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Delegations will find attached document COM(2023) 661 final.

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EUROPEAN
COMMISSION

Brussels, 17.10.2023
COM(2023) 661 final

2023/0378 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2016/2031 of the European Parliament and of the Council as regards multiannual survey programmes, notifications concerning the presence of regulated non-quarantine pests, temporary derogations from import prohibitions and special import requirements and establishment of procedures for granting them, temporary import requirements for high risk plants, plant products and other objects, the establishment of procedures for the listing of high risk plants, the content of phytosanitary certificates, the use of plant passports and as regards certain reporting requirements for demarcated areas and surveys of pest

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Legislation on protective measures against pests of plants or plant products has been established at Union level since the 1970s. That legislation has been of major importance for the protection of the agriculture, the landscape and the environment in the Union. The first evaluation and revision of the Union phytosanitary policy took place between 2008 and 2016 and resulted in the adoption of Regulation (EU) 2016/2031 of the European Parliament of the Council¹ ('the Regulation'), which repealed and replaced Council Directive 2000/29/EC². The Regulation is currently the basic legal framework for the Union plant health policy.

Article 50 and Article 79(6) of the Regulation prescribed that the Commission submits, by the end of 2021, to the European Parliament and the Council reports on the enforcement and effectiveness of the import measures, and the experience gained by operators from the extension of the plant passport to all plants for planting ('the reports submitted in accordance with Article 50 and Article 79(6)').

The Commission submitted those reports on 10 December 2021.

The report on import measures concluded that it could be considered that those import measures, as well the inclusion of the plant health controls within the scope of Regulation (EU) 2017/625 of the European Parliament and of the Council³ have contributed towards achieving the objectives to enhance the phytosanitary protection of the Union and to increase proactive action against pests in compliance with the rules of the International Plant Protection Convention (IPPC) through risk-based and transparent approaches.

The report on the extension of the plant passport system to all plants for planting concluded that that extension has contributed towards achieving the objectives of the

¹ 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 (OJ L 317, 23.11.2016, p. 4).

² Council Directive 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, 10.07.2000, p. 1).

³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

Regulation. More specifically it contributed to increased effectiveness of the protection against quarantine pests, improved preparedness for the identification of new plant pests of Union concern, improved understanding and awareness on the part of relevant stakeholders concerning the plant health importance, and increased possibility to identify pests.

The reports identified areas for further discussion to enhance the effectiveness and practical implementation of the rules for plant health but also for official controls. Those discussions took place in 2022 with the Member States' Chief Plant Health Officers, as well as with Union associations relevant to plant health. They led to the conclusion that certain improvements of the system were needed, which were only possible by amending the Regulation. Those improvements refer to the need for (i) declarations on the phytosanitary certificate for regulated non-quarantine pests (RNQPs), (ii) reporting the non-compliances with the RNQP rules in the electronic notification system (Information Management System for Official Controls – IMSOC), (iii) procedural rules for the submission and examination of non-EU countries' requests for temporary derogations from import prohibitions, (iv) procedures for identifying and listing of high-risk plants and (v) rationalising the obligation to attach a plant passport to certain plants.

Further improvements were identified through elements deriving from the experience gained by the Commission during the first 5 years of the application of the Regulation, with regard to (i) measures against pests qualifying as quarantine pests but not yet fully assessed, (ii) the need for autonomous acts for adopting temporary derogations from import prohibitions, and special import requirements, (iii) the need for setting temporary import requirements for the introduction into the Union of plants, plant products or other objects which have been removed from the list of high risk plants but for which the phytosanitary risk has not been fully assessed, (iv) setting out requirements for third countries' equivalence, and (v) the alternative official attestations.

Finally, certain reporting elements were identified as falling under the scope of the Commission's commitment to rationalise the reporting obligations of Member States and professional operators on the basis of its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'⁴.

Rationalisation of the reporting obligations

As regards the rationalisation of reporting obligations, the Commission has taken a horizontal initiative. In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030', it stressed the importance of a regulatory system that ensures that objectives are reached at minimum costs. It has committed therefore to a fresh push to rationalise and simplify reporting requirements, with the ultimate aim to reduce such burdens by 25%, without undermining the related policy objectives.

