries or specific areas of third countries to which the prohibition applies.

The first of those implementing acts shall include the plants, plant products and other objects as well as their countries of origin as listed in Part A of Annex III to Directive 2000/29/EC.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2) of this Regulation.

In the list established by those implementing acts, the plants, plant products and other objects shall also be identified by their respective code in accordance with the classification in the Combined Nomenclature as laid down in Council Regulation (EEC) No 2658/87 ⁽¹⁾ ('CN code') where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

3. Where a plant, plant product or other object originating in or being dispatched from a third country poses a pest risk of an unacceptable level due to the likelihood that it hosts a Union quarantine pest, and that pest risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend the implementing act referred to in paragraph 2 accordingly to include in it that plant, plant product or other object and the third countries, groups of third countries or specific areas of third countries concerned.

Where a plant, plant product or other object included in that implementing act does not pose a pest risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend that implementing act accordingly.

⁽¹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

The acceptability of the level of that pest risk shall be assessed in accordance with the principles set out in Section 2 of Annex II, where appropriate with regard to one or more specific third countries.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 107(2).

On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt those amendments by immediately applicable implementing acts, in accordance with the procedure referred to in Article 107(3).

4. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States where plants, plant products or other objects have been introduced into the Union territory in violation of paragraph 1.

That notification shall also be made to the third country from which the plants, plant products or other objects were introduced into the Union territory.

Article 41

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

1. Certain plants, plant products or other objects may only be introduced into, or moved within, the Union territory if special requirements, or equivalent requirements, are fulfilled. Those plants, plant products or other objects may originate from third countries or within the Union territory.

2. The Commission shall, by means of implementing acts, adopt a list containing the plants, plant products and other objects and the corresponding special requirements as referred to in paragraph 1. That list shall, where applicable, include the third countries, groups of third countries or specific areas within third countries concerned.

The first of those implementing acts shall include the plants, plant products and other objects, the special requirements and, where applicable, their third country of origin as listed in Part A of Annex IV to Directive 2000/29/EC.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2) of this Regulation.

In the list established by those implementing acts, those plants, plant products and other objects shall also be identified by their respective CN code where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

3. Where a plant, plant product or other object poses a pest risk of an unacceptable level due to the likelihood that it hosts a Union quarantine pest, and that pest risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend the implementing act referred to in paragraph 2 to include in it that plant, plant product or other object and the measures to be applied to it. Those measures and the requirements referred to in paragraph 2 constitute 'special requirements'.

The measures referred to in the first subparagraph may take the form of specific requirements, adopted in accordance with Article 44(1), for the introduction into the Union territory of particular plants, plant products or other objects which are equivalent to special requirements for the introduction into, and movement within, the Union territory of those plants, plant products or other objects ('equivalent requirements').

Where a plant, plant product or other object included in that implementing act does not pose a pest risk of an unacceptable level, or it poses such a risk but that risk cannot be reduced to an acceptable level by the special requirements, the Commission shall amend that implementing act accordingly by removing that plant, plant product or other object from the list or by including it in the list referred to in Article 40(2).

The acceptability of the level of that pest risk shall be assessed, and the measures to reduce that risk to an acceptable level shall be adopted, in accordance with the principles set out in Section 2 of Annex II, where appropriate with regard to one or more specific third countries or parts thereof.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 107(2).

On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(3).

4. In the event that plants, plant products or other objects have been introduced into, or moved within, the Union territory in violation of paragraph 1, Member States shall adopt the necessary measures, as referred to in Union legislation on official controls, and shall notify the Commission and other Member States through the electronic notification system referred to in Article 103.

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

Article 42

Restrictions on the basis of a preliminary assessment for the introduction into the Union territory of high-risk plants, plant products and other objects

1. A plant, plant product or other object originating in a third country and which is not listed in accordance with Article 40 or not sufficiently covered by the requirements referred to in Article 41 or not subject to the temporary measures of Article 49 and which, on the basis of a preliminary assessment, presents a pest risk of an unacceptable level for the Union territory is a 'high-risk plant', 'high-risk plant product' or 'high-risk other object' ('high-risk plants, plant products or other objects').

That preliminary assessment shall take into account, as appropriate for the plant, plant product or other object concerned, the criteria set out in Annex III.

2. High-risk plants, plant products or other objects listed in the implementing act provided for in paragraph 3 shall not be introduced into the Union territory from the third countries, groups of third countries or specific areas of third countries of origin concerned by that listing.

3. The Commission shall adopt implementing acts provisionally listing at the appropriate taxonomic level, pending the risk assessment referred to in paragraph 4, the high-risk plants, plant products or other objects referred to in paragraph 1 and, where appropriate, the third countries, groups of third countries or specific areas of third countries concerned.

The first of those implementing acts shall be adopted by 14 December 2018.

In the list established by those implementing acts, those plants, plant products and other objects, where applicable, shall also be identified by their respective CN code where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

4. If it is concluded, on the basis of a risk assessment, that the plant, plant product or other object originating in the third country, group of third countries or specific area of the third country concerned referred to in paragraph 2, on the taxonomic level as listed in the implementing act provided for in paragraph 3 or below that level, does not pose a risk of an unacceptable level by its likelihood to host a Union quarantine pest, the Commission shall adopt an implementing act removing that plant, plant product or other object from the list referred to in that paragraph for the third countries concerned.

If it is concluded, on the basis of a risk assessment, that the plant, plant product or other object originating in the third country, group of third countries or specific area of the third country concerned referred to in paragraph 2 poses an unacceptable risk due to the likelihood that it hosts a Union quarantine pest, and that that pest risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall adopt an implementing act removing that plant, plant product or other object and the third countries concerned from the list referred to in paragraph 2 and add it to the list referred to in Article 40.

If it is concluded, on the basis of a risk assessment, that the plant, plant product or other object originating in the third country, group of third countries or specific area of the third country concerned referred to in paragraph 2 poses an unacceptable risk, but that that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall adopt an implementing act removing that plant, plant product or other object and the third country, group of third countries or specific area of the third country concerned from the list referred to in paragraph 2 and add it to the list referred to in Article 41.

5. Provided that demand for import of plants, plant products or other objects listed in the implementing act provided for in paragraph 3 is identified, the risk assessment referred to in paragraph 4 shall be carried out within an appropriate and reasonable period of time.

Where appropriate, that assessment may be limited to plants, plant products or other objects of a particular third country of origin or dispatch, or a group of third countries of origin or dispatch.

6. The Commission may, by means of implementing acts, lay down specific rules concerning the procedure to be followed in order to carry out the risk assessment referred to in paragraph 4.

7. The implementing acts referred to in paragraphs 3, 4 and 6 shall be adopted in accordance with the examination procedure referred to in Article 107(2).

Article 43

Specific import conditions for the introduction into the Union territory of wood packaging material

1. Wood packaging material, whether or not actually in use in the transport of objects of all kinds, shall only be introduced into the Union territory if it fulfils all of the following requirements:

- (a) it has been subject to one or more of the approved treatments and complies with the applicable requirements set out in Annex 1 to the International Standard for Phytosanitary Measures No 15 *Regulation of Wood Packaging Material in International Trade* (ISPM15);
- (b) it is marked with the mark referred to in Annex 2 of ISPM15 attesting that it has been subject to the treatments referred to in point (a).

This paragraph shall not apply to wood packaging material which is subject to the exemptions provided for in ISPM15.

2. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending the requirements set out in paragraph 1 of this Article to take into account the development of international standards, and in particular of ISPM15.

Those delegated acts may also determine that wood packaging material not subject to the exemptions provided for in ISPM15 is exempted from the requirements of paragraph 1 of this Article or is subject to less stringent requirements.

Article 44

Setting out of equivalent requirements

1. The Commission shall set out equivalent requirements, by means of implementing acts, on request of a particular third country, if both of the following conditions are fulfilled:

- (a) the third country concerned ensures, through the application under its official control of one or more specified measures, a level of phytosanitary protection which is equivalent to the special requirements in respect of the movement within the Union territory of the plants, plant products and other objects concerned;
- (b) the third country concerned demonstrates to the Commission that the specified measures referred to in point (a) achieve the level of phytosanitary protection referred to in that point.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

2. Where appropriate, the Commission shall carry out investigations in the third country concerned to verify whether the conditions referred to in points (a) and (b) of the first subparagraph of paragraph 1 are fulfilled. Those investigations shall comply with requirements for Commission investigations as referred to in Union legislation on official controls.

Article 45

Information to be provided to travellers and clients of postal services

1. Member States, seaports, airports and international transport operators shall make information available to passengers concerning prohibitions referred to in Article 40(2), requirements referred to in Articles 41(2) and 42(3) and the exemption referred to in Article 75(2) as regards the introduction of plants, plant products and other objects into the Union territory.

They shall provide that information in the form of posters or brochures and, where applicable, on their internet sites.

Postal services and professional operators involved in sales through distance contracts shall also make available to their clients that information concerning plants, plant products and other objects referred to in the first subparagraph at least through the internet.

The Commission may, by means of implementing acts, set out arrangements for the presentation and use of those posters and brochures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

2. Member States shall, on request, submit to the Commission a report summarising the information provided pursuant to this Article.

Article 46

Exception from prohibitions and requirements for frontier zones

1. By way of derogation from Article 40(1), Article 41(1) and Article 42(2), Member States may authorise the introduction into the Union territory of plants, plant products and other objects which fulfil all of the following conditions:

- (a) they are grown or produced in areas of third countries in the vicinity of their land border with Member States ('third country frontier zones');
- (b) they are introduced into areas of Member States immediately across that border ('Member State frontier zones');
- (c) they are to be subject to processing in those Member State frontier zones in such a manner that any pest risk is eliminated;
- (d) they do not pose any risk of spreading Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1) caused by movements within the frontier zone.

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

2. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by setting out the following:

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

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

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

Those acts shall be adopted in accordance with Annex II and, where appropriate, taking into account the development of scientific and technical knowledge and international standards.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

4. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and the other Member States where plants, plant products or other objects have been introduced into, or moved within, Member State frontier zones or third country frontier zones in violation of paragraphs 1, 2 and 3 of this Article.

That notification shall also be made to the third country from which the plants, plant products or other objects were introduced into the frontier zone concerned.

Article 47

Requirements for phytosanitary transit

1. By way of derogation from Article 40(1), Article 41(1), Article 42(2), Article 72(1) and Article 73, plants, plant products and other objects may be introduced into, and be passed through, the Union territory to a third country, either in the form of transit or transshipment ('phytosanitary transit'), if they fulfil both of the following conditions:

- (a) they are accompanied by a signed declaration of the professional operator in control of those plants, plant products and other objects stating that those plants, plant products or other objects are in phytosanitary transit;
- (b) they are packed and moved in such a way that there is no risk of spreading of Union quarantine pests during their introduction into, and passing through, the Union territory.

2. Competent authorities shall prohibit phytosanitary transit if the plants, plant products or other objects concerned do not comply, or there is reasonable evidence that they will not comply, with paragraph 1.

Article 48

Plants, plant products and other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding

1. By way of derogation from Article 40(1), Article 41(1) and Article 42(2), Member States may, on application, authorise temporarily the introduction into, and the movement within, their territory of plants, plant products and other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding.

That authorisation shall be granted for the activity concerned only if adequate restrictions are imposed to ensure that the presence of the plants, plant products or other objects concerned does not cause an unacceptable risk of the spread of a Union quarantine pest or pest subject to the measures adopted pursuant to Article 30(1), taking into account the identity, biology and means of dispersal of the pests concerned, the activity envisaged, the interaction with the environment and other relevant factors relating to the pest risk posed by those plants, plant products or other objects.

2. Where an authorisation is granted in accordance with paragraph 1, it shall include all of the following conditions:

- (a) the plants, plant products or other objects concerned are to be kept in a location and under conditions found to be appropriate by the competent authorities and referred to in the authorisation;

- (b) the activity involving those plants, plant products or other objects is to be carried out in a quarantine station or a confinement facility designated in accordance with Article 60 by the competent authority and referred to in the authorisation;
 - (c) the activity involving those plants, plant products or other objects is to be carried out by personnel whose scientific and technical competence is found to be appropriate by the competent authority and referred to in the authorisation;
 - (d) those plants, plant products or other objects are to be accompanied by the authorisation when introduced into, or moved within, the Union territory.
3. The authorisation referred to in paragraph 1 shall be limited to the amount and duration that is adequate for the activity concerned and shall not exceed the capacity of the designated quarantine station or confinement facility.

It shall include the restrictions necessary to adequately eliminate the risk of the spread of the relevant Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1).

4. The competent authority shall monitor compliance with the conditions referred to in paragraph 2 and the limitation and the restrictions referred to in paragraph 3 and take the necessary action in case those conditions, that limitation or those restrictions are not complied with.

Where appropriate, that action shall be the revocation of the authorisation referred to in paragraph 1.

5. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by laying down detailed rules concerning:

- (a) the exchange of information between Member States and the Commission concerning the introduction into, and movement within, the Union territory of the plants, plant products and other objects concerned;
- (b) the procedures and conditions for granting the authorisation referred to in paragraph 1 of this Article; and
- (c) the requirements for the monitoring of compliance and the actions to be taken in the event of non-compliance, as referred to in paragraph 4 of this Article.

Article 49

Temporary measures concerning plants, plant products and other objects likely to pose newly identified pest risks or other suspected phytosanitary risks

1. The Commission may adopt, by means of implementing acts, temporary measures as regards the introduction into, and movement within, the Union territory of plants, plant products and other objects from third countries where the following conditions are fulfilled:

- (a) the plants, plant products or other objects are likely to pose newly identified pest risks which are not sufficiently covered by any Union measures and are not linked, or cannot yet be linked, to Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1);
- (b) there is insufficient phytosanitary experience, such as in relation to new plant species or pathways, as regards trade in the plants, plant products and other objects concerned originating in or dispatched from the third countries concerned;
- (c) no assessment has been carried out as regards the newly identified pest risks for the Union territory in respect of those plants, plant products or other objects from the third countries concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

2. The temporary measures referred to in paragraph 1 shall be adopted taking into account Section 2 of Annex II and Annex IV.

They shall provide for one or more of the following, as necessary in the case concerned:

- (a) systematic and intensive inspections and sampling, at the point of introduction, of each lot of plants, plant products or other objects introduced into the Union territory and the testing of samples;
- (b) a quarantine period, within a quarantine station or a confinement facility as referred to in Article 60, to verify the absence of the newly identified pest risk concerned in those plants, plant products or other objects;
- (c) a prohibition of the introduction of those plants, plant products or other objects into the Union territory.

In the cases referred to in points (a) and (b) of the second subparagraph, the implementing act referred to in paragraph 1 may also set out specific measures to be taken before the introduction into the Union territory of those plants, plant products or other objects.

3. The temporary measures referred to in paragraph 1 shall apply for an appropriate and reasonable period of time, pending the characterisation of pests likely to be associated with those plants, plant products or other objects from those third countries and the full assessment of the risks posed by those pests in accordance with Section 1 of Annex I.

4. On duly justified imperative grounds of urgency to address a serious newly identified pest risk, the Commission shall adopt immediately applicable implementing acts, in accordance with the procedure referred to in Article 107(3). Those acts shall be adopted in accordance with the principles set out in Section 2 of Annex II.

5. By way of derogation from the measures adopted pursuant to paragraph 1 of this Article, Article 48 shall apply to the introduction into, and the movement within, the Union territory of plants, plant products or other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding.

6. Member States shall submit a report to the Commission and the other Member States, by 30 April of each year, on the application of the measures referred to in point (a) or (b) of the second subparagraph of paragraph 2 during the preceding calendar year.

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

Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and the other Member States of any case where the introduction of a plant, plant product or other object into the Union territory was refused, or its movement within the Union territory prohibited, because the Member State concerned considered that the prohibition referred to in point (c) of the second subparagraph of paragraph 2 was violated. Where applicable, that notification shall include the measures taken by that Member State on the plants, plant products or other objects concerned, as referred to in Union legislation on official controls.

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

Article 50

Report from the Commission on the enforcement and effectiveness of measures relating to imports into the Union territory

By 14 December 2021, the Commission shall present a report to the European Parliament and the Council on the enforcement and effectiveness of measures relating to imports into the Union territory, including a cost-benefit analysis, and, where appropriate, present a legislative proposal.

Article 51

Amendment of Annexes III and IV

The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Annexes III and IV in order to adapt them to the development of scientific and technical knowledge and of relevant international standards.