Its overall objectives are summarised as follows:

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Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions 'Long-term competitiveness of the EU: looking beyond 2030', COM(2023)168.

- (a) to improve legal certainty and clarity for competent authorities and professional operators, both in the Union and in third countries;
- (b) to increase transparency, flexibility and consistency of the Union regulatory procedures;
- (c) to contribute through digitalisation, to the rationalisation of reporting obligations and the administrative tasks linked to them.

Reporting requirements play a key role in ensuring correct enforcement and proper monitoring of legislation. Their costs are overall largely offset by the benefit they bring, in particular in monitoring and ensuring compliance with key policy measures. Reporting requirements can however also impose disproportionate burden on stakeholders, particularly affecting SMEs and micro-companies. Their cumulation over time can result in redundant, duplicating or obsolete obligations, inefficient frequency and timing, or inadequate methods of collection.

The proposal thus aims also at rationalising reporting obligations by a combination of measures:

- removal of reports which are not necessary any longer;
- digitalisation of transmission of information;
- reduction of frequency of reporting requirements

The reporting requirements concern public authorities and, in certain cases, indirectly, professional operators. According to the proposed amendments, certain reporting obligations are removed, while others are digitalised or are requested with reduced frequency.

- **Consistency with existing provisions in the policy area**

The proposal introduces amendments that concern the implementation of provisions which constitute the Union's plant health policy. They do not change the Union's plant health policy itself. Therefore, the proposed amendments are highly consistent with the existing plant health policy of the Union, and aim at contributing to the improvement of its application.

The proposals on reporting obligations are part of a first package of Commission initiatives to rationalise reporting requirements. This is a step in a continuous process looking comprehensively at existing reporting requirements, with a view to assess their continued relevance and to make them more efficient.

The proposal will only positively affect the achievement of objectives in the policy area, as it will increase transparency and decrease administrative burden for the competent authorities, the professional operators and the Commission.

- **Consistency with other Union policies**

The consistency of the Regulation with other Union policies related to agriculture, and the environment, such as biodiversity and climate change, is ensured by its

existing provisions and their implementation. Since the proposed technical amendments do not change the policy direction of the Regulation, the consistency with those policies remains unchanged.

The Commission ensures that its legislation is fit for purpose and targeted to the needs of stakeholders. It minimizes administrative burdens, while achieving its objectives under the Regulatory Fitness and Performance Programme (REFIT). The proposed amendments concerning the rationalisation of reporting obligations, by reducing the complexity of reporting burdens arising from the Union legal framework.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposal amends the technical implementation of rules necessary for the pursuit of the objectives of the common agricultural policy, in the sector of production and marketing of plants, plant products and other objects in the Union.

In this respect, Article 43(2) of the Treaty on the Functioning of the European Union (TFEU), which provides the legal basis for adopting provisions necessary for the pursuit of the objectives of the common agricultural policy, has been selected.

- **Subsidiarity (for non-exclusive competence)**

According to Article 4(2), point (d), of the TFEU a shared competence between the Union and Member States applies in the area of agriculture and fisheries, excluding the conservation of marine biological resources.

Since the adoption of Directive 2000/29/EC and also under the Regulation, all fields of plant health have been regulated at Union level to a very large extent. Those rules have proven to be a major contributor to the protection of the Union territory from pests and diseases. Similarly, the objectives of the proposed amendments can be better achieved by exclusively regulating the issues concerned at Union level.

As regards the reporting obligations, the requirements concerned are already established by the Union law. Similarly, their rationalisation should be done at Union level.

- **Proportionality**

The measures proposed are limited to actions that need to be taken at Union level in order to be effective and efficient. To achieve the effectiveness and efficiency of these actions, the amendment of the Regulation is considered most appropriate, considering that a key element of the proposal is to reinforce the implementation of harmonised measures for Member States. The uniform requirements through the Regulation are the only way to ensure a high level of quality for those applying the Regulation, the functioning of internal market and a level playing field for the operators as well as sustainable agricultural and food production.