*Article 52***Temporary measures by Member States concerning imminent danger**

1. Where a Member State considers that the introduction into, or movement within, its territory of plants, plant products or other objects from certain third countries or certain other Member States poses an unacceptable level of pest risk concerning the entry into, and establishment and spread in, its territory of a Union quarantine pest or a pest assessed to fulfil the conditions for inclusion in the list of Union quarantine pests, and that risk is not adequately mitigated by the measures referred to in Article 17(1) and (2), Article 18(1), Article 19(1), Article 28(1) and (2), Article 29(1), Article 30(1) and (3), Article 40(2) and (3), Article 41(2) and (3), Article 42(3), Article 49(1) and Article 53, it shall notify in writing the Commission and the other Member States of the Union measures it would like to be taken, together with the technical or scientific justification for those measures.
2. If a Member State considers that the Union measures referred to in paragraph 1 are not being, or cannot be, taken in sufficient time to mitigate the risk referred to that paragraph, it may take temporary measures to protect its territory against the imminent danger. Those temporary measures, and the technical justification for those measures, shall be notified immediately to the Commission and the other Member States.
3. Where the Commission receives the notification referred to in paragraph 1, it shall immediately assess whether the risk referred to in paragraph 1 is adequately mitigated by the measures referred to in Article 17(1) and (2), Article 18(1), Article 19(1), Article 28(1) and (2), Article 29(1), Article 30(1) and (3), Article 40(2) and (3), Article 41(2) and (3), Article 42(3), Article 49(1) and Article 53, or whether any new measure should be adopted pursuant to those Articles.
4. Where, on the basis of the assessment referred to in paragraph 3, the Commission concludes that the risk referred to in paragraph 1 is not adequately mitigated by the temporary measures taken by the Member State pursuant to paragraph 2, or if those measures are disproportionate or not adequately justified, it may decide, by means of implementing acts, that those measures are to be repealed or amended. Until such an implementing act has been adopted by the Commission, the Member State may maintain the measures that it has taken.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Section 2***Measures relating to protected zones***Article 53***Prohibition of introduction of plants, plant products and other objects into protected zones**

1. Certain plants, plant products or other objects originating from third countries or within the Union territory shall not be introduced into certain protected zones.
2. The Commission shall, by means of implementing acts, adopt a list containing the plants, plant products and other objects referred to in paragraph 1 which are prohibited from being introduced into certain protected zones. The first of those implementing acts shall include the plants, plant products and other objects and their respective protected zones and, where applicable, their country of origin as listed in Part B of Annex III to Directive 2000/29/EC.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2) of this Regulation.

In the list established by those implementing acts, the plants, plant products and other objects shall also be identified by their respective CN code where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

3. Where a plant, plant product or other object coming from outside a protected zone poses a pest risk of an unacceptable level by its likelihood of hosting the respective protected zone quarantine pest and that risk cannot be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend the implementing act referred to in paragraph 2 accordingly to include in it that plant, plant product or other object and the protected zone or zones concerned.

Where a plant, plant product or other object included in that implementing act does not pose a pest risk of an unacceptable level, or it poses such a risk but that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend that implementing act accordingly.

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 107(2).

The acceptability of the level of that pest risk shall be assessed in accordance with the principles set out in Section 2 of Annex II.

On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(3).

4. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States of any cases where plants, plant products or other objects have been introduced into, or moved within, the protected zone concerned in violation of the prohibitions adopted pursuant to this Article.

Where applicable, the Member States or the Commission shall notify the third country from which the plants, plant products or other objects were introduced into the protected zone concerned.

Article 54

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

1. Certain plants, plant products or other objects may only be introduced into, or moved within, certain protected zones if special requirements for those protected zones are fulfilled.

2. The Commission shall, by means of implementing acts, adopt a list containing the plants, plant products and other objects, their respective protected zones and the corresponding special requirements for protected zones. The first of those implementing acts shall include the plants, plant products and other objects, their respective protected zones and the special requirements for protected zones as listed in Part B of Annex IV to Directive 2000/29/EC.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2) of this Regulation.

In the list established by those implementing acts, those plants, plant products and other objects shall also be identified by their respective CN code where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

3. Where a plant, plant product or other object coming from outside the protected zone concerned poses a pest risk of an unacceptable level for that protected zone by its likelihood of hosting a protected zone quarantine pest, and that risk can be reduced to an acceptable level by applying one or more of the measures set out in points 2 and 3 of Section 1 of Annex II, the Commission shall amend the implementing act referred to in paragraph 2 to include in it that plant, plant product or other object and the measures to be applied to it. Those measures and the requirements referred to in paragraph 2 constitute 'special requirements for protected zones'.

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

Those amendments shall be adopted in accordance with the examination procedure referred to in Article 107(2).

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

On duly justified imperative grounds of urgency to address a serious pest risk, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 107(3).

4. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States where plants, plant products or other objects have been introduced into, or moved within, the protected zone concerned in violation of the measures adopted pursuant to this Article.

Where applicable, the Member States or the Commission shall notify the third country from which the plants, plant products or other objects were introduced into the Union territory.

Article 55

Information to be provided to travellers and clients of postal services as regards protected zones

Article 45 shall apply *mutatis mutandis* to the introduction into, or the movement within, protected zones of plants, plant products and other objects.

Article 56

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

Article 46 shall apply *mutatis mutandis* to the plants, plant products and other objects listed in the implementing acts provided for in Article 53(2) and (3) and Article 54(2) and (3) which are introduced from a third country frontier zone into the respective protected zones bordering that frontier zone.

Article 57

Requirements for phytosanitary transit as regards protected zones

Article 47 shall apply *mutatis mutandis* to the phytosanitary transit of the plants, plant products and other objects listed in the implementing acts provided for in Article 53(2) and (3) and Article 54(2) and (3) through protected zones.

Article 58

Plants, plant products and other objects used for official testing, scientific or educational purposes, trials, varietal selection or breeding as regards protected zones

By way of derogation from the prohibitions and requirements provided for in Article 53(1) and Article 54(1), Article 48 shall apply *mutatis mutandis* to the introduction into, and the movement within, protected zones of plants, plant products and other objects listed in the implementing acts provided for in Article 53(2) and (3) and Article 54(2) and (3) and used for official testing, scientific or educational purposes, trials, varietal selection or breeding.

Section 3

Other measures concerning plants, plant products and other objects

Article 59

General requirements for vehicles, machinery and packaging material

1. Vehicles, machinery and packaging material used for plants, plant products or other objects referred to in the implementing acts adopted pursuant to Article 28(1) and (2), Article 30(1) and (3), Article 40(2), Article 41(2) and (3), Article 42(3) and Article 49(1) and moving into or within the Union territory, or through the Union territory pursuant to Article 47, shall be free from Union quarantine pests and from the pests subject to measures adopted pursuant to Article 30(1).

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

*Article 60***Designation of quarantine stations and confinement facilities**

1. For the purposes referred to in Articles 8, 48, 49 and 58, Member States shall take one or more of the following actions, taking into account the relevant pest risk:
 - (a) designate in their territory quarantine stations or confinement facilities;
 - (b) authorise the use of designated quarantine stations or confinement facilities in another Member State, provided that, where applicable, that other Member State has agreed to such authorisation;
 - (c) designate temporarily the premises of professional operators or other persons as confinement facilities for the pests, plants, plant products or other objects and their relevant uses as set out in Articles 8, 48 and 49.
2. Member States shall, on request, communicate a list of the designated quarantine stations and confinement facilities in their territory to the Commission and the other Member States.

*Article 61***Requirements for quarantine stations and confinement facilities**

1. Quarantine stations and confinement facilities referred to in Article 60 shall meet the following requirements to prevent the spread of Union quarantine pests:
 - (a) they provide physical isolation of the pests, plants, plant products and other objects to be kept in quarantine or confinement and ensure they cannot be accessed or removed from those stations or facilities without consent of the competent authority;
 - (b) they have systems, or access to systems, for sterilisation, decontamination or destruction of infested plants, plant products and other objects, waste and equipment before removal from the stations or facilities;
 - (c) they have an identification and description of the tasks of those stations and facilities, the persons responsible for carrying out those tasks and the conditions under which they shall carry out those tasks;
 - (d) they have a sufficient number of suitably qualified, trained and experienced personnel; and
 - (e) they have a contingency plan for the purpose of effectively eliminating any unintended presence of Union quarantine pests and pests subject to measures adopted pursuant to Article 30(1) and preventing their spread.
2. The Commission may, by means of implementing acts, lay down specific rules in order to provide uniform conditions of application for the requirements set out in paragraph 1 in relation to the type of plants, plant products and other objects and the actual or potential risk, including specific requirements for official testing, scientific or educational purposes, trials, varietal selection or breeding.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Article 62***Operation of quarantine stations and confinement facilities**

1. The person responsible for the quarantine station or confinement facility shall monitor that station or facility and its immediate vicinity for the unintended presence of Union quarantine pests and pests subject to measures adopted pursuant to Article 30(1).
2. Where an unintended presence of a pest referred to in paragraph 1 is found or suspected, the person responsible for the quarantine station or confinement facility concerned shall take the appropriate action, based on the contingency plan referred to in point (e) of Article 61(1). The obligations set out for professional operators in Article 14 shall apply *mutatis mutandis* to the person responsible for the quarantine station or confinement facility.

3. The person responsible for the quarantine station or confinement facility shall keep records on the following:
 - (a) the personnel employed;
 - (b) the visitors accessing the station or facility;
 - (c) the pests, plants, plant products and other objects entering and leaving the station or facility;
 - (d) the place of origin of such plants, plant products and other objects; and
 - (e) observations concerning the presence of pests on such plants, plant products and other objects inside the quarantine station or confinement facility and in its immediate vicinity.

Those records shall be kept for three years.

Article 63

Supervision of quarantine stations and confinement facilities and revocation of designation

1. The competent authority shall regularly inspect the quarantine stations and confinement facilities to verify whether they meet the requirements set out in Article 61 and the operation conditions set out in Article 62.

It shall determine the frequency of those inspections according to the pest risk related to the operation of the quarantine stations or confinement facilities.

2. On the basis of the inspection referred to in paragraph 1, the competent authority may require the person responsible for the quarantine station or confinement facility to implement corrective actions to ensure compliance with Articles 61 and 62, either immediately or within a specified period of time.

Where the competent authority concludes that the quarantine station or confinement facility or the person responsible for it fails to comply with Articles 61 and 62, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue. Those measures may include the revocation or suspension of the designation referred to in Article 60(1).

3. Where the competent authority has taken measures in accordance with paragraph 2 of this Article other than the revocation of the designation referred to in Article 60(1), and non-compliance with Articles 61 and 62 continues, that authority shall without delay revoke that designation.

Article 64

Release of plants, plant products and other objects from quarantine stations and confinement facilities

1. Plants, plant products and other objects shall only leave the quarantine stations or confinement facilities, upon authorisation by the competent authorities, if it is confirmed that they are free from Union quarantine pests and pests subject to measures adopted pursuant to Article 30(1), or, where applicable, protected zone quarantine pests.
2. The competent authority may authorise the movement of plants, plant products or other objects infested by a Union quarantine pest or pest subject to measures adopted pursuant to Article 30(1) from a quarantine station or a confinement facility to another quarantine station or confinement facility if that movement is justified by official testing or scientific reasons and takes place under the conditions set by the competent authority.
3. The Commission may, by means of implementing acts, lay down specific rules concerning the release of plants, plant products and other objects from quarantine stations and confinement facilities, and, where appropriate, labelling requirements related to that release or to the movement referred to in paragraph 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

CHAPTER V

Registration of professional operators and traceability

Article 65

Official register of professional operators

1. The competent authority shall keep and update a register containing the following professional operators who operate in the territory of the Member State concerned:

- (a) professional operators introducing into, or moving within, the Union plants, plant products and other objects for which a phytosanitary certificate or a plant passport is required on the basis of the implementing acts adopted pursuant to Article 72(1), Article 73, Article 74(1), Article 79(1) and Article 80(1);
- (b) professional operators authorised to issue plant passports in accordance with Article 89;
- (c) professional operators who request the competent authority to issue the certificates referred to in Articles 100, 101 and 102;
- (d) professional operators authorised to apply the marks referred to in Article 98, authorised to issue the attestations referred to in Article 99, providing information in accordance with Articles 45 or 55, introducing plants, plant products or other objects to frontier zones in accordance with Article 46(1) or Article 56, or carrying out activities concerning the relevant plants in demarcated areas, unless those operators are listed in another official register which is accessible to the competent authorities; and
- (e) professional operators other than the ones referred to in points (a) to (d) of this subparagraph, if so required by an implementing act adopted pursuant to Article 28(1), Article 30(1), Article 41(2), Article 49(1), Article 53(2) or Article 54(2).

Member States may decide for further categories of growers or other professional operators to be registered if so justified by the pest risk presented by the plants that they grow or by any other of their activities.

2. A professional operator may be registered only once in the register of a competent authority. Where applicable, that registration shall be carried out with explicit references to each of the different premises referred to in point (d) of Article 66(2).

3. Paragraph 1 of this Article shall not apply to a professional operator who fulfils one or more of the following criteria:

- (a) it supplies exclusively and directly to final users small quantities of plants, plant products and other objects by means other than sales through distance contracts;
- (b) it supplies exclusively and directly to final users small quantities of seeds, other than the seeds subject to Article 72;
- (c) its professional activity concerning plants, plant products and other objects is limited to transporting them for another professional operator;
- (d) its professional activity exclusively concerns the transport of objects of all kinds using wood packaging material.

Member States may decide not to apply the exemption referred to in point (a) of the first subparagraph to all or certain growers or other professional operators if so justified by the pest risk presented by the plants that they grow or that are concerned by any other of their activities.

4. The Commission is empowered to adopt delegated acts in accordance with Article 105 concerning one or more of the following:

- (a) amending this Regulation by adding further categories of professional operators to be exempted from the application of paragraph 1 of this Article, where registration would constitute an administrative burden for them disproportionate to the low pest risk related to their professional activities;

- (b) supplementing this Regulation by setting out particular requirements for the registration of certain categories of professional operators, taking into account the nature of the activity or of the plant, plant product or other object concerned;
- (c) supplementing this Regulation by setting out the maximum figures for small quantities of particular plants, plant products or other objects as referred to in point (a) of the first subparagraph of paragraph 3. Those figures shall be established as appropriate for the plants, plant products and other objects concerned and the respective pest risks.

Article 66

Procedure of registration

1. Professional operators falling within the scope of Article 65(1) shall submit to the competent authorities an application for registration.
2. The application for registration shall include the following elements:
 - (a) name, address in the Member State of registration and contact details of the professional operator;
 - (b) a statement concerning the intention of the professional operator to exercise one or more of the activities referred to in Article 65(1) concerning plants, plant products and other objects;
 - (c) a statement concerning the intention of the professional operator to carry out, as applicable, one or more of the following activities:
 - (i) issuing of plant passports for plants, plant products and other objects pursuant to Article 84(1);
 - (ii) placing of the mark on wood packaging material referred to in Article 96(1);
 - (iii) issuing of any other attestation referred to in Article 99(1);
 - (d) address of the premises and, where applicable, the location of land plots used by the professional operator in the Member State concerned to carry out the activities referred to in Article 65(1) for the purpose of the registration; and
 - (e) the commodity types, families, genera or species of the plants and plant products and, where appropriate, the nature of other objects concerned by the activities of the professional operator, as referred to in Article 65(1).
3. The competent authorities shall register a professional operator without delay where the application for registration contains the elements set out in paragraph 2.
4. By way of derogation from paragraphs 1 and 2 of this Article, a competent authority shall register a professional operator without the submission of an application for registration if that operator is registered in accordance with the third subparagraph of Article 6(5), Article 6(6) or point (b) of Article 13c(1) of Directive 2000/29/EC or national plant health rules and if all elements set out in paragraph 2 of this Article are available to that competent authority. Where relevant, the professional operator concerned shall submit an update of those elements by 14 March 2020.
5. Registered operators shall, where relevant, submit annually an update concerning any changes in the data referred to in points (d) and (e) of paragraph 2 and the statements referred to in points (b) and (c) of paragraph 2. That submission shall take place by 30 April of each year with regard to the updating of the data of the preceding year.

An application for updating the data referred to in point (a) of paragraph 2 shall be submitted no later than 30 days after the change in those data.

6. Where the competent authority becomes aware that the registered operator no longer carries out the activities referred to in Article 65(1), or that the elements included in the application submitted by the registered operator in accordance with paragraph 2 of this Article are no longer correct, it shall request that operator to correct those elements immediately or within a specified period of time.

Where the registered operator does not correct those elements within the period of time set by the competent authority, the competent authority shall, as appropriate, amend or revoke the registration of that operator.

*Article 67***Content of the register**

The register shall contain the elements set out in points (a), (b), (d) and (e) of Article 66(2) and the following elements:

- (a) the official registration number, which shall include the two-letter code indicated in norm ISO 3166-1-alpha-2 ⁽¹⁾ for the Member State in which the professional operator is registered;
- (b) where applicable, an indication for which of the activities referred to in point (c) of Article 66(2) the professional operator is authorised, and, where applicable, the specific plants, plant products or other objects concerned.

*Article 68***Availability of information of official registers**

1. The Member State keeping the register shall make available, on reasoned request, the information contained therein to the other Member States or the Commission, for their own use.
2. The Member State keeping the register shall make available, on justified request, the information referred to in points (a) and (b) of Article 66(2) and point (b) of Article 67 concerning a particular registered operator to any professional operator established in the Union, for its own use.
3. This Article shall apply without prejudice to national and Union rules on confidentiality, access to information and private data protection.

*Article 69***Traceability**

1. A professional operator to whom plants, plant products or other objects are supplied that are subject to requirements or conditions pursuant to points (a) to (d) of the first subparagraph of Article 28(1), Article 28(2) and (3), Article 30(1), (3) and (4), Article 37(2), Article 41(2) and (3), Article 46(1) and (3), Article 48(1) and (2), Article 49(1), Article 54(2) and (3), Articles 56, 57 and 58 and Article 79(1) shall keep a record allowing that operator to identify, for each trade unit of plant, plant product or other object supplied, the professional operators who supplied it.
2. A professional operator supplying plants, plant products or other objects that are subject to requirements or conditions pursuant to points (a) to (d) of the first subparagraph of Article 28(1), Article 28(2), and (3), Article 30(1), (3) and (4), Article 37(2), Article 41(2) and (3), Article 46(1) and (3), Article 47(1), Article 48(1) and (2), Article 49(1), Article 54(2) and (3), Articles 56, 57 and 58 and Article 79(1) shall keep a record allowing that operator to identify, for each trade unit of plant, plant product or other object it supplied, the professional operators to whom it was supplied.
3. Where an authorised operator issues a plant passport pursuant to Article 84(1), and where the competent authority issues a plant passport pursuant to Article 84(2) for a registered operator, that operator shall ensure, for the purpose of ensuring traceability pursuant to paragraphs 1 and 2 of this Article, that it records the following information as regards that plant passport:
 - (a) where applicable, the professional operator who supplied the trade unit concerned;
 - (b) the professional operator to whom the trade unit concerned was supplied; and
 - (c) relevant information relating to the plant passport.
4. Professional operators shall keep the records referred to in paragraphs 1, 2 and 3 for at least three years after the date on which the plant, plant product or other object concerned was supplied to or by them.
5. The Commission may, by means of implementing acts, set out the following elements:
 - (a) a shorter or longer minimum period than the one referred to in paragraph 4 with regards to specific plants, where so justified by the length of the cultivation period of those plants; and

⁽¹⁾ ISO 3166-1:2006, Codes for the representation of names of countries and their subdivisions — Part 1: Country codes. International Organisation for Standardization, Geneva.

- (b) requirements as to the accessibility of the records to be kept by the professional operators referred to in paragraphs 1 and 2.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

6. On request, the professional operators referred to in paragraph 4 shall communicate the information in the records referred to in paragraphs 1, 2 and 3 to the competent authority.

7. This Article shall not apply to the professional operators referred to in points (c) and (d) of the first subparagraph of Article 65(3).

Article 70

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

1. The professional operators who are supplied with, or supply, the plants, plant products or other objects referred to in Article 69(1) and (2) shall have in place traceability systems or procedures to allow identification of the movements of those plants, plant products and other objects within and between their own premises.

The first subparagraph shall not apply to the professional operators referred to in points (c) and (d) of the first subparagraph of Article 65(3).

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

CHAPTER VI

Certification of plants, plant products and other objects

Section 1

Phytosanitary certificates required for the introduction of plants, plant products and other objects into the Union territory

Article 71

Phytosanitary certificate for introduction into the Union territory

1. A phytosanitary certificate for introduction of plants, plant products and other objects into the Union territory shall be a document, issued by a third country, which fulfils the conditions of Article 76, has the contents set out in Part A of Annex V, or, where applicable, Part B of Annex V, and certifies that the plant, plant product or other object concerned complies with all of the following requirements:

- (a) it is free from Union quarantine pests and pests subject to measures adopted pursuant to Article 30(1);
- (b) it complies with the provisions of Article 37(1) concerning the presence of Union regulated non-quarantine pests on plants for planting;
- (c) it complies with the requirements referred to in Article 41(2) and (3) or, where applicable, Article 54(2) and (3);
- (d) where applicable, it complies with rules adopted in accordance with the provisions adopted pursuant to point (d) of the first subparagraph of Article 28(1), Article 28(2) and Article 30(1).

2. The phytosanitary certificate shall specify under the heading 'Additional Declaration' which specific requirement is fulfilled, whenever the respective implementing act, adopted pursuant to Article 28(1) and (2), Article 30(1) and (3), Article 37(2), Article 41(2) and (3) and Article 54(2) and (3), allows for several different options for such requirements. That specification shall include the full wording of the relevant requirement.

3. Where applicable, the phytosanitary certificate shall state that the plants, plant products or other objects concerned comply with phytosanitary measures recognised as equivalent, pursuant to Article 44, to the requirements of the implementing act adopted pursuant to Article 41(3).

4. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Parts A and B of Annex V to adapt them to the development of the relevant international standards.

*Article 72***Plants, plant products and other objects for which phytosanitary certificates are required**

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

That list shall include:

- (a) all plants for planting, other than seeds;
- (b) the plants, plant products and other objects listed in Point I of Part B of Annex V to Directive 2000/29/EC;
- (c) plants, plant products and other objects for which requirements have been adopted pursuant to point (d) of the first subparagraph of Article 28(1) and Article 30(1) concerning their introduction into the Union territory;
- (d) seeds or, as applicable, seed potatoes listed in the implementing act provided for in Article 37(2) of this Regulation and subject to equivalence decisions adopted pursuant to Directives 66/401/EEC, 66/402/EEC, 98/56/EC, 1999/105/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC;
- (e) plants, plant products and other objects listed in the implementing acts provided for in Article 41(2) and (3); and
- (f) plants, plant products and other objects subject to points (a) and (b) of the second subparagraph of Article 49(2).

Points (a) to (e) of the first subparagraph shall not apply and a phytosanitary certificate shall not be required where an implementing act adopted pursuant to point (d) of the first subparagraph of Article 28(1), Article 30(1) or Article 41(2) and (3) requires proof of compliance in the form of an official mark, as referred to in Article 96(1), or another official attestation, as referred to in Article 99(1).

In the list established by that implementing act, the plants, plant products and other objects shall also be identified by their respective CN code, where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

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

- (a) where a plant, plant product or other object listed in that act does not fulfil point (c), (d) or (e) of the first subparagraph of paragraph 1;
- (b) where a plant, plant product or other object not listed in that act fulfils point (c), (d) or (e) of the first subparagraph of paragraph 1.

3. In addition to the cases referred to in paragraph 2, the Commission may, by means of implementing acts, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2 of Annex II, where there is a risk that a plant, plant product or other object not listed in that act hosts a Union quarantine pest or pest subject to measures adopted pursuant to Article 30(1), or where, for a plant, plant product or other object listed in that act, that risk no longer exists.

4. The implementing acts referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the examination procedure referred to in Article 107(2).

5. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects which are subject to Articles 46, 47 and 48 and Article 75(1).

*Article 73***Other plants for which phytosanitary certificates are required**

The Commission shall, by means of implementing acts, provide that for plants, other than the plants included in the list referred to in Article 72(1), a phytosanitary certificate is required for introduction into the Union territory.

However, those implementing acts shall provide that a phytosanitary certificate is not required for those plants where an assessment, based on evidence about pest risks and experience with trade, demonstrates that such a certificate is not necessary. That assessment shall take into account the criteria set out in Annex VI. Where appropriate, that assessment may only concern plants of a particular third country of origin or dispatch, or a group of third countries of origin or dispatch.

In the list established by those implementing acts, the plants shall also be identified by their respective CN code, where that code is available.

Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2). The first of those acts shall be adopted by 14 December 2018.

Article 74

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

1. Phytosanitary certificates are required, in addition to the cases referred to in Article 72(1), (2) and (3), for the introduction of some plants, plant products and other objects into certain protected zones from certain third countries of origin or dispatch.

The Commission shall, by means of implementing acts, establish a list of those plants, plant products and other objects, and the respective third countries of origin or dispatch referred to in the first subparagraph.

That list shall include:

- (a) in the first of those implementing acts, the plants, plant products and other objects listed in Point II of Part B of Annex V to Directive 2000/29/EC;
- (b) plants, plant products and other objects listed in the implementing acts provided for in Article 54(2) or (3) of this Regulation.

In the list established by those implementing acts, the plants, plant products and other objects shall also be identified by their respective CN code where that code is available. Other codes laid down by Union legislation shall, in addition, be referred to where they specify further the applicable CN code for a specific plant, plant product or other object.

A phytosanitary certificate shall not be required for plants, plant products and other objects on that list where an implementing act adopted pursuant to Article 54(2) or (3) requires proof of compliance in the form of an official mark, as referred to in Article 96(1), or another official attestation, as referred to in Article 99(1).

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

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

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

4. The implementing acts referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the examination procedure referred to in Article 107(2).

5. By way of derogation from paragraphs 1, 2 and 3, no phytosanitary certificate shall be required for the plants, plant products or other objects which are subject to Articles 56, 57 and 58 and Article 75(1).

*Article 75***Exceptions for travellers' luggage**

1. Small quantities of particular plants, other than plants for planting, and of plant products and other objects from a third country may be exempted from the requirement for a phytosanitary certificate set out in accordance with Article 72(1), Article 73 or Article 74(1), if they comply with all of the following conditions:

- (a) they are introduced into the Union territory as part of travellers' personal luggage;
- (b) they are not to be used for professional or commercial purposes;
- (c) they are listed in an implementing act provided for in paragraph 2 of this Article.

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

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Article 76***Conditions to be fulfilled by a phytosanitary certificate**

1. Without prejudice to obligations under the International Plant Protection Convention (IPPC) and taking into account relevant international standards, the competent authority shall only accept a phytosanitary certificate accompanying plants, plant products or other objects to be introduced from a third country, if the content of that certificate complies with Part A of Annex V. Where the plants, plant products or other objects are to be introduced from a third country from which they do not originate, the competent authority shall only accept a phytosanitary certificate complying either with Part A or Part B of Annex V.

It shall not accept that phytosanitary certificate where the additional declaration referred to in Article 71(2), where applicable, is not present or not correct, and where the statement referred to in Article 71(3), where applicable, is not present.

It shall not accept a phytosanitary certificate for re-export if that phytosanitary certificate is not accompanied by the original phytosanitary certificate for export, or a certified copy of the original phytosanitary certificate for export.

2. The competent authority shall only accept a phytosanitary certificate if it fulfils the following requirements:

- (a) it is issued in at least one of the official languages of the Union;
- (b) it is addressed to the national plant protection organisation of a Member State; and
- (c) it has been issued no more than 14 days before the date on which the plants, plant products or other objects covered by it have left the third country in which it was issued.

3. In the case of a third country which is a contracting party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the official national plant protection organisation of that third country or, under its responsibility, by a public officer who is technically qualified and duly authorised by that official national plant protection organisation.

4. In the case of a third country which is not a contracting party to the IPPC, the competent authority shall only accept the phytosanitary certificates issued by the authorities which are competent in accordance with the national rules of that third country and notified to the Commission. The Commission shall inform the Member States and the operators, through the electronic notification system referred to in Article 103, of the notifications received.

The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing the conditions for acceptance referred to in the first subparagraph of this paragraph to ensure the reliability of those certificates.

5. Electronic phytosanitary certificates shall only be accepted when provided through, or in electronic exchange with, a computerised information management system for official controls at Union level.

Article 77

Invalidation of phytosanitary certificate

1. Where a phytosanitary certificate has been issued in accordance with Article 71(1), (2) and (3), and the competent authority concerned concludes that the conditions referred to in Article 76 are not fulfilled, it shall invalidate that phytosanitary certificate and ensure that it no longer accompanies those plants, plant products or other objects concerned. In that case, and in respect of the plants, plant products or other objects concerned, the competent authority shall take one of the measures to be taken in the event of non-compliant consignments entering the Union from third countries, referred to in Union legislation on official controls.

Upon invalidation, the certificate concerned shall bear on its face and in a prominent position a triangular stamp in red, marked 'certificate cancelled' from the respective competent authority, together with its denomination and the date of invalidation. It shall be in capital letters, and in at least one of the official languages of the Union.

2. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States where a phytosanitary certificate was invalidated pursuant to paragraph 1 of this Article.

The third country which had issued that phytosanitary certificate shall also be notified by the Member State concerned.

3. The Commission may, by means of implementing acts, set out technical arrangements concerning the invalidation of the electronic phytosanitary certificates, as referred to in Article 76(5). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

Section 2

Plant passports required for the movement of plants, plant products and other objects within the Union territory

Article 78

Plant passports

A plant passport shall be an official label for movement of plants, plant products and other objects within the Union territory and, where applicable, into and within protected zones, which attests compliance with all requirements set out in Article 85 and, for movement into and within protected zones, Article 86, and has the content and format set out in Article 83.

Article 79

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

1. Plant passports are required for movement of certain plants, plant products and other objects within the Union territory. The Commission shall, by means of implementing acts, establish a list of those plants, plant products and other objects, for which a plant passport is required for their movement within the Union territory.

That list shall include:

- (a) all plants for planting, other than seeds;
- (b) in the first of those implementing acts, the plants, plant products and other objects listed in point (I) of Part (A) of Annex V to Directive 2000/29/EC, provided that they are not already covered by point (a) of this subparagraph;

- (c) plants, plant products and other objects for which requirements have been adopted pursuant to Article 28(1), (2) or (3) or Article 30(1), (3) or (4) concerning their movement within the Union territory;
 - (d) seeds listed in the implementing act provided for in Article 37(2); and
 - (e) plants, plant products and other objects listed in the implementing acts provided for in Article 41(2) and (3) with regard to their movement within the Union, with the exception of plants for planting, plant products and other objects requiring another specific label or other type of attestation pursuant to that Article.
2. The Commission shall, by means of implementing acts, amend the implementing act referred to in paragraph 1 in the following cases:
- (a) where a plant, plant product or other object not listed in that act fulfils point (c), (d) or (e) of the second subparagraph of paragraph 1; or
 - (b) where a plant, plant product or other object listed in that act does not fulfil point (c), (d) or (e) of the second subparagraph of paragraph 1.
3. In addition to the cases referred to in paragraph 2, the Commission may, by means of implementing acts, amend the implementing act referred to in paragraph 1, in accordance with the principles set out in Section 2 of Annex II, where there is a risk that a plant, plant product or other object not listed in that act hosts a Union quarantine pest or where, for a plant, plant product or other object listed in that act, that risk no longer exists.
4. The implementing acts referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the examination procedure referred to in Article 107(2).
5. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects which are subject to Articles 46, 47, 48 and 75.
6. The Commission shall, not later than 14 December 2021, submit a report to the European Parliament and the Council to present the experience gained from the extension of the plant passport system to all movement of plants for planting within the Union territory including a clear cost-benefit analysis for the operators, accompanied, if appropriate, by a legislative proposal.

Article 80

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

1. Plant passports are required for certain plants, plant products and other objects being introduced into, or moved within, certain protected zones.

The Commission shall, by means of implementing acts, establish a list of those plants, plant products and other objects for which a plant passport is required for their introduction into, and movement within, certain protected zones.

That list shall include:

- (a) in the first of those implementing acts, the plants, plant products and other objects listed in point (II) of Part A of Annex V to Directive 2000/29/EC;
 - (b) other plants, plant products and other objects listed in the implementing acts provided for in Article 54(3) of this Regulation.
2. The Commission may, by means of implementing acts, amend the implementing act referred to in paragraph 1 in the following cases:
- (a) where a plant, plant product or other object not listed in that act fulfils point (b) of the third subparagraph of paragraph 1; or
 - (b) where a plant, plant product or other object listed in that act does not fulfil point (b) of the third subparagraph of paragraph 1.

3. In addition to the cases referred to in paragraph 2, the Commission may, by means of implementing acts, amend the implementing act referred to in paragraph 1, and in accordance with the principles set out in Section 2 of Annex II, where there is a risk that a plant, plant product or other object not listed in that act hosts the respective protected zone quarantine pest, or where, for a plant, plant product or other object listed in that act, that risk no longer exists.
4. The implementing acts referred to in paragraphs 1, 2 and 3 shall be adopted in accordance with the examination procedure referred to in Article 107(2).
5. By way of derogation from paragraphs 1, 2 and 3, no plant passport shall be required for the plants, plant products or other objects which are subject to Articles 56, 57 and 58.

Article 81

Exception for direct supply to final users

1. No plant passport shall be required for the movement of plants, plant products or other objects supplied directly to a final user, including home gardeners.

That exception shall not apply to:

- (a) final users receiving those plants, plant products or other objects by means of sales through distance contracts; or
- (b) final users of plants, plant products or other objects for which a plant passport for protected zones is required pursuant to Article 80.

The Commission may, by means of implementing acts, specify that the requirements of point (b) of the second subparagraph shall only apply for particular protected zone pests, plants, plant products or other objects. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

2. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by setting out the cases where, for particular plants, plant products or other objects, the exception of paragraph 1 of this Article shall only apply to small quantities. Those delegated acts shall define those quantities per period of time as appropriate to the plant, plant product or other object concerned and the respective pest risks.

Article 82

Exceptions for movements within and between the premises of a registered operator

No plant passport shall be required for the movements of plants, plant products and other objects within and between the premises of the same registered operator which are in close proximity to each other.

Member States may further define close proximity in their respective territories and whether any documents need to be issued for those movements instead of the plant passport.