The rationalisation of reporting requirements simplifies the legal framework by introducing minimum changes to existing requirements that do not affect the substance of the wider policy objective. The proposal is therefore limited to those changes that are necessary to ensure efficient reporting without changing any of the substantive elements of the legislation concerned.

- **Choice of the instrument**

The proposal takes the form of a Regulation of the European Parliament and of the Council. Other means would not be appropriate because the proposal amends basic provisions of a Regulation of the European Parliament and of the Council for which the Commission does not have the empowerment to achieve through implementing acts.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The reports submitted in accordance with Article 50 and Article 79(6) of the Regulation were supported by a stakeholder consultation which included, where necessary, gathering of the available data concerning imports.

As regards the reporting obligations, an ex-post evaluation or fitness check is not applicable.

- **Stakeholder consultations**

For the preparation of the reports submitted in accordance with Article 50 and Article 79 of the Regulation, an extensive consultation took place addressing all relevant stakeholders. At a first stage the Expert Group on Plant Health, consisting of Member States' competent authorities for plant health, and for the certification of plant and forest propagating material, the European Parliament, and the relevant professional associations at Union level, were invited to participate in the process of developing fit-for-purpose questionnaires. A total of 5 detailed questionnaires were developed regarding import procedures, import prohibitions, phytosanitary certificates for imports, official controls, and plant passports, comprising a total of 234 questions and covering the main changes introduced with the Regulation.

The competent authorities of the Union and the professional associations at Union level, were invited to participate in the consultation process by a dedicated invitation, while the national associations and individual Union operators were informed by those competent authorities and professional associations at Union level about the possibility to participate in the consultation through an open-access link. Due to the highly technical nature of the changes very few questions were addressed to the public which was approached through social media.

A total of 563 responses were received, a detailed analysis of which was presented in the 5 technical reports⁵ produced by the Commission's DG SANTE and the Joint Research Centre (JRC).

As regards import related provisions, Member States' views were positive on provisions and proposals that provided clarity in plant health controls and further enhanced protection of the Union against pests. Union- and Member State- level associations considered certain provisions, such as the temporary prohibitions of high-risk plants, to have caused difficulties in already established trade, thus requested more legal clarity, transparency. The associations requested more legal clarity and transparency also for other procedures that can positively contribute to trade, such as the derogations from permanent prohibitions. This is being addressed with the current proposal. As regards plant passports, stakeholders considered that attaching them to each trade unit poses additional administrative burden and associated costs that outweigh their perceived additional benefits. This is also addressed in this proposal.

- **Collection and use of expertise**

Besides the proposed amendments deriving from the reports submitted in accordance with Article 50 and Article 79(6) of the Regulation the proposal includes amendments deriving from the experience gained by the Commission during the first 5 years of application of the Regulation. While no stakeholder consultation was carried out for these proposals, the specific proposed amendments refer to procedures that were considered problematic in their implementation and they aim at providing legal clarity and certainty for the competent authorities, the operators and the third countries.

As regards the reporting obligations, these proposals have been identified following a process of internal scrutiny of existing reporting obligations and based on the experience from the application of the related legislation. Since this is a step in the process of continuous assessment of reporting requirements arising from Union legislation, the scrutiny of such burdens and of their impact on stakeholders will continue.

- **Impact assessment**

According to the analysis carried out by the Commission, the proposed amendments do not bare significant economic, environmental, or social impacts. The Commission hence decided not to carry out an impact assessment for the targeted technical amendments included in the proposal.