Where such movements take place within two or more Member States, the exception from the requirement for a plant passport shall require approval by the competent authorities of the Member States concerned.

Article 83

Content and format of the plant passport

1. The plant passport shall take the form of a distinct label, made on any substrate suitable for printing the elements referred to in paragraph 2, provided that the plant passport is clearly distinguishable from any other information or label which may also be indicated on that substrate.

The plant passport shall be easily visible and clearly legible, and the information on it shall be unchangeable and durable.

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

By way of derogation from point 1(e) of Part A of Annex VII, the traceability code shall not be required where plants for planting fulfil all of the following conditions:

(a) they are prepared in such a way that they are ready for the sale to final users without any further preparation and no risk exists concerning the spread of Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1);

(b) they do not belong to types or species listed in an implementing act provided for in paragraph 3 of this Article.

3. The Commission shall, by means of implementing acts, identify types and species of plants for planting for which the exemption referred to in paragraph 2 shall not apply. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

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

5. In the case of plants for planting produced, or made available on the market, as pre-basic, basic or certified material or pre-basic, basic or certified seed or seed potatoes, as respectively referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC and 2008/90/EC, the plant passport shall be included, in a distinct form, in the official label produced in accordance with the respective provisions of those Directives.

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

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

6. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Parts A, B, C and D of Annex VII in order to adapt the elements set out therein, where applicable, to the development of scientific and technical knowledge.

7. By 14 December 2017, the Commission shall adopt, by means of implementing acts, the format specifications of the plant passport for movement within the Union territory and the plant passport for introduction into, and movement within, a protected zone, as regards the plant passports referred to in the first and second subparagraphs of paragraph 2 and in the second and third subparagraphs of paragraph 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

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

8. A plant passport may also be issued in an electronic form ('electronic plant passport'), provided that it contains all the elements referred to in paragraph 2, and that the technical arrangements have been set out through the implementing acts referred to in the second subparagraph of this paragraph.

The Commission may, by means of implementing acts, set out technical arrangements for the issuance of electronic plant passports, to ensure their compliance with the provisions of this Article and an appropriate, credible and effective mode for the issuance of those plant passports. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

Article 84

Issuance of plant passports by authorised professional operators and competent authorities

1. Plant passports shall be issued by authorised operators, under the supervision of the competent authorities.

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

2. By way of derogation from paragraph 1, competent authorities may also issue plant passports.
3. Authorised operators shall only issue plant passports in the premises, collective warehouses and dispatching centres which are under their responsibility and declared by them pursuant to point (d) of Article 66(2) or, where Article 94(1) applies, in another location if so authorised by the competent authority.

Article 85

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

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

- (a) it is free from Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1);
- (b) it complies with the provisions of Article 37(1) concerning the presence of Union regulated non-quarantine pests on plants for planting and the provisions of Article 37(4) concerning the measures to be taken;
- (c) it complies with the requirements concerning its movement within the Union, as referred to in Article 41(2) and (3);
- (d) where applicable, it complies with rules adopted in accordance with the relevant measures adopted pursuant to Article 17(3), points (a) to (d) of the first subparagraph of Article 28(1), Article 28(2) and Article 30(1) and (3); and
- (e) where applicable, it complies with measures adopted by the competent authorities for the eradication of Union quarantine pests pursuant to Article 17(1) or pests subject to measures adopted pursuant to Article 30(1) and the eradication of pests provisionally qualifying as Union quarantine pests pursuant to Article 29(1).

Article 86

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

1. A plant passport shall be issued for introduction into, and movement within, a protected zone for a plant, plant product and other object which fulfils all of the requirements of Article 85, and in addition the following requirements:

- (a) it is free from the respective protected zone quarantine pest; and
- (b) it complies with the requirements referred to in Article 54(2) and (3).

2. Where Article 33(2) applies, the plant passport referred to in paragraph 1 of this Article shall not be issued for plants, plant products or other objects originating in the demarcated area concerned and which may host the protected zone pest concerned.

Article 87

Examinations for plant passports

1. A plant passport may only be issued for plants, plant products and other objects for which a meticulous examination in accordance with paragraphs 2, 3 and 4 has shown that they fulfil the requirements of Article 85, and, where applicable, Article 86.

Plants, plant products and other objects may either be examined individually or by representative samples. The examination shall also cover the packaging material of the plants, plant products or other objects concerned.

2. The examination shall be carried out by the authorised operator. However, in the following cases, the examination shall be carried out by the competent authority:

- (a) where point (c) of the first subparagraph of paragraph 3 of this Article applies concerning inspections, sampling and testing;

- (b) where Article 84(2) applies; or
 - (c) where an examination is carried out in the immediate vicinity as referred to in point (b) of the first subparagraph of paragraph 3 of this Article and the authorised operator does not have access to that immediate vicinity.
3. The examination shall fulfil all of the following conditions:
- (a) it shall be carried out at appropriate times and taking into account the risks involved;
 - (b) it shall be carried out at the premises referred to in point (d) of Article 66(2). Where so required by the implementing acts adopted pursuant to Article 28(1), Article 30(1), Article 37(4), Article 41(2) or Article 54(2), an examination shall also be carried out in the immediate vicinity of the place of production of the plants, plant products or other object concerned;
 - (c) it shall be made at least by visual examination, complemented by:
 - (i) inspections, sampling and testing by the competent authority in the event of suspicion of the presence of a Union quarantine pest or pests subject to measures adopted pursuant to Article 30(1), or in the event of the suspicion of the presence of a protected zone quarantine pest in the respective protected zone; or
 - (ii) sampling and testing in the event of suspicion of the presence of a Union regulated non-quarantine pest, where applicable above the respective thresholds;
 - (d) its results shall be recorded and stored for at least three years.

That examination shall take place without prejudice to any specific examination requirements or measures adopted in accordance with Article 28(1), (2) or (3), Article 30(1), (3) or (4), Article 37(4), Article 41(2) or (3) or Article 54(2) or (3). Where those examination requirements or measures require the examination to be carried out by the competent authority, that examination shall not be carried out by the authorised operator referred to in paragraph 2 of this Article.

4. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by setting out detailed measures concerning visual examination, sampling and testing, and the frequency and timing of the examinations, referred to in paragraphs 1, 2 and 3 of this Article, with regard to specific plants, plant products and other objects, on the basis of the particular pest risks they may present. Those examinations shall, where appropriate, concern certain plants for planting belonging to pre-basic, basic, or certified material, seed or seed potatoes, or standard or CAC material or seed, as respectively referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC.

Where the Commission adopts such delegated acts for specific plants for planting, and those plants for planting are subject to certification schemes pursuant to Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC and 2008/90/EC, the Commission shall set out the requirements as regards the examinations for the presence of Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1) of this Regulation and Union regulated non-quarantine pests and the examinations for other characteristics of the plants for planting pursuant to those Directives in a single certification scheme.

When adopting those delegated acts, the Commission shall take into account the development of scientific and technical knowledge and international standards.

Article 88

Attaching of the plant passports

Plant passports shall be attached by the professional operators concerned to the trade unit of the plants, plant products and other objects concerned before they are moved within the Union territory pursuant to Article 79 or into or within a protected zone pursuant to Article 80. Where such plants, plant products or other objects are moved in a package, bundle or container, the plant passport shall be attached to that package, bundle or container.

*Article 89***Authorisation of professional operators to issue plant passports**

1. The competent authority shall grant an authorisation to a professional operator to issue plant passports ('the authorisation to issue plant passports') for particular families, genera or species, and commodity types of plants, plant products and other objects where that professional operator complies with both of the following conditions:
 - (a) it possesses the necessary knowledge to carry out the examinations referred to in Article 87 concerning the Union quarantine pests or pests subject to measures adopted pursuant to Article 30(1), protected zone quarantine pests and Union regulated non-quarantine pests that could affect the plants, plant products and other objects concerned, and concerning the signs of the presence of those pests, the symptoms caused by them, and the means to prevent the presence and spread of those pests;
 - (b) it has in place systems and procedures enabling it to fulfil its obligations concerning traceability pursuant to Articles 69 and 70.
2. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by setting out criteria to be fulfilled by the professional operators in order for them to comply with the conditions set out in point (a) of paragraph 1 of this Article and procedures to ensure that those criteria are met.

*Article 90***Obligations of authorised operators**

1. Where an authorised operator intends to issue a plant passport, it shall identify and monitor the points of its production process, and the points concerning the movement of plants, plant products and other objects, which are critical as regards compliance with Article 37(1), Article 41(1), Articles 85 and 87 and, where applicable, Article 33(2), Article 54(1) and Article 86, and the rules adopted pursuant to Article 28(1), (2) and (3), Article 30(1), (3) and (4), and, where applicable, Article 37(4).

It shall keep for at least three years records concerning the identification and monitoring of those points.

2. The authorised operator referred to in paragraph 1 shall ensure that appropriate training is provided, when necessary, to its personnel involved in the examinations referred to in Article 87, in order to ensure that that personnel possesses the necessary knowledge to carry out those examinations.

*Article 91***Pest risk management plans**

1. Authorised operators may have in place pest risk management plans. The competent authority shall approve those plans, if they fulfil all of the following conditions:

- (a) they set out measures which are appropriate for those operators to fulfil the obligations set out in Article 90(1);
- (b) they fulfil the requirements set out in paragraph 2 of this Article.

Authorised operators implementing an approved pest risk management plan may be subject to inspections with a reduced frequency.

2. The pest risk management plans shall cover, where appropriate in the form of standard operating procedure manuals, at least the following:

- (a) the information required under Article 66(2) concerning the registration of the authorised operator;
- (b) the information required under Articles 69(4) and 70(1) concerning the traceability of plants, plant products and other objects;
- (c) a description of the production processes of the authorised operator and its activities as regards movement and sales of plants, plant products and other objects;

- (d) an analysis of the critical points referred to in Article 90(1) and the measures taken by the authorised operator to mitigate the pest risks associated with those critical points;
- (e) the procedures in place and actions foreseen where quarantine pests are suspected or found to be present, the recording of those suspicions or findings and the recording of the actions taken;
- (f) the roles and responsibilities of the personnel involved in the notifications referred to in Article 14, the examinations referred to in Article 87(1), the issuance of plant passports pursuant to Article 84(1), Article 93(1) and (2) and Article 94, and the attaching of plant passports pursuant to Article 88; and
- (g) the training provided to the personnel referred to in point (f) of this paragraph.

3. Where the competent authority becomes aware that the professional operator concerned does not apply the measures referred to in point (a) of the first subparagraph of paragraph 1, or that a pest risk management plan is no longer up to date with any of the requirements referred to in point (b) of the first subparagraph of paragraph 1, that authority shall without delay take the measures necessary to ensure that non-compliance with those conditions does not continue. Those measures may include the withdrawal of the approval of that plan.

Where the competent authority has taken measures in accordance with the first subparagraph other than the withdrawal of the approval of the plan, and the non-compliance continues, that authority shall without delay withdraw that approval.

Article 92

Inspections and withdrawal of authorisation

1. The competent authority shall carry out inspections at least once per year, and sampling and testing if appropriate, to verify whether the authorised operators comply with Article 83(1), (2), (4) or (5), Article 87, Article 88, Article 89(1), Article 90 or Article 93(1), (2), (3) or (5).

2. Where the competent authority becomes aware that an authorised operator does not comply with the provisions referred to in paragraph 1 or that a plant, plant product or other object, for which that professional operator has issued a plant passport, does not comply with Article 85 or, where applicable, Article 86, that authority shall without delay take the measures necessary to ensure that non-compliance with those provisions does not continue.

Those measures may include the withdrawal of the authorisation to issue plant passports for the plants, plant products and other objects concerned.

3. Where the competent authority has taken measures in accordance with paragraph 2 other than the withdrawal of the authorisation to issue plant passports for the plants, plant products and other objects concerned, and non-compliance with Article 85 or, where applicable, Article 86 continues, that authority shall without delay withdraw that authorisation.

Article 93

Replacing a plant passport

1. An authorised operator which has received a trade unit of plants, plant products or other objects for which a plant passport has been issued, or the competent authority acting on request of a professional operator, may issue a new plant passport for that trade unit, replacing the plant passport initially issued for that trade unit, provided that the conditions of paragraph 3 are fulfilled.

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

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

- (a) the traceability requirements referred to in Article 69(3) concerning the plants, plant products or other objects concerned are fulfilled;

- (b) as applicable, the plants, plant products or other objects concerned continue to comply with the requirements referred to in Articles 85 and 86; and
 - (c) the characteristics of the plants, plant products or other objects concerned have not changed.
4. Where a plant passport is issued pursuant to paragraph 1 or 2, the examination referred to in Article 87(1) shall not be required.
5. Following the replacement of a plant passport pursuant to paragraph 1 or 2, the authorised operator concerned shall retain the replaced plant passport or its content for at least three years.

Where the replacement of a plant passport pursuant to paragraph 1 or 2 is carried out by the competent authority, the professional operator on whose request it is issued shall retain the replaced plant passport or its content for at least three years.

That retainment may take the form of storage of the information contained in the plant passport in a computerised database, provided that this includes the information contained in any traceability barcode, hologram, chip or other data carrier which may supplement the traceability code as referred to in Annex VII.

Article 94

Plant passports replacing phytosanitary certificates

1. By way of derogation from Article 87, where a plant, plant product or other object, introduced into the Union territory from a third country which, for movement within the Union territory, requires a plant passport pursuant to Article 79(1) and Article 80(1), the passport shall be issued if the checks by means of official controls at the border control post concerning its introduction have been completed satisfactorily and have led to the conclusion that the plant, plant product or other object concerned fulfils the substantive requirements for issuance of a plant passport according to Article 85 and, where appropriate, Article 86.

The replacement of a phytosanitary certificate by a plant passport may be carried out at the place of destination of the plant, plant product or other object concerned, instead of the point of entry, where checking at the place of destination is allowed, as referred to in Union legislation on official controls.

2. By way of derogation from the first subparagraph of paragraph 1, Member States may decide to replace a phytosanitary certificate at the place of entry of the plant, plant product or other object concerned into the Union territory by a certified copy of the original phytosanitary certificate.

That certified copy of the original phytosanitary certificate shall be issued by the competent authority and shall accompany the movement of the plant, plant product or other object concerned only up to the point where the plant passport is issued and only within the territory of the respective Member State.

3. The competent authority shall retain the phytosanitary certificate for at least three years. That retainment may take the form of storage of the information contained in the phytosanitary certificate in a computerised database.

Where point (a) of Article 101(2) applies, that phytosanitary certificate shall be replaced by a certified copy thereof.

Article 95

Invalidation and removal of the plant passport

1. The professional operator which has under its control a trade unit of plants, plant products or other objects shall invalidate the plant passport and, where possible, remove it from that trade unit where it becomes aware that any of the requirements of Articles 83 to 87, 89, 90, 93 or 94 are not fulfilled.

Without prejudice to the notification obligation referred to in Article 14, that professional operator shall inform the competent authority under the competence of which it operates.

2. Where the professional operator fails to comply with paragraph 1, the competent authority shall invalidate the plant passport and, where possible, remove it from the trade unit concerned.

3. Where paragraphs 1 and 2 apply, the professional operator concerned shall retain the invalidated plant passport or its content for at least three years.

That retention may take the form of storage of the information contained in the invalidated plant passport in a computerised database, provided that this includes the information contained in any traceability barcode, hologram, chip or other data carrier which may supplement the traceability code as referred to in Annex VII, and a statement concerning that invalidation.

4. Where paragraphs 1 and 2 apply, the professional operator concerned shall inform accordingly the authorised operator, or competent authority, who issued the invalidated plant passport.

5. Member States shall notify, through the electronic notification system referred to in Article 103, the Commission and other Member States where a plant passport was removed and invalidated pursuant to paragraph 2 of this Article.

Section 3

Other attestations

Article 96

Marking of wood packaging material, wood, or other objects

1. The mark applied on wood packaging material, wood or other objects to attest that a treatment has been applied in accordance with Annex 1 to ISPM15 shall comply with the requirements set out in Annex 2 to ISPM15 in all of the following cases:

- (a) wood packaging material introduced into the Union territory from a third country, as referred to in Article 43;
- (b) wood packaging material marked within the Union territory, moving out of the Union territory;
- (c) wood packaging material, wood or other objects moving within the Union territory, if required so by an implementing act adopted pursuant to Article 28, 30, 41 or 54;
- (d) any other wood packaging material, wood or other object marked within the Union territory.

The mark shall only be applied where the wood packaging material, wood or other objects have been subject to one or more of the approved treatments referred to in Annex 1 to ISPM15, without prejudice to Regulations (EC) No 1005/2009 ⁽¹⁾, (EC) No 1107/2009 ⁽²⁾ and (EU) No 528/2012 ⁽³⁾ of the European Parliament and of the Council.

For wood packaging material, wood or other objects marked in the Union territory, the mark shall only be applied by a registered operator authorised in accordance with Article 98.

Points (a) and (b) of the first subparagraph shall not apply to wood packaging material which is subject to the exemptions provided for in ISPM15.

2. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending the requirements set out in paragraph 1 of this Article in order to adapt them to the development of international standards and in particular to ISPM15.

Article 97

Repairing of wood packaging material in the Union territory

1. Wood packaging material that is marked with the mark referred to in Article 96 shall only be repaired if all of the following conditions are fulfilled:

- (a) the person carrying out that repair is a registered operator authorised in accordance with Article 98;

⁽¹⁾ Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1).

⁽²⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁽³⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

- (b) the material and treatment used are eligible for repair;
- (c) the mark is applied anew, as appropriate.

2. The Commission may, by means of implementing acts, set out specific arrangements concerning the material, treatment and marking referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2). Those implementing acts shall take into account relevant international standards and in particular ISPM15.

3. Paragraphs 1 and 2 shall not apply where a professional operator permanently obliterates by any means all earlier applications of that mark from the wood packaging material.

Article 98

Authorisation and supervision of registered operators applying the mark of wood packaging material in the Union territory

1. An authorisation to apply the mark referred to in Article 96 and to repair wood packaging material in accordance with Article 97 shall be granted by the competent authority on application to a registered operator provided that the registered operator fulfils both of the following conditions:

- (a) it possesses the necessary knowledge to carry out the treatment of the wood packaging material, wood and other objects required pursuant to the acts referred to in Articles 96 and 97;
- (b) it operates appropriate facilities and equipment to carry out that treatment ('treatment facilities');

The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by specifying the requirements for authorisation, where appropriate in view of the development of scientific and technical knowledge and international standards.

2. An authorisation to apply the mark referred to in Article 96 and to repair wood packaging material according to Article 97 shall be granted by the competent authority on application to a registered operator using wood treated in a facility of another operator, provided that it fulfils all of the following conditions in respect of wood packaging material marked with that mark:

- (a) it exclusively uses wood:
 - (i) which has been subject to one or more of the approved treatments referred to in Annex 1 of ISPM15 and has been treated in facilities operated by a registered operator authorised pursuant to paragraph 1 of this Article; or
 - (ii) which has been subject to one or more of the approved treatments referred to in Annex 1 of ISPM15 in a treatment facility in a third country that has been approved by the national plant protection organisation of that third country;
- (b) it ensures that the wood used for that purpose can be traced back to those treatment facilities in the Union territory or to the third country treatment facilities concerned;
- (c) where applicable pursuant to Article 28(1) and (2), Article 30(1) and (3), Article 41(2) and (3) and Article 54(2) and (3), it exclusively uses wood referred to in point (a) of this subparagraph which is accompanied by a plant passport or any other document providing guarantees that the treatment requirements referred to in Annex 1 to ISPM15 are fulfilled.

3. The competent authority shall supervise at least once per year the registered operators authorised pursuant to paragraphs 1 and 2 to verify and ensure that they treat and mark as appropriate wood packaging material, wood and other objects in accordance with Article 96(1) and Article 97 and fulfil the conditions set out respectively in paragraphs 1 and 2 of this Article.

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

Where the competent authority has taken those measures other than the withdrawal of the authorisation referred to in paragraphs 1 or 2, and the non-compliance continues, that authority shall without delay withdraw the authorisation referred to in paragraphs 1 or 2.

*Article 99***Attestations other than the mark of wood packaging material**

1. The Commission is empowered to adopt delegated acts in accordance with Article 105 supplementing this Regulation by setting out the elements to be contained in official attestations specific for plants, plant products or other objects, other than wood packaging material, which are required by the applicable international standards as form of proof of the implementation of measures adopted pursuant to Article 28(1) or (2), Article 30(1) or (3), Article 41(2) or (3), Article 44, or Article 54(2) or (3).
2. The delegated acts referred to in paragraph 1 may also set out requirements concerning one or more of the following:
 - (a) the authorisation of professional operators as regards the issuance of the official attestations referred to in paragraph 1;
 - (b) the supervision by the competent authority of the professional operators authorised pursuant to point (a) of this paragraph;
 - (c) the withdrawal of that authorisation referred to in point (a) of this paragraph.
3. The Commission shall adopt, by means of implementing acts, the format specifications of the attestations referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

*Section 4***Export of plants, plant products and other objects from the Union territory***Article 100***Phytosanitary certificate for export from the Union**

1. Where, for the export of a plant, plant product or other object from the Union territory to a third country, a phytosanitary certificate is required by the phytosanitary import requirements of that third country ('phytosanitary certificate for export'), that certificate shall be issued by the competent authority, at the request of the professional operator, when all of the following conditions are fulfilled:

- (a) the professional operator is registered by that competent authority in accordance with Article 65;
- (b) the professional operator has under its control the plant, plant product or other object to be exported;
- (c) it is ensured that that plant, plant product or other object complies with the phytosanitary import requirements of the third country concerned.

The competent authority shall also issue a phytosanitary certificate for export at the request of persons other than professional operators, provided that the conditions set out in points (b) and (c) of the first subparagraph are fulfilled.

For the purpose of this paragraph, the competent authority shall not delegate the issuance of the phytosanitary certificate for export to any other person.

2. Without prejudice to obligations under the IPPC, and taking into account the relevant international standards, the phytosanitary certificate for export shall be issued where the information available allows the competent authority to certify compliance of the plant, plant product or other object concerned with the phytosanitary import requirements of the third country concerned. That information may originate from one or more of the following elements, as applicable:

- (a) inspections, sampling and testing of the plants, plant products or other objects concerned, or their place of production and its vicinities;
- (b) official information on the pest status in the production site, place of production, area or country of origin of the plants, plant products or other objects concerned;
- (c) a plant passport, as referred to in Article 78, accompanying the plants, plant products or other objects concerned, where that plant passport attests the results of inspections by the competent authority;
- (d) the mark of wood packaging material as referred to in Article 96(1), or the attestations referred to in Article 99(1);

- (e) the information included in the pre-export certificate referred to in Article 102;
 - (f) official information included in the phytosanitary certificate as referred to in Article 71, where the plants, plant products or other objects concerned have been introduced into the Union territory from a third country.
3. The phytosanitary certificate for export shall comply with the description and format of the model set out in Part A of Annex VIII.
4. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending the elements referred to in paragraph 2 of this Article and Part A of Annex VIII to adapt them to the development of the relevant international standards.
5. Electronic phytosanitary certificates for export shall be provided through, or in electronic exchange with, a computerised information management system for official controls at Union level.

Article 101

Phytosanitary certificate for re-export from the Union

1. For the re-export of a plant, plant product or other object which originates in a third country and has been introduced into the Union territory from that, or another, third country, a phytosanitary certificate for re-export from the Union ('the phytosanitary certificate for re-export') shall, where possible, be issued instead of the phytosanitary certificate for export.

The phytosanitary certificate for re-export shall be issued by the competent authority at the request of the professional operator when all of the following conditions are fulfilled:

- (a) that professional operator is registered by that competent authority in accordance with Article 65;
- (b) the professional operator has under its control the plant, plant product or other object to be re-exported;
- (c) it is ensured that that plant, plant product or other object complies with the phytosanitary import requirements of the third country concerned.

The competent authority shall also issue a phytosanitary certificate for re-export at the request of persons other than professional operators, provided that the conditions set out in points (b) and (c) of the second subparagraph are fulfilled.

For the purpose of this paragraph, the competent authority shall not delegate the issuance of the phytosanitary certificate for re-export to any other person.

2. Without prejudice to obligations under the IPPC, and taking into account the relevant international standards, the phytosanitary certificate for re-export shall be issued where the information available allows certifying of compliance with the phytosanitary import requirements of the third country concerned and that all of the following conditions are complied with:

- (a) the original phytosanitary certificate accompanying the plant, plant product or other object concerned from the third country of origin, or a certified copy of it, is attached to the phytosanitary certificate for re-export;
- (b) the plant, plant product or other object concerned has not been grown, produced or processed to change its nature since its introduction in the Union territory;
- (c) the plant, plant product or other object concerned has not been exposed to any risk of infestation or contamination with quarantine pests or regulated non-quarantine pests, listed as such by the third country of destination, during storage in the Member State from which it is to be exported to that third country;
- (d) the identity of the plant, plant product or other object concerned has been maintained.

3. Article 100(2) shall apply *mutatis mutandis*.

4. The phytosanitary certificate for re-export shall comply with the description and format of the model set out in Part B of Annex VIII.

5. The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Part B of Annex VIII to adapt it to the development of the relevant international standards.

6. Electronic phytosanitary certificates for re-export shall be provided through, or in electronic exchange with, a computerised information management system for official controls at Union level.

Article 102

Pre-export certificates

1. The competent authorities of the Member State from which the plants, plant products or other objects referred to in Article 100(1) are exported and the competent authorities of the Member State in which the plants, plant products or other objects were grown, produced, stored or processed shall exchange the necessary phytosanitary information as the basis for issuing the phytosanitary certificate for export.

2. The exchange of information referred to in paragraph 1 shall take the form of a harmonised document ('pre-export certificate'), in which the competent authorities of the Member State, in which the plants, plant products and other objects were grown, produced, stored or processed, certify compliance of those plants, plant products or other objects with specific phytosanitary requirements concerning one or more of the following:

- (a) the absence, or presence below a specified threshold, of particular pests in the plants, plants products or other objects concerned;
- (b) the origin of the plants, plant products or other objects concerned in a specific field, production site, place of production or area;
- (c) the pest status in the field, production site, place of production or area of origin or country of origin of the plants, plant products or other objects concerned;
- (d) the results of the inspections, sampling and testing of the plants, plant products or other objects concerned;
- (e) the phytosanitary procedures applied to the production or processing of the plants, plant products or other objects concerned.

3. The pre-export certificate shall be issued, on request of the professional operator, by the competent authorities of the Member State in which the plants, plant products or other objects were grown, produced, stored or processed, while those plants, plant products or other objects are on the premises of the professional operator concerned.

4. The pre-export certificate shall accompany the plants, plant products and other objects concerned during their movement within the Union territory, unless the information contained in it is exchanged between the Member States concerned through, or in electronic exchange with, a computerised information management system for official controls at Union level.

5. Without prejudice to the requirements set out in paragraph 3, the pre-export certificate may be issued when the plants, plant products or other objects have left the premises of the professional operator concerned, provided that inspections and, where necessary, sampling have been carried out, confirming the compliance of those plants, plant products or other objects with one or more of the specific phytosanitary requirements referred to in paragraph 2.

6. The pre-export certificate shall contain the elements and shall be in the format as set out in Part C of Annex VIII.

The Commission is empowered to adopt delegated acts in accordance with Article 105 amending Part C of Annex VIII in order to adapt it to the development of scientific and technical knowledge and of relevant international standards.

7. The Commission may, by means of implementing acts, lay down the procedures for the issuance of the pre-export certificate. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

CHAPTER VII

Supporting measures by the Commission*Article 103***Establishment of electronic notification system**

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

That system shall be connected to, and compatible with, a computerised information management system for official controls at Union level.

*Article 104***Information items, format and deadlines of notifications, and notifications in the case of suspected presence of pests**

The Commission may, by means of implementing acts, lay down specific rules concerning the submission of notifications referred to in Article 9(1) and (2), Article 11, Article 17(3), Article 18(6), Article 19(2), Article 28(7), the first subparagraph of Article 29(3), Article 30(8), Article 33(1), Article 40(4), Article 41(4), Article 46(4), Article 49(6), Article 53(4), Article 54(4), Article 62(1), Article 77(2) and Article 95(5). Those rules shall concern one or more the following elements:

- (a) the information items to be included in those notifications;
- (b) the format of those notifications and instructions on how to fill in that format;
- (c) deadlines for the submission of particular information items as referred to in point (a);
- (d) the cases where the suspected presence of a pest shall be notified due to the need to take swift action in view of its biology and possibility of rapid and wide spread;
- (e) the cases of non-compliance to be notified where that non-compliance creates a risk for spread of a Union quarantine pest or a pest provisionally qualifying as Union quarantine pest.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(2).

CHAPTER VIII

Final provisions*Article 105***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 power to adopt delegated acts referred to in Article 6(2), Article 7, Article 8(5), Article 19(7), Article 21, Article 32(5), Article 34(1), Article 38, Article 43(2), Article 46(2), Article 48(5), Article 51, Article 65(4), Article 71(4), Article 76(4), Article 81(2), Article 83(6), Article 87(4), Article 89(2), Article 96(2), Article 98(1), Article 99(1), Article 100(4), Article 101(5) and Article 102(6) shall be conferred on the Commission for a period of five years from 13 December 2016. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 6(2), Article 7, Article 8(5), Article 19(7), Article 21, Article 32(5), Article 34(1), Article 38, Article 43(2), Article 46(2), Article 48(5), Article 51, Article 65(4), Article 71(4), Article 76(4), Article 81(2), Article 83(6), Article 87(4), Article 89(2), Article 96(2), Article 98(1), Article 99(1), Article 100(4), Article 101(5) and Article 102(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke 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. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 6(2), Article 7, Article 8(5), Article 19(7), Article 21, Article 32(5), Article 34(1), Article 38, Article 43(2), Article 46(2), Article 48(5), Article 51, Article 65(4), Article 71(4), Article 76(4), Article 81(2), Article 83(6), Article 87(4), Article 89(2), Article 96(2), Article 98(1), Article 99(1), Article 100(4), Article 101(5) and Article 102(6) shall enter into force only if no objection has been expressed either by the European Parliament or by 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 of the Council.

Article 106

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 105(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 107

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 ⁽¹⁾. That committee is a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

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

Article 108

Penalties

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

The Member States shall notify those provisions to the Commission by 14 December 2019 and shall notify it without delay of any subsequent amendments affecting them.

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

*Article 109***Repeals**

1. Directive 2000/29/EC is repealed, with the exception of the following provisions:
 - (a) Article 1(4);
 - (b) the introductory part and points (g), (i), (j), (k), (l), (m), (n), (p), (q) and (r) of Article 2(1);
 - (c) Article 11(3);
 - (d) Article 12;
 - (e) Article 13;
 - (f) Article 13a;
 - (g) Article 13b;
 - (h) Article 13c;
 - (i) Article 13d;
 - (j) Article 21(1) to (5);
 - (k) Article 27a;
 - (l) Annex VIIIa.
2. The following Directives are repealed:
 - (a) Directive 69/464/EEC;
 - (b) Directive 74/647/EEC;
 - (c) Directive 93/85/EEC;
 - (d) Directive 98/57/EC;
 - (e) Directive 2006/91/EC;
 - (f) Directive 2007/33/EC.
3. References to the acts repealed in accordance with paragraphs 1 and 2 shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IX.

*Article 110***Amendment of Regulation (EU) No 228/2013**

In Article 24(2) of Regulation (EU) No 228/2013, the following subparagraph is added:

‘Union financing of the programmes for the control of pests in the outermost regions of the Union shall be implemented in accordance with Regulation (EU) No 652/2014 of the European Parliament and of the Council (*).

(*) Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).’.

*Article 111***Amendment of Regulation (EU) 652/2014**

Regulation (EU) No 652/2014 is amended as follows:

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

‘(e) on protective measures against pests of plants;’.

(2) in Article 5(2), the following point is added:

‘(c) the programmes for the control of pests in the outermost regions of the Union as referred to in Article 25;’

(3) in Article 16(1), points (a), (b) and (c) are replaced by the following:

‘(a) measures to eradicate a pest from an infested area, taken by the competent authorities pursuant to Article 17(1), Article 28(1), Article 29(1) or Article 30(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council (*);

(b) measures to contain a priority pest, listed pursuant to Article 6(2) of Regulation (EU) 2016/2031, against which Union containment measures have been adopted pursuant to Article 28(2) of that Regulation, in an infested area from which that priority pest cannot be eradicated, where those measures are essential to protect the Union territory against further spread of that priority pest. Those measures shall concern the eradication of that pest from the buffer zone surrounding that infested area if it is found to be present in that buffer zone; and

(c) prevention measures taken against the spread of a priority pest, listed pursuant to Article 6(2) of Regulation (EU) 2016/2031, against which Union measures have been adopted pursuant to Article 28(3) of that Regulation, where those measures are essential to protect the Union territory against further spread of that priority pest.

(*) Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).’;

(4) Article 17 is replaced by the following:

‘Article 17

Conditions

The measures referred to in Article 16 may qualify for grants provided that they have been applied immediately and the applicable provisions laid down in the relevant Union law have been complied with, and provided that one or more of the following conditions are fulfilled:

(a) they concern Union quarantine pests, listed pursuant to Article 5(2) of Regulation (EU) 2016/2031 as not known to occur in the Union territory;

(b) they concern pests, not listed as Union quarantine pests, which are subject to a measure adopted by the competent authority of a Member State pursuant to Article 29(1) of Regulation (EU) 2016/2031;

(c) they concern pests, not listed as Union quarantine pests, which are covered by a measure adopted by the Commission pursuant to Article 30(1) of Regulation (EU) 2016/2031;

(d) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) 2016/2031.