The proposal is partly the result of the reports submitted by the Commission to the European Parliament and the Council pursuant to Articles 50 and 79 of Regulation 2016/2031. It is also based on experience gained from the application of Regulation (EU) 2016/2031. For the preparation of the report an extensive consultation took place with all relevant stakeholders. Following the submission of those reports to the European Parliament and the Council on 10 December 2021, areas which merited further discussion were identified. Therefore, discussions took place in 2022 with the

⁵ [Reports-2021 \(europa.eu\)](#)

Chief Plant Health Officers and EU associations relevant to plant health and plant and forest reproductive material, which led to the conclusion that certain improvements were needed and were only possible by amending the Regulation. As regards the reporting obligations, the proposed amendments concern limited and targeted changes of the legislation in view of rationalising the reporting requirements. They are based on experience from implementing the respective legislation. Those amendments do not have significant impacts on the policy, but only ensure a more efficient and effective implementation. Their targeted nature and the lack of relevant policy options make an impact assessment not necessary.

Overall, any impacts of the proposed amendments are expected to be minimal and positive both for the competent authorities and the professional operators. They will reduce administrative burden, increase legal clarity and facilitate the trade of the respective commodities.

- **Regulatory fitness and simplification**

The proposal introduces targeted provisions that improve an already functioning system through a simpler, clearer and less burdensome regulatory regime for EU operators and competent authorities and through increased transparency for third countries.

As regards the reporting obligations, this proposal aims to simplify legislation and cut burdens for stakeholders, in particular administrative authorities. It aims at minimizing compliance costs by reducing the administrative burden and workload of national authorities through removal of certain reporting obligations. As regards the removal of the obligation for annual reporting of the locations of the demarcated areas, that information can be retrieved from the Commission information system (EUROPHYT) on reporting of outbreaks.

The proposal also aims at rationalising the reporting obligation regarding the multi-annual survey programmes through extending the current frequency of performing those surveys from 5-7 years to 10 years. This will provide national authorities with additional time to carry out the respective surveys. Finally, the proposal aims at digitalising certain reporting obligations, taking into account the information systems developed and currently applicable for the purposes of Regulation (EU) 2017/625 as well as an IT system for plant health surveys. Such digitalisation would make the application of the respective reporting provisions more suitable to the digital environment.

- **Fundamental rights**

The proposed amendments do not have any effect on the fundamental rights protected by the Chapter of Fundamental Rights of the European Union.

4. BUDGETARY IMPLICATIONS

There are no budgetary implications.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Reporting arrangements are rationalised. No amendment is introduced concerning implementation plans and monitoring obligations. A 6-month transition period will be granted to the third countries as regards the obligation to indicate on the additional declaration of the phytosanitary certificate the measures applied by them, concerning the RNQPs rules.

- **Explanatory documents (for Directives)**

Not applicable

- **Detailed explanation of the specific provisions of the proposal**

- (i) *Clarification concerning the measures against pests which are provisionally qualifying as quarantine pests but have not been fully assessed yet.*

Article 30 of the Regulation empowers the Commission to adopt, through implementing acts, temporary measures concerning the risk of pests which are not yet fully assessed and not yet regulated as Union quarantine pests. It offers the possibility to treat those pests as listed Union quarantine pests. That provision does not clearly state whether those measures also cover special import requirements for plants and other commodities.

Therefore, and for reasons of enhanced clarity, the proposal amends Article 30(1) of the Regulation to specify that the temporary measures to be adopted may cover both the internal movement of plants and other commodities within the Union and their imports into the Union.

- (ii) *Amendment of the requirements regarding the declarations on the phytosanitary certificate for regulated non-quarantine pests (RNQPs)*

- Article 71(1) of the Regulation requires that the third country certifies the absence of Union quarantine pests and the absence of (or compliance with the relevant tolerance levels for) regulated non-quarantine pests (RNQPs) on the respective plants and commodities. This is done by a standard statement on the phytosanitary certificate regarding the compliance of the consignment with the import rules for quarantine pests as well as for RNQPs.
- In line with the International Standard for Phytosanitary Measures (ISPM) No 12, Article 71(2) of the Regulation requires that, where several options are possible under the applicable special import requirements, the third country declares on the phytosanitary certificate which option it applied, in order to ensure freedom from quarantine pests. However, this provision applies only to quarantine pests and not RNQPs.

The proposal therefore amends Article 71(2) of the Regulation, in order for the third countries to declare on the phytosanitary certificate how compliance with the RNQP rules has been ensured, if different options are available in the

Union legislation. This amendment would also be in line with the relevant International Standard.