For measures fulfilling the condition laid down in point (b) of the first paragraph, the grant shall not cover costs incurred later than two years after the entry into force of the measure adopted by the competent authority of the Member State concerned pursuant to Article 29 of Regulation (EU) 2016/2031, or incurred after the expiry of that measure. For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 30(1) of Regulation (EU) 2016/2031.’;

(5) in paragraph 1 of Article 18, point (d) is replaced by the following:

‘(d) costs of compensation to the owners concerned for the value of the destroyed plants, plant products or other objects subject to the measures referred to in Article 16, limited to the market value of such plants, plant products and other objects as if they were not affected by those measures; the salvage value, if any, shall be deducted from the compensation; and’;

(6) Article 19 is amended as follows:

(a) the first paragraph is replaced by the following:

‘Grants may be awarded to Member States for annual and multiannual survey programmes that they carry out concerning the presence of pests (“survey programmes”), provided that those survey programmes comply with at least one of the following three conditions:

- (a) they concern Union quarantine pests listed pursuant to Article 5(2) of Regulation (EU) 2016/2031 as not known to occur in the Union territory;
- (b) they concern priority pests listed pursuant to Article 6(2) of Regulation (EU) 2016/2031; and
- (c) they concern pests not listed as Union quarantine pests which are covered by a measure adopted by the Commission pursuant to Article 30(1) of Regulation (EU) 2016/2031.’;

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

‘For measures fulfilling the condition laid down in point (c) of the first paragraph, the grant shall not cover costs incurred after the expiry of the measure adopted by the Commission pursuant to Article 30(1) of Regulation (EU) 2016/2031.’;

(7) in Article 20, a new point is inserted before point (a):

‘(-a) costs for visual examinations.’;

(8) in Article 47, point 2 is replaced by the following:

‘(2) The following Article is inserted:

“Article 15a

Member States shall provide that anyone who becomes aware of the presence of a pest listed in Annex I or Annex II or a pest covered by a measure pursuant to Article 16(2) or 16(3), or has reason to suspect such a presence, shall immediately notify the competent authority, and, if so requested by that competent authority, shall provide the information concerning that presence which is in its possession. Where the notification is not submitted in writing, the competent authority shall officially record it.”’.

Article 112

Amendment of Regulation (EU) No 1143/2014

In Article 2(2) of Regulation (EU) No 1143/2014, point (d) is replaced by the following:

‘(d) pests of plants listed pursuant to Article 5(2) or Article 32(3), or subject to measures pursuant to Article 30(1), of Regulation (EU) 2016/2031 of the European Parliament and of the Council (*);

(*) Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).’.

Article 113

Entry into force and application

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

It shall apply from 14 December 2019. However:

- (a) point 8 of Article 111 shall apply from 1 January 2017;
- (b) Article 100(3) and Article 101(4) shall apply from 1 January 2021.

2. The acts referred to in points (a), (c), (d) and (f) of Article 109(2) are repealed with effect from 1 January 2022. In the event of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

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

Done at Strasbourg, 26 October 2016.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

I. LESAY

ANNEX I

CRITERIA FOR THE QUALIFICATION OF PESTS ACCORDING TO THEIR RISK TO THE UNION TERRITORY

SECTION 1

Criteria to identify pests which qualify as a quarantine pest, as referred to in Article 3, Article 6(1), Article 7, Article 29(2), Article 30(2) and Article 49(3)

(1) Identity of the pest

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

The taxonomic identity of the pest shall be defined at species level or, alternatively, a higher or lower taxonomic level, where that taxonomic level is scientifically appropriate based on its virulence, host range or vector relationships.

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

One or more of the following conditions shall apply:

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

Where point (b) or (c) applies, the pest shall be considered to be not widely distributed.

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

(a) Capability of entry

The pest shall be considered capable of entry into the territory in question, or, if present but not widely distributed, into the part of that territory where it is absent ('relevant part of the endangered area'), either by natural spread, or if all of the following conditions are fulfilled:

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

(b) Capability of establishment

The pest shall be considered capable of 'establishment' in the territory in question, or, if present but not widely distributed, in the part of that territory where it is absent, if all of the following conditions are fulfilled:

- (i) hosts of the pest and, where relevant, vectors for transmission of the pest are available;
- (ii) the decisive environmental factors are favourable for the pest concerned and, where applicable, its vector, enabling it to survive periods of climatic stress and complete its life cycle;

- (iii) cultivation practices and control measures applied in that territory are favourable;
- (iv) the survival methods, reproductive strategy, genetic adaptability of the pest and its minimum viable population size support its establishment.

(c) Capability of spread

The pest shall be considered capable of territorial spread in the territory in question, or, if present but not widely distributed, in the part of that territory where it is absent, if one or more of the following conditions is fulfilled:

- (i) the environment is suitable for natural spread of the pest;
- (ii) barriers to natural spread of the pest are insufficient;
- (iii) commodities or conveyances allow for movement of the pest;
- (iv) hosts and, where relevant, vectors of the pest are present;
- (v) cultivation practices and control measures applied in that territory are favourable;
- (vi) natural enemies and antagonists of the pest are not present or not sufficiently capable of suppressing the pest.

(4) Potential economic, social and environmental impact

The entry, establishment and spread of the pest in the territory in question, or, if present but not widely distributed, in the part of that territory where it is absent, shall have an unacceptable economic, social and/or environmental impact on that territory, or the part of that territory where it is not widely distributed, as regards one or more of the following points:

- (a) crop losses in terms of yield and quality;
- (b) costs of control measures;
- (c) costs of replanting and/or losses due to the necessity of growing substitute plants;
- (d) effects on existing production practices;
- (e) effects on street trees, parks and natural and planted areas;
- (f) effects on native plants, biodiversity and ecosystem services;
- (g) effects on the establishment, spread and impact of other pests, for example due to the capacity of the pest concerned to act as a vector for other pests;
- (h) changes to producer costs or input demands, including control costs and costs of eradication and containment;
- (i) effects on producer profits that result from changes in quality, production costs, yields or price levels;
- (j) changes to domestic or foreign consumer demand for a product resulting from quality changes;
- (k) effects on domestic and export markets and prices paid, including effects on export market access and likelihood of phytosanitary restrictions imposed by trading partners;
- (l) resources needed for additional research and advice;
- (m) environmental and other undesired effects of control measures;
- (n) effects on Natura 2000 or other protected areas;
- (o) changes in ecological processes and the structure, stability or processes of an ecosystem, including further effects on plant species, erosion, water table changes, fire hazards, nutrient cycling;

- (p) costs of environmental restoration and prevention measures;
- (q) effects on food security and food safety;
- (r) effects on employment;
- (s) effects on water quality, recreation, tourism, landscape heritage, animal grazing, hunting, fishing.

SECTION 2

Criteria to identify Union quarantine pests which qualify as a priority pest as referred to in Article 6(1) and (2)

Union quarantine pests shall be considered to have the most severe economic, social or environmental impact in respect of the Union territory if their entry, establishment and spread fulfils one or more of the following points:

- (a) Economic impact: the pest has the potential to cause major losses in terms of the direct and indirect effects referred to in point (4) of Section 1 for plants with a significant economic value in the Union territory.

The plants referred to in the first subparagraph may be trees that are not in production.

- (b) Social impact: the pest has the potential to cause one or more of the following effects:
 - (i) a significant employment decrease in the agriculture, horticulture or forestry sector concerned or industries related to those sectors, including tourism and recreation;
 - (ii) significant risks to food security or food safety;
 - (iii) the disappearance of, or long-term large-scale damage to, important tree species growing or cultivated in the Union territory or tree species of high importance in terms of landscape as well as cultural or historical heritage for the Union.
- (c) Environmental impact: the pest has the potential to cause one or more of the following effects:
 - (i) significant effects on biodiversity and ecosystems services, including effects on species and habitats listed under Council Directive 92/43/EEC ⁽¹⁾ and Directive 2009/147/EC of the European Parliament and of the Council ⁽²⁾;
 - (ii) significant and long-term increases of the use of plant protection products on the plants concerned;
 - (iii) the disappearance of, or long-term large-scale damage to, important tree species growing or cultivated in the Union territory or tree species of high importance in terms of landscape as well as cultural or historical heritage for the Union.

SECTION 3

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 29(1) and Article 30(1)

Subsection 1

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 29(1)

- (1) Identity of the pest

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

⁽¹⁾ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

⁽²⁾ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

(2) Presence of the pest in the Member State's territory

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

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

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

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

Based on the information available to the Member State, the pest would have an unacceptable economic, social and/or environmental impact on its territory and, to the extent possible for the Member State to assess this, the Union territory, if it established and spread in that territory.

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

Subsection 2

Criteria for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 30(1)

(1) Identity of the pest

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

(2) Presence of the pest in the Union territory

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

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

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

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

Based on the information available to the Union, the pest would have an unacceptable economic, social and/or environmental impact on the Union territory, if it established and spread in that territory.

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

SECTION 4

Criteria to identify pests which qualify as a Union regulated non-quarantine pest as referred to in Articles 36 and 38

(1) Identity of the pest

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

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

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

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

- (a) the number of life cycles of the pest on the hosts concerned;
- (b) the biology, epidemiology and survival of the pest;
- (c) possible natural, human-assisted or other pathways for transmission of the pest to the host concerned and pathway efficiency, including mechanisms of dispersal and dispersal rate;
- (d) subsequent infestation and transmission of the pest from the host concerned to other plants and vice versa;
- (e) climatological factors;
- (f) cultural practices before and after harvest;
- (g) soil types;
- (h) susceptibility of the host concerned and relevant stages of host plants;
- (i) presence of vectors for the pest;
- (j) presence of natural enemies and antagonists of the pest;
- (k) presence of other hosts susceptible to the pest;
- (l) prevalence of the pest in the Union territory;
- (m) intended use of the plants.

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

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

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

ANNEX II

MEASURES AND PRINCIPLES FOR THE MANAGEMENT OF THE RISKS OF PESTS

SECTION 1

Measures to manage the risks of quarantine pests as referred to in Article 17(1), Article 21, Article 25(2), Article 28(4) and (6), Article 29(1), Article 30(5) and (7), Article 40(3), Article 41(3), Article 42(4), Article 46(3), Article 53(3), Article 54(3) and Article 75(2)

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

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

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

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

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

- (i) the registration, authorisation and official supervision of professional operators applying the treatment concerned;
- (ii) 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 96(1) following the application of the treatment concerned.

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

- (a) Restrictions on the identity, nature, origin, provenance, ancestry, production method, production history and traceability of plants, plant products and other objects.
- (b) Restrictions on the introduction, movement, use, handling, processing, packaging, storage, distribution and destination of plants, plant products and other objects.

- (c) Surveillance, visual examination, sampling, laboratory testing of plants, plant products and other objects for the presence of quarantine pests, including through subsection to quarantine procedures and pre-export inspections in third countries.
- (d) Physical, chemical and biological treatment and, where appropriate, destruction of plants, plant products and other objects infested or potentially infested with quarantine pests.
- (e) Information, data recording, communication and reporting obligations.
- (f) Registration of professional operators concerned.

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

- (i) the issuance of a phytosanitary certificate, plant passport, label or other official attestation, including the placing of the mark referred to in Article 96(1) to attest compliance with points (a) to (d);
 - (ii) the registration, authorisation and official supervision of professional operators applying the treatment referred to in point (d).
- (3) Measures targeting pathways for quarantine pests, other than consignments of plants, plant products or other objects
- (a) Restrictions on the introduction and movement of quarantine pests as a commodity.
 - (b) Surveillance, visual examination, sampling and laboratory testing and where appropriate destruction of quarantine pests as a commodity.
 - (c) Restrictions on plants, plant products and other objects carried by travellers.
 - (d) Surveillance, visual examination, sampling and laboratory testing and where appropriate treatment or destruction of plants, plant products and other objects carried by travellers.
 - (e) Restrictions on vehicles, packaging and other objects used in transport of commodities.
 - (f) Surveillance, visual examination, sampling and laboratory testing and where appropriate treatment or destruction of vehicles, packaging and other objects used in transport of commodities.
 - (g) Information, data recording, communication and reporting obligations.
 - (h) Registration of professional operators concerned.

SECTION 2

Principles for the management of the risks of pests as referred to in Article 17(1), Article 18(3), Article 21, Article 28(4) and (6), Article 29(1), Article 30(5) and (7), Article 31(1), Article 37(4) and (8), Article 40(3), Article 41(3), Article 46(3), Article 49(2) and (4), Article 53(3), Article 54(3), Article 72(3), Article 74(3), Article 75(2), Article 79(3) and Article 80(3)

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

(1) Necessity

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

(2) Proportionality

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

(3) Minimal impact

Measures taken to manage the risk of a pest shall represent the least restrictive measures available, and result in the minimum impediment to the international movement of people, commodities and conveyances.

(4) Non-discrimination

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

(5) Technical justification

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

(6) Feasibility

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

ANNEX III

**CRITERIA TO ASSESS HIGH-RISK PLANTS, PLANT PRODUCTS OR OTHER OBJECTS AS REFERRED TO IN
ARTICLE 42**

The criteria to be taken into account for the assessment referred to in Article 42 are the following:

(1) as regards plants for planting other than seeds:

- (a) they are introduced into the Union usually in the form of a shrub or tree or they are present in the Union territory in such form or are taxonomically related to such plants;
- (b) they are collected in the wild or grown from plants collected in the wild;
- (c) they are grown outdoors or grown from plants grown outdoors in the third countries, group of third countries or specific areas of third countries concerned;
- (d) they are known to host commonly hosted pests known to have a major impact on plant species which are of major economic, social or environmental importance to the Union territory;
- (e) they are known to commonly harbour pests without signs and symptoms of those pests, or with a latent period for the expression of those signs or symptoms, implying that the presence of pests is likely to be missed during inspections at introduction into the Union territory;
- (f) they are perennial plants commonly traded as old plants;

(2) as regards other plants, plant products or other objects:

- (a) they are known to host and provide a significant pathway for commonly hosted pests known to have major impact on plant species which are of a major economic, social or environmental importance to the Union territory;
 - (b) they are known to commonly harbour and provide a significant pathway for pests without signs and symptoms of those pests, or with a latent period for the expression of those signs or symptoms, implying that the presence of pests is likely to be missed during inspections at introduction into the Union territory.
-

ANNEX IV

ELEMENTS TO IDENTIFY PLANTS OR PLANT PRODUCTS WHICH ARE LIKELY TO POSE NEWLY IDENTIFIED PEST RISKS OR OTHER SUSPECTED PHYTOSANITARY RISKS FOR THE UNION TERRITORY, AS REFERRED TO IN ARTICLE 49

Plants or plant products from third countries shall be considered likely to pose pest risks for the Union territory, as referred to in Article 49(1), where those plants or plant products fulfil at least three of the following conditions, including at least one of the conditions provided in point (1)(a), (b) and (c):

(1) Characteristics of the plants or plant products:

- (a) they belong to, or are produced from, a plant genus or family known to commonly host pests regulated as quarantine pests in the Union territory or in third countries;
- (b) they belong to, or are produced from, a plant genus or family known to host commonly hosted pests known to have major impact on plant species grown in the Union territory which have major economic, social or environmental importance to the Union territory;
- (c) they belong to, or are produced from, a plant genus or family known to commonly harbour pests without signs and symptoms of those pests, or with a latent period for the expression of those signs or symptoms of at least three months, implying that the presence of pests on those plants or plant products is likely to be missed during official controls at introduction into the Union territory, without recourse to sampling and testing or submission to quarantine procedures;
- (d) they are grown outdoors or grown from plants grown outdoors in the third countries of origin;
- (e) they are not shipped in closed containers or packaging, or when shipped in such a way, the shipments because of their size cannot be opened in closed premises for purposes of official controls at introduction into the Union territory.

(2) Origin of the plants or plant products:

- (a) they originate from, or are moved from, a third country which is the source of repetitive notifications of interception of quarantine pests not listed pursuant to Article 5(2);
 - (b) they originate from, or are moved from, a third country which is not a contracting party to the IPPC.
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ANNEX V

CONTENTS OF PHYTOSANITARY CERTIFICATES FOR INTRODUCTION INTO THE UNION TERRITORY

PART A

*Phytosanitary certificates for export as referred to in Article 76(1)***Model Phytosanitary Certificate**

No _____

Plant Protection Organisation of _____

TO: Plant Protection Organisation(s) of _____

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

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

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

II. Additional Declaration

[Enter text here]

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

Place of issue _____

(Stamp of Organisation) _____ Name of authorised officer _____

Date _____

(Signature)

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

(*) Optional clause

PART B

*Phytosanitary certificates for re-export as referred to in Article 76(1)***Model Phytosanitary Certificate for Re-Export**

No _____

Plant Protection Organisation of _____ (contracting party of re-export)

TO: Plant Protection Organisation(s) of _____ (contracting party(ies) of import)

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

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

(*) original ☐ (*) certified true copy ☐

of which is attached to this certificate; that they are

(*) packed ☐ (*) repacked ☐

in

(*) original ☐ (*) new ☐

containers, that based on the

(*) original phytosanitary certificate ☐

and

(*) additional inspection ☐

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

II. Additional Declaration

[Enter text here]

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

Place of issue _____

(Stamp of Organisation) _____ Name of authorised officer _____

Date _____

(Signature)

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

(*) Insert tick in appropriate

☐

boxes

(**) Optional clause

ANNEX VI

**CRITERIA TO IDENTIFY PLANTS REFERRED TO IN ARTICLE 73 WHICH DO NOT REQUIRE
A PHYTOSANITARY CERTIFICATE**

The assessment referred to in Article 73 shall take into account the following criteria:

- (1) the plants do not host Union quarantine pests or pests subject to measures adopted pursuant to Article 30, or commonly hosted pests which may impact on plant species grown in the Union;
 - (2) the plants have a history of compliance with the requirements for introduction into the Union territory relevant to the third country or countries of origin;
 - (3) no indication of outbreak(s) is linked to the introduction of the plants concerned from one or more third countries, and those plants have not been subject to repetitive interceptions of Union quarantine pests or pests subject to the measures adopted pursuant to Article 30 during the introduction into the Union territory.
-

ANNEX VII

PLANT PASSPORTS

PART A

Plant passports for movement within the Union territory as referred to in the first subparagraph of Article 83(2)

- (1) The plant passport for movement within the Union territory shall contain the following elements:
- (a) the words 'Plant Passport' in its upper right-hand corner, in one of the official languages of the Union and in English, if different, separated by a slash;
 - (b) the flag of the Union in its upper left-hand corner, printed in colour or in black and white;
 - (c) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in the case of plants and plant products, or, where appropriate, the name of the object concerned, and, optionally, the name of the variety;
 - (d) the letter 'B.', followed by subsequently the two-letter code, referred to in point (a) of Article 67, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned who issues the plant passport or for whom the plant passport is issued by the competent authority;
 - (e) the letter 'C.', followed by the traceability code of the plant, plant product or the other object concerned;
 - (f) the letter 'D.', where applicable followed by:
 - (i) the name of the third country of origin, or
 - (ii) two-letter code, referred to in point (a) of Article 67, of the Member State of origin.
- (2) The traceability code referred to in point (1)(e) may also be supplemented by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the trade unit.

PART B

Plant passports for movement into and within protected zones as referred to in the second subparagraph of Article 83(2)

- (1) The plant passport for movement into and within protected zones shall contain the following elements:
- (a) the words 'Plant Passport — PZ' in its upper right-hand corner, in one of the official languages of the Union and in English, if different, separated by a slash;
 - (b) immediately underneath those words, the scientific name(s) or the code(s) of the respective protected zone quarantine pest(s), as referred to in Article 32(3);
 - (c) the flag of the Union in its upper left-hand corner, printed in colour or in black and white;
 - (d) the letter 'A.', followed by the botanical name of the plant species or taxon concerned, in the case of plants and plant products, or, where appropriate, the name of the object concerned and, optionally, the name of the variety;
 - (e) the letter 'B.', followed by subsequently the two-letter code, referred to in point (a) of Article 67, for the Member State in which the professional operator issuing the plant passport is registered, a hyphen and the registration number of the professional operator concerned who issues the plant passport or for whom the plant passport is issued by the competent authority;

- (f) the letter 'C.', followed by the traceability code of the plant, plant product or the other object concerned;
- (g) the letter 'D.', where appropriate followed by:
 - (i) the name of the third country of origin, or
 - (ii) two-letter code, referred to in point (a) of Article 67, of the Member State of origin and, in the case of replacement of the plant passport, the registration number of the professional operator concerned who issued the initial plant passport or for whom the initial plant passport was issued by the competent authority as referred in Article 93(1) and (2).
- (2) The traceability code referred to in point (1)(f) may also be supplemented by a reference to a unique traceability barcode, hologram, chip or other data carrier, present on the trade unit.

PART C

Plant passports for movement within the Union territory, combined with a certification label, as referred to in the second subparagraph of Article 83(5)

- (1) The plant passport for movement within the Union territory, combined in a joint label with the official label for seeds or other propagating material referred to respectively in Article 10(1) of Directive 66/401/EEC, Article 10(1) of Directive 66/402/EEC, Article 10(1) of Directive 68/193/EEC, Article 12 of Directive 2002/54/EC, Article 28(1) of Directive 2002/55/EC, Article 13(1) of Directive 2002/56/EC, and Article 12(1) of Directive 2002/57/EC, and the label for pre-basic, basic or certified material as referred to in point (b) of Article 9(1) of Directive 2008/90/EC, shall contain the following elements:
 - (a) the words 'Plant Passport' in the upper right-hand corner of the joint label, in one of the official languages of the Union and in English, if different, separated by a slash;
 - (b) the flag of the Union in the upper left-hand corner of the joint label printed in colour or in black and white.

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

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

PART D

Plant passports for movement into and within protected zones, combined with a certification label, as referred to in the third subparagraph of Article 83(5)

- (1) The plant passport for movement into and within protected zones, combined in a joint label with the official label for seeds or other propagating material referred to respectively in Article 10(1) of Directive 66/401/EEC, Article 10(1) of Directive 66/402/EEC, Article 10(1) of Directive 68/193/EEC, Article 12 of Directive 2002/54/EC, Article 28(1) of Directive 2002/55/EC, Article 13(1) of Directive 2002/56/EC and Article 12(1) of Directive 2002/57/EC, and the label for pre-basic, basic or certified material as referred to in point (b) of Article 9(1) of Directive 2008/90/EC, shall contain the following elements:
 - (a) the words 'Plant Passport — PZ' in the upper right-hand corner of the joint label in one of the official languages of the Union and in English, if different, separated by a slash;
 - (b) immediately underneath those words, the scientific name(s) or code(s) of the protected zone quarantine pest(s) concerned;
 - (c) the flag of the Union in the upper left-hand corner of the joint label printed in colour or in black and white.

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

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

ANNEX VIII

CONTENTS OF PHYTOSANITARY CERTIFICATES FOR EXPORT, RE-EXPORT AND PRE-EXPORT AS REFERRED TO IN ARTICLE 100(3), ARTICLE 101(4) AND ARTICLE 102(6)

PART A

Phytosanitary certificates for export as referred to in Article 100(3)

1. The phytosanitary certificate for movement out of the Union territory, for the purpose of export to a third country, shall contain the following elements:
 - (a) the words 'Phytosanitary certificate', followed by subsequently:
 - (i) the letters 'EU';
 - (ii) the two-letter code, referred to in point (a) of Article 67, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for export is registered;
 - (iii) a slash;
 - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
 - (b) the words 'Name and address of exporter', followed by the name and address of the registered operator, or private person, requesting the issuance of the phytosanitary certificate for export;
 - (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
 - (d) the words 'Plant Protection Organisation of', followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the Plant Protection Organisation(s) of', followed by the name or, as applicable, names of the country or, as applicable, countries of destination;
 - (e) the words 'Place of origin', followed by the place or places of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued. In all cases, the name of the country or countries of origin should be stated;
 - (f) an unnumbered box, reserved for the EU logo. Optionally, other official logos can be added;
 - (g) the words 'Declared means of conveyance', followed by the declared means of conveyance of that consignment;
 - (h) the words 'Declared point of entry', followed by the declared point of entry into the country of destination of that consignment;
 - (i) the words 'Distinguishing marks; number and description of packages; name of produce; botanical name of plants', followed by a description of the consignment including botanical name of plants or the name of the produce, distinguishing marks, and the number and type of packages included in the consignment;
 - (j) the words 'Quantity declared', followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;
 - (k) the words 'This is to certify that the plants, plant products or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party, including those for regulated non-quarantine pests'. Optionally, the following clause may be added: 'They are deemed to be practically free from other pests.';

- (l) the words 'Additional declaration', followed by the additional declaration referred to in Article 71(2) and the statement referred to in Article 71(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, an attachment may be added. The information in the attachment should only include what is required on the phytosanitary certificate. All the pages of the attachment should bear the number of the phytosanitary certificate and should be dated, signed and stamped in the same manner as required for the phytosanitary certificate. The phytosanitary certificate should refer to any attachments in the appropriate section;
 - (m) the words 'Disinfestation and/or disinfection treatment';
 - (n) the word 'Treatment', followed by the treatment that has been applied to that consignment;
 - (o) the words 'Chemical (active ingredient)', followed by the active ingredient of the chemical used for the treatment referred to in point (n);
 - (p) the words 'Duration and temperature', followed by the duration and, where applicable, temperature of that treatment;
 - (q) the word 'Concentration', followed by the concentration of that chemical reached during that treatment;
 - (r) the word 'Date', followed by the date on which that treatment was applied;
 - (s) the word 'Additional information', followed by any additional information that the competent authority wishes to include in the certificate;
 - (t) the words 'Place of issue', followed by the place of issuance of the phytosanitary certificate;
 - (u) the word 'Date', followed by the date of issuance of the phytosanitary certificate;
 - (v) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
 - (w) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate; and
 - (x) optionally, the sentence 'No financial liability with respect to this certificate shall attach to (name of Plant Protection Organisation) or to any of its officials or representatives' may be added on the certificate below the frame.
2. Where the phytosanitary certificate is not issued electronically, the paper used shall contain a watermark, embossed seal or embossed logo determined by the competent authority that signs the certificate. The colour of the preprinted text shall be green except for the number of the original certificate as referred to in point (a)(iv) of paragraph 1, which may be in another colour.

Model phytosanitary certificate for export

1. Name and address of exporter	2. PHYTOSANITARY CERTIFICATE No EU XX /00000000	
3. Declared name and address of consignee	4. Plant Protection Organisation of to Plant Protection Organisation(s) of	
	5. Place of origin	
6. Declared means of conveyance		
7. Declared point of entry		
8. Distinguishing marks; number and description of packages; name of produce; botanical name of plants		9. Quantity declared

[illegible]

(*) optional clause

PART B

Phytosanitary certificates for re-export as referred to in Article 101(4)

1. The phytosanitary certificate for movement out of the Union territory, for the purpose of re-export to a third country, shall contain the following elements:

- (a) the words 'Phytosanitary certificate for re-export', followed by subsequently:
 - (i) the letters 'EU';
 - (ii) the two-letter code, referred to in point (a) of Article 67, for the Member State in which the professional operator requesting the issuance of the phytosanitary certificate for re-export is registered;
 - (iii) a slash; and
 - (iv) a unique identification code for the certificate, consisting of numbers or a combination of letters and numbers, the letters representing, as applicable, the province and district of the Member State where the certificate is issued;
- (b) the words 'Name and address of exporter', followed by the name and address of the registered operator requesting the issuance of the phytosanitary certificate for re-export;
- (c) the words 'Declared name and address of consignee', followed by the declared name and address of the consignee;
- (d) the words 'Plant Protection Organisation of', followed by the name of the Member State of which the plant protection organisation issues the certificate, and subsequently the words 'to the Plant Protection Organisation(s) of', followed by the name or, as applicable, names, of the country or, as applicable, countries of destination;
- (e) the words 'Place of origin', followed by the place or places of origin of the plants, plant products or other objects included in the consignment for which the certificate is issued. In all cases, the name of the country or countries of origin should be stated;
- (f) an unnumbered box, reserved for the EU logo. Optionally, other official logos can be added;
- (g) the words 'Declared means of conveyance', followed by the declared means of conveyance of that consignment;
- (h) the words 'Declared point of entry', followed by the declared point of entry into the country of destination of that consignment;
- (i) the words 'Distinguishing marks; number and description of packages; name of produce; botanical name of plants', followed by a description of the consignment including botanical name of plants or the name of the produce, distinguishing marks, and the number and type of packages included in the consignment;
- (j) the words 'Quantity declared', followed by the quantity of the plants, plant products or other objects included in that consignment, expressed by number or weight;
- (k) the following text:

'This is to certify

— that the plants, plant products or other regulated articles described above were imported into
(country/ contracting party of re-export) from (country/ contracting party of origin)
covered by phytosanitary certificate No

☐ original ☐ certified true copy of which is attached to this certificate,

— that they are

☐ packed ☐ repacked

in

☐ original ☐ new containers,

- that based on the
 - ☐ original phytosanitary certificate and
 - ☐ additional inspection,they are considered to conform with the current phytosanitary requirements of the importing country/contracting party, and
- that during storage in (contracting party of re-export) the consignment has not been subjected to the risk of infestation or infection.'

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

- (l) the words 'Additional declaration', followed by the additional declaration referred to in Article 71(2) and the statement referred to in Article 71(3) and, optionally, any further phytosanitary information relevant to the consignment. If there is insufficient space for the whole of the additional declaration, an attachment may be added. The information in the attachment should only include what is required on the phytosanitary certificate. All the pages of the attachment should bear the number of the phytosanitary certificate and should be dated, signed and stamped in the same manner as required for the phytosanitary certificate. The phytosanitary certificate should refer to any attachments in the appropriate section;
 - (m) the words 'Disinfestation and/or disinfection treatment';
 - (n) the word 'Treatment', followed by the treatment that has been applied to that consignment;
 - (o) the words 'Chemical (active ingredient)', followed by the active ingredient of the chemical used for the treatment referred to in point (n);
 - (p) the words 'Duration and temperature', followed by the duration and, where applicable, temperature of that treatment;
 - (q) the word 'Concentration', followed by the concentration of that chemical reached during that treatment;
 - (r) the word 'Date', followed by the date on which that treatment was applied;
 - (s) the word 'Additional information', followed by any additional information that the competent authority wishes to include in the certificate;
 - (t) the words 'Place of issue', followed by the place of issuance of the phytosanitary certificate;
 - (u) the word 'Date', followed by the date of issuance of the phytosanitary certificate;
 - (v) the words 'Name and signature of authorised officer', followed by the name and signature of the officer issuing and signing the phytosanitary certificate;
 - (w) the words 'Stamp of organisation', followed by the official stamp of the competent authority issuing the phytosanitary certificate; and
 - (x) optionally, the sentence 'No financial liability with respect to this certificate shall attach to (name of Plant Protection Organisation) or to any of its officials or representatives' may be added on the certificate below the frame.
2. Where the phytosanitary certificate is not issued electronically, the paper used shall contain a watermark, embossed seal or embossed logo determined by the competent authority that signs the certificate. The colour of the preprinted text shall be brown except for the number of the original certificate as referred to in point (a)(iv) of paragraph 1, which may be in another colour.

Model phytosanitary certificate for re-export

1. Name and address of exporter	2. PHYTOSANITARY CERTIFICATE FOR RE-EXPORT No EU XX/00000000	
3. Declared name and address of consignee	4. Plant Protection Organisation of to Plant Protection Organisation(s) of	
	5. Place of origin	
6. Declared means of conveyance		
7. Declared point of entry		
8. Distinguishing marks; number and description of packages; name of produce; botanical name of plants		9. Quantity declared

10. This is to certify

- that the plants, plant products or other regulated articles described above were imported into (country/contracting party of re-export)
from (country/contracting party of origin) covered by phytosanitary certificate No

(*) ☐ original ☐ certified true copy of which is attached to this certificate;

- that they are

(*) ☐ packed ☐ repacked in ☐ original ☐ new containers

- that based on the

(*) ☐ original phytosanitary certificate ☐ and additional inspection,

they are considered to conform with the current phytosanitary requirements of the importing country/contracting party, and

- that during storage in (country/contracting party of re-export) the consignment has not been subjected to the risk of infestation or infection.