- (iii) ***The reporting of non-compliances with the RNQP rules in the electronic notification system (Information Management System for Official Controls – IMSOC).***

Under the Regulation there is an obligation to report to IMSOC non-compliances with the rules on Union quarantine pests (e.g. presence of Union quarantine pests on imported plants). That obligation does not exist in the Regulation for the rules on RNQPs.

The absence of this requirement for RNQPs has led to non-harmonised, non-digitalised approaches among Member States regarding the means of reporting to the Union and the third country about non-compliances with the rules on RNQPs.

The proposal therefore amends Articles 37 and 104 of the Regulation to ensure that non-compliances with the rules on RNQPs and the follow-up actions are notified in a harmonised way within the Union. This will also ensure consistency with the respective rules on quarantine pests and will overall increase the level of the EU phytosanitary protection.

- (iv) ***The introduction of an empowerment for a Commission act to adopt with autonomous acts, temporary derogations from import prohibitions and special import requirements and temporary special import requirements for commodities that have been removed from the list of high-risk plants, plant products and other objects but for which the pest risk has not been fully assessed. .***

Article 40 of the Regulation on prohibitions of imports of plants, plant products or other objects from third countries, sets out the obligation for the Commission to establish a single list containing those prohibitions. Those prohibitions are related to one or more specific quarantine pests, they do not have an expiration date, and they usually apply to all or many third countries.

However, according to SPS rules, a third country should be allowed to request a derogation from those import prohibitions if it considers that it has a system in place that could guarantee the level of phytosanitary protection required by the Union. For such cases there is a need to grant temporary derogations from the relevant prohibitions.

Similarly to the case of derogating from the import prohibitions, there are cases where the need arises to grant temporary derogations from the special and equivalent requirements described under the list of Article 41(2). As an example, a third country might request that the Union accepts alternative measures that it considers efficient to reduce the risk to an acceptable level the risk of introducing into the Union of plants, plant products or other objects with pests.. The proposal introduces the possibility to adopt a derogation from the special requirements of Article 41(2) based on a provisional assessment.

Such temporary derogations, usually concern one third country, or a part of it. They should be granted, only if very detailed special import requirements are complied with. Those requirements could cover all steps from production to export to the Union, such as production methods, treatments and other methods to mitigate the risk of the relevant pests, as well as visual inspections, sampling, testing and other phytosanitary measures for achieving the level of protection required by the Union. Those derogations should be provided for in autonomous acts for a temporary period of time to allow for a full assessment of the effectiveness of the measures and for a flexible modification of the conditions or the derogation itself, if so needed. Once the temporary measures have been established and audited, and a full assessment becomes available, the temporary status of the derogation can be dropped. As regards commodities subject to derogations from the import prohibitions, at that point the respective commodity from the third country concerned will be as a result included in the list of special import requirements adopted under Article 41(2) of the Regulation. Equally, if in the period of application of a temporary derogation it becomes evident that the risk is not reduced to an acceptable level, that derogation will be immediately dropped and the respective commodity from the third country concerned will be moved in the list of prohibited commodities under Article 40 of the Regulation.

Besides the derogations from import prohibitions and special import requirements, experience with the removal of commodities from the high-risk plants, plant products and other objects has shown that there are cases where while the overall risk of the commodity has been assessed, certain identified pests have not been assessed. Therefore, a need arises to adopt temporary special import requirements in order to allow for those pests risks to be fully assessed. Once that risk has been fully addressed, respective commodity from the third country concerned will be included in the list adopted under Article 41(2) of the Regulation or be granted equivalence.

To bring more clarity and transparency to the process of granting temporary derogations from import prohibitions and special import requirements, and to the process of imposing special import requirements and temporary special import requirements for commodities that have been removed from the list of high-risk plants, as well as for plant products and other objects for which the pest risk has not been fully assessed, the proposal introduces a new Article 42a in the Regulation, providing for a separate empowerment for the Commission to adopt autonomous implementing acts, addressing those temporary derogations from of the established prohibitions, or special import requirements.

- (v) ***The introduction of an empowerment for a Commission act to adopt procedural rules for the submission and examination of third countries' requests for temporary derogations from import prohibitions or from import requirements.***

Article 40 of the Regulation introduces the rules concerning prohibitions of imports for certain plants of certain origins, while Article 41 introduces the rules concerning import and movement requirements for certain plants of certain origin. As explained regarding the previous proposed amendment, upon

request from a third country, the Commission grants in certain cases temporary derogations to third countries from those prohibitions, to allow the import of some of their plants or other commodities or from import and movement requirements, to allow the import and further movement into the Union [of some of their plants or other commodities.

However, no standardised procedures for assessing those third countries' requests exist. Currently, when receiving a request for such a temporary derogation from a third country, the procedure for granting the derogation is based on an ad-hoc request for information and an ad-hoc decision to involve or not the European Food Safety Authority (EFSA) in that assessment. A standardised procedure would provide rules for the decision-making process and consequently the currently lacking transparency.

The proposal therefore introduces in the new Article 42a of the Regulation an empowerment for the Commission to adopt rules on a standardised procedure on how to submit and examine a request for granting temporary derogations from the import prohibitions or import requirements. Those rules could include instructions on the submission of the respective dossiers and the elements for the assessment.

(vi) *The introduction of an empowerment for a Delegated act to adopt procedures for identifying and listing of high-risk plants.*

According to Article 42 of the Regulation, the provisional listing of the plants as high-risk plants should be based on a preliminary assessment. However, no further details are set out on how to carry out this assessment. To date, there has been only one listing of several plant species as high-risk plants with Commission Implementing Regulation (EU) 2018/2019⁶. Member States experts took part in the process of drawing up the list of high-risk plants by submitting proposals which were thoroughly assessed and that assessment took into consideration scientific and technical evidence.

However, the procedure has been characterised by several actors as not transparent enough, especially in view of the fact that this process led to a provisional prohibition of an already existing trade.

Therefore, and for reasons of transparency, that procedure and the elements needed for the assessment should be described. In this respect, the proposal amends Article 42 of the Regulation by introducing an empowerment to allow the Commission to adopt a delegated act describing the procedure for identifying and listing those high-risk plants, and the specific elements needed to carry out the assessment.

(vii) *The clarification of the legal basis for setting out requirements for third countries' equivalence, in order to refer not only to internal movement*

⁶ Commission Implementing Regulation (EU) of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation (OJ L 323, 19.12.2018, p. 10).

requirements but also to existing import requirements, in line with the relevant International Standard.

In accordance with Article 44 of the Regulation, the Commission is empowered, through implementing acts, to set out equivalent requirements for third countries' systems, when such countries provide a level of phytosanitary protection which is equivalent to the special requirements applicable to the movement of plants and other goods within the Union territory. In such cases, the third country's phytosanitary system is assessed by the European Food Safety Authority (EFSA), followed by a Union decision to consider the respective requirements as equivalent or not.

The possibility to set out equivalent requirements for third countries' systems only when requirements for internal movement of plants, plant products or other objects are in place is restrictive, because it does not cover the cases where no such requirements for movement within the Union exist, as the respective pest is not known to be present in the Union territory, nevertheless, special import requirements are in place. For this reason, and according to the proposed amendment, the third country concerned will be required to ensure a level of phytosanitary protection which is equivalent not only to the requirements for internal movement of the respective plants and commodities, but also to the special import requirements from other third countries for the same plants and other commodities, if such special import requirements are in place.

The proposal therefore amends Article 44(1) of the Regulation to expand the scope of such requirements.

(viii) The introduction of an empowerment for a Commission act, to rationalise the obligation to attach a plant passport to certain plants.

Article 88 of the Regulation sets out an obligation of attaching the plant passport to all respective plants, plant products or other objects, without allowing for any exception. However, in certain cases, such as that of wood logs or grass sods (turf), the nature of certain commodities, or the speed of the their trade between professional operators, is such that compliance with that obligation is rendered impractical, if not impossible.

The proposal therefore amends