(*) Insert tick in the appropriate boxes

11. Additional declaration

DISINFESTATION AND/OR DISINFECTION TREATMENT

12. Treatment

13. Chemical (active ingredient)

14. Duration and temperature

15. Concentration

16. Date

17. Additional information

18. Place of issue

Date

Name and signature of
authorised officer

Stamp of organisation

PART C

*Pre-export certificates as referred to in Article 102(6)***Model pre-export certificate**

1. PRE-EXPORT CERTIFICATE [No EU/Code Member State/Internal individual reference number] This document is issued by the competent authority of an EU Member State according to [Regulation on protective measures against pests of plants] on request of a professional operator in order to communicate to competent authorities of EU Member States that certain phytosanitary procedures have been applied.		
2. Name of Member State of origin and name of the declaring competent authority [and if wanted logo of competent authority of origin]		
3. Professional operator		
4. Description of the consignment	5. Quantity declared	
6. The consignment as described above: [Boxes(A-G) of applicable options to be ticked combined with information under 'pest specifications'] ☐ Comply with the specific requirements of EU Regulation on protective measures against pests of plants: [List the publishing number of the relevant implementing act (for the consignment concerned) adopted pursuant to Article 41 and the applicable alternative of the specific requirements that is certified as being complied with.] ☐ have been inspected according to an appropriate official procedure: [if necessary list procedure], and found free from (A) ☐ have been tested according to an appropriate official procedure: [if necessary list procedure], and found free from (B) ☐ originate in a field, officially recognised as being free from (C) ☐ originate in a production site, officially recognised as being free from (D) ☐ originate in a place of production, officially recognised as being free from (E) ☐ originate in an area, officially recognised as being free from (F) ☐ originate in a country, officially recognised as being free from (G) Pest specifications and identification of field/production site/area (with ref. to (A)-(G) above as appropriate):		

7 Other official information [e.g. related to phytosanitary import requirements, treatment of consignment, etc.]	
8 Place of issue: Contact details (phone/email/fax): Date:	9 Name and signature of the authorised officer (Stamp of the competent authority)

ANNEX IX

CORRELATION TABLE

Council Directive 69/464/EEC	This Regulation
Article 1	Article 28(1)
Article 2	Article 28(1)(e)
Articles 3, 4 and 5	Article 28(1)(d)
Article 6	Article 28(1)(f)
Article 7	—
Article 8	Article 8
Article 9	Article 31(1)
Articles 10 and 11	Article 28(1)(d)
Articles 12 and 13	—

Council Directive 93/85/EEC	This Regulation
Article 1	Article 28(1)
Article 2	Article 28(1)(g)
Article 3	Articles 14(1) and 15(1)
Articles 4 to 8	Article 28(1)(a) to (d)
Article 9	—
Article 10	Article 8
Article 11	Article 31
Article 12	Article 28(1)
Articles 13 to 15	—
Annexes I to V	Article 28(1)

Council Directive 98/57/EC	This Regulation
Article 1	Article 28(1)
Article 2	Article 28(1)(g)
Article 3	Articles 14(1) and 15(1)
Article 4 to 7	Article 28(1)(a) to (c)
Article 8	—
Article 9	Article 8
Article 10	Article 31
Article 11	Article 28(1)

Council Directive 98/57/EC	This Regulation
Articles 12 to 14	—
Annexes I to VII	Article 28(1)
Council Directive 2007/33/EC	This Regulation
Article 1	Article 28(1)
Articles 2 and 3	Article 28(1) and (2)
Articles 4 to 8	Article 28(1)(g)
Articles 9 to 13	Article 28(1) and (2)
Article 14	Article 8
Article 15	Article 31
Article 16	Article 28(1)
Article 17	Article 107
Articles 18 to 20	—
Annexes I to IV	Article 28(1)
Council Directive 2000/29/EC	This Regulation
Article 1(1)	Article 1(1) and (2)
Article 1(2)	—
Article 1(3)	Article 1(3)
Article 1(4)	— (*)
Article 1(5) and (6)	—
Article 2(1)(a)	Article 2, point (1)
Article 2(1)(b)	Article 2, point (2), first subparagraph
Article 2(1)(c)	Article 2, point (3)
Article 2(1)(d)	Article 2, point (4)
Article 2(1)(e)	Article 1(1) and (2)
Article 2(1)(f)	Article 78
Article 2(1)(g)	— (*)
Article 2(1)(h)	Articles 32 to 35
Article 2(1)(i), first subparagraph	Article 76 (*)
Article 2(1)(i), second and third subparagraphs	— (*)
Article 2(1)(j) to (n)	— (*)
Article 2(1)(o)	Article 2, point (7)
Article 2(1)(p), (q) and (r)	— (*)

Council Directive 2000/29/EC	This Regulation
Article 2(2)	Article 2, point (2), second subparagraph
Article 3(1)	Article 5(1)
Article 3(2) and (3)	Articles 5(1), 37(1) and 41(1)
Article 3(4)	Articles 5(1) and 37(1)
Article 3(5)	Articles 32(2) and 54(1)
Article 3(6)	Articles 5(2) and 32(3)
Article 3(7)	Articles 5(2) and (3), 28(1) and 37(2)
Articles 3(8) and (9)	Articles 8, 39, 48 and 58
Article 4(1)	Article 40(1)
Article 4(2)	Article 53(1)
Article 4(3)	—
Article 4(4)	—
Article 4(5)	Articles 8, 48 and 58
Article 4(6)	Article 46
Article 5(1)	Articles 40(1) and 41(1)
Article 5(2)	Article 53(1)
Article 5(3)	Articles 40(3) and 53(3)
Article 5(4)	Articles 41(1) and 75
Article 5(5)	Articles 8, 48 and 58
Article 5(6)	Article 46
Article 6(1) to (4)	Article 87(1), (2) and (3)
Article 6(5), first and second subparagraphs	Article 87(1), (2) and (3)
Article 6(5), third subparagraph	Articles 65 and 68
Article 6(5), fourth subparagraph	Article 9(3)
Article 6(5), fifth subparagraph	Article 81
Article 6(6)	Articles 65 and 69
Article 6(7)	Article 81
Article 6(8), first indent	—
Article 6(8), second indent	Article 57
Article 6(8), third indent	Article 87(4)
Article 6(8), fourth indent	Articles 66, 69 and 90
Article 6(8), fifth indent	—
Article 6(8), sixth indent	Article 81
Article 6(9)	Article 66

Council Directive 2000/29/EC	This Regulation
Article 10(1)	Articles 78, 83(5), 85, 86 and 87
Article 10(2)	Articles 79, 80 and 81
Article 10(3)	Article 93
Article 10(4), first indent	Article 83(7) and (8)
Article 10(4), second, third and fourth indent	—
Article 11(1)	Article 87(1)
Article 11(2)	—
Article 11(3)	— (*)
Article 11(4)	Article 92(2) and (3)
Article 11(5)	Article 92(2) and (3)
Article 12(1)	— (*)
Article 12(2)	Articles 69(4), 93(5) and 95(3) (*)
Article 12(3)	— (*)
Article 12(4)	Articles 41(4) and 95(5) (*)
Article 13(1) and (2)	Article 76(5) (*)
Article 13(3) and (4)	— (*)
Article 13a(1) and (2)	— (*)
Article 13a(3)	Article 76 (*)
Article 13a(4)	Article 76 (*)
Article 13a(5)	— (*)
Article 13b	— (*)
Article 13c(1)(a)	— (*)
Article 13c(1)(b)	Article 65 (*)
Article 13c(1)(c)	— (*)
Article 13c(2) to (4)	— (*)
Article 13c(6)	Article 94 (*)
Article 13c(7)	Article 77 (*)
Article 13c(8)	Articles 40(4), 41(4), 53(4), 54(4) and 103 (*)
Article 13d	— (*)
Article 13e	Articles 100 and 101
Article 14	Articles 5(3) and (4), 32(3), 37(2) and (3), 40(2), 41(2), 53(3), 54(3), 72(2) and (3), 74(2) and (3), 79(2) and (3) and 80(2) and (3)
Article 15(1)	Article 41(3), first subparagraph
Article 15(2)	Article 41(3), second subparagraph

Council Directive 2000/29/EC	This Regulation
Article 15(3)	Article 71(3)
Article 15(4)	—
Article 16(1)	Article 9(1) and (2) and Article 17
Article 16(2), first subparagraph	Article 29
Article 16(2), second and third subparagraph	Article 13
Article 16(2), fourth subparagraph	—
Article 16(3)	Article 30
Article 16(4)	Articles 28(1), 30(1) and 49(1)
Article 16(5)	Articles 28(6), 30(7) and 49(4)
Article 18	Article 107
Article 20	—
Article 21(1) to (5)	— (*)
Article 21(6)	Article 103
Article 21(7) and (8)	—
Article 27	—
Article 27a	— (*)
Article 28 and 29	—
Annex I, Part A	Article 5(2)
Annex I, Part B	Article 32(3)
Annex II, Part A, Section I	Article 5(2)
Annex II, Part A, Section II	Article 37(2)
Annex II, Part B	Article 32(3)
Annex III, Part A	Article 40(2)
Annex III, Part B	Article 53(2)
Annex IV, Part A	Article 41(2)
Annex IV, Part B	Article 54(2)
Annex V, Part A, Point I	Article 79(1)
Annex V, Part A, Point II	Article 80(1)
Annex V, Part B, Point I	Article 72
Annex V, Part B, Point II	Article 74
Annex VI	—
Annex VII	Annex VIII
Annex VIII	—
Annex VIIIa	— (*)
Annex IX	—

(*) See Article 109(1).

**REGULATION (EU) 2016/2032 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 26 October 2016**

**amending Regulation (EC) No 91/2003 on rail transport statistics, as regards the collection of data
on goods, passengers and accidents**

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 338(1) thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) Regulation (EC) No 91/2003 of the European Parliament and of the Council ⁽²⁾ establishes a common framework for producing, transmitting, evaluating and disseminating comparable rail transport statistics in the Union.
- (2) Statistics on the transport of goods and passengers by rail are necessary to enable the Commission to monitor and develop the common transport policy, as well as the transport elements of policies relating to the regions and to trans-European networks.
- (3) Statistics on rail safety are also necessary to enable the Commission to prepare and monitor Union action in the field of transport safety. The European Union Agency for Railways collects data on accidents under Annex I to Directive 2004/49/EC of the European Parliament and of the Council ⁽³⁾ as regards common safety indicators and common methods of calculating accident costs.
- (4) It is important to avoid duplication of work and to optimise the use of existing information that is capable of being used for statistical purposes. To that end, and with a view to providing easily accessible and useful information to Union citizens and other stakeholders on rail transport safety and interoperability of the rail system, including the rail infrastructure, appropriate cooperation agreements on statistical activities should be established between the Commission's services and relevant entities, including at international level.
- (5) Most Member States transmitting passenger data to the Commission (Eurostat) under Regulation (EC) No 91/2003 have regularly provided the same data for both the provisional and final datasets.
- (6) A balance should be struck between the needs of the users and the burden on respondents when producing European statistics.
- (7) Within its Working Group and Task Force on rail transport statistics, Eurostat has conducted a technical analysis of the existing data on rail transport statistics collected pursuant to relevant binding Union legal acts and of the dissemination policy, in order to simplify as much as possible the various activities necessary for producing statistics, while ensuring that the final output remains in line with the present and future needs of users.

⁽¹⁾ Position of the European Parliament of 11 March 2014 (not yet published in the Official Journal) and position of the Council at first reading of 18 July 2016 (not yet published in the Official Journal). Position of the European Parliament of 26 October 2016 (not yet published in the Official Journal).

⁽²⁾ Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics (OJ L 14, 21.1.2003, p. 1).

⁽³⁾ Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44).

- (8) In its report to the European Parliament and to the Council on its experience acquired in applying Regulation (EC) No 91/2003, the Commission referred to the fact that long-term developments will probably result in the suppression or the simplification of the data already collected under that Regulation, and that the aim is to reduce the data transmission period for annual data on rail passengers. The Commission should continue to provide reports at regular intervals on the implementation of that Regulation.
- (9) Regulation (EC) No 91/2003 confers powers on the Commission to implement some of its provisions. As a consequence of the entry into force of the Treaty on the Functioning of the European Union ('the Treaty'), the powers conferred on the Commission under that Regulation need to be aligned with Articles 290 and 291 of the Treaty.
- (10) In order to reflect new developments in the Member States while, at the same time, maintaining the harmonised collection of rail transport data across the Union, and with a view to maintaining the high quality of the data transmitted by the Member States, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of amending Regulation (EC) No 91/2003 to adapt the technical definitions and to provide for additional technical definitions. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽¹⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (11) The Commission should ensure that those delegated acts do not impose a significant additional burden on the Member States or on the respondents.
- (12) In order to ensure uniform conditions for implementation of Regulation (EC) No 91/2003, implementing powers should be conferred on the Commission as regards the specification of the information to be supplied for the reports on the quality and comparability of the results, and the arrangements for the dissemination of those results by the Commission (Eurostat). Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽²⁾.
- (13) The European Statistical System Committee has been consulted.
- (14) Regulation (EC) No 91/2003 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 91/2003 is amended as follows:

(1) Article 3 is amended as follows:

- (a) in paragraph 1, points 24-30 are deleted;
- (b) paragraph 2 is replaced by the following:

'2. The Commission is empowered to adopt delegated acts in accordance with Article 10 concerning the amendment of the present Article to adapt the technical definitions set out in points 8 to 10 and 21 to 23 of paragraph 1 and to provide for additional technical definitions, when needed to take into account new developments which require a certain level of technical detail to be defined in order to ensure the harmonisation of statistics.

⁽¹⁾ OJ L 123, 12.5.2016, p. 1.

⁽²⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

When exercising that power the Commission shall ensure that the delegated acts do not impose a significant additional burden on the Member States or on the respondents. Furthermore, the Commission shall duly justify the statistical actions for which those delegated acts provide, using, where appropriate, cost-effectiveness analysis, including an assessment of the burden on respondents and of the production costs, as referred to in point (c) of Article 14(3) of Regulation (EC) No 223/2009 of the European Parliament and of the Council (*).

(*) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).;

(2) Article 4 is amended as follows:

(a) in paragraph 1, points (b), (d) and (h) are deleted;

(b) paragraph 2 is replaced by the following:

‘2. Member States shall report under Annexes A and C data for undertakings that have:

(a) a total volume of goods transport of at least 200 000 000 tonne-km or at least 500 000 tonnes;

(b) a total volume of passenger transport of at least 100 000 000 passenger-km.

Reporting under Annexes A and C shall be optional in respect of undertakings falling below the thresholds referred to in points (a) and (b).’;

(c) paragraph 3 is replaced by the following:

‘3. Member States shall report under Annex L the total data for undertakings falling below the thresholds referred to in paragraph 2 if those data are not reported under Annexes A and C, as specified in Annex L.’;

(3) in Article 5(2), point (b) is replaced by the following:

‘(b) administrative data, including data collected by regulatory authorities, in particular the rail freight waybill if one is available.’;

(4) Article 7 is replaced by the following:

‘Article 7

Dissemination

Statistics based on the data specified in Annexes A, C, E, F, G and L shall be disseminated by the Commission (Eurostat).

The Commission shall adopt implementing acts laying down the arrangements for the dissemination of results. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 11(2).’;

(5) Article 8 is amended as follows:

(a) the following paragraph is inserted:

‘1a. Member States shall take all measures necessary to ensure the quality of the data transmitted.’;

(b) the following paragraphs are added:

‘3. For the purposes of this Regulation, the quality criteria to be applied to the data to be transmitted are those referred to in Article 12(1) of Regulation (EC) No 223/2009.

4. The Commission shall adopt implementing acts specifying the detailed arrangements, structure, periodicity and comparability elements for the standard quality reports. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 11(2).;

(6) Article 9 is replaced by the following:

‘Article 9

Reports on implementation

By 31 December 2020 and every four years thereafter, the Commission, after consulting the European Statistical System Committee, shall submit a report to the European Parliament and to the Council on the implementation of this Regulation and on future developments.

In that report, the Commission shall take account of relevant information provided by Member States relating to the quality of the data transmitted, the data collection methods used and information on potential improvements and on users' needs.

In particular, that report shall:

- (a) assess the benefits, accruing to the Union, the Member States and the providers and users of statistical information, of the statistics produced, in relation to their costs;
- (b) assess the quality of the data transmitted, the data collection methods used and the quality of the statistics produced.;

(7) Article 10 is replaced by the following:

‘Article 10

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 power to adopt delegated acts referred to in Article 3(2) shall be conferred on the Commission for a period of five years from 13 December 2016. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 3(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke 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. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (*).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 3(2) 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 of the Council.

(*) OJ L 123, 12.5.2016, p. 1.;

(8) Article 11 is replaced by the following:

'Article 11

Committee procedure

1. The Commission shall be assisted by the European Statistical System Committee established by Regulation (EC) No 223/2009. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

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

(*) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).;

(9) Article 12 is deleted;

(10) Annexes B, D, H and I are deleted;

(11) Annex C is replaced by the text appearing in Annex I to this Regulation;

(12) Annex L, as set out in Annex II to this Regulation, is added.

Article 2

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

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

Done at Strasbourg, 26 October 2016.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
I. LESAY

ANNEX I

ANNEX C

ANNUAL STATISTICS ON PASSENGER TRANSPORT — DETAILED REPORTING

List of variables and units of measurement	Passengers transported in: — number of passengers — passenger-km Passenger train movements in: — train-km
Reference period	One year
Frequency	Every year
List of tables with the breakdown for each table	Table C3: passengers transported, by type of transport Table C4: international passengers transported, by country of embarkation and by country of disembarkation Table C5: passenger train movements
Deadline for transmission of data	Eight months after end of reference period
First reference period	2016
Notes	1. Type of transport is broken down as follows: — national — international 2. For Tables C3 and C4, Member States shall report data including information from ticket sales outside the reporting country. This information may be obtained either directly from the national authorities of other countries or through international compensation arrangements for tickets'

ANNEX II

ANNEX L

Table L.1

LEVEL OF TRANSPORT ACTIVITY IN GOODS TRANSPORT	
List of variables and units of measurement	Goods transported in: — total tonnes — total tonne-km Goods train movements in: — total train-km
Reference period	One year
Frequency	Every year
Deadline for transmission of data	Five months after end of reference period
First reference period	2017
Notes	Only for undertakings with a total volume of freight transport of less than 200 million tonne-km and less than 500 000 tonnes and not reporting under Annex A (detailed reporting)

Table L.2

LEVEL OF TRANSPORT ACTIVITY IN PASSENGER TRANSPORT	
List of variables and units of measurement	Passengers transported in: — total passengers — total passenger-km Passenger train movements in: — total train-km
Reference period	One year
Frequency	Every year
Deadline for transmission of data	Eight months after end of reference period
First reference period	2017
Notes	Only for undertakings with a total volume of passenger transport of less than 100 million passenger-km and not reporting under Annex C (detailed reporting)

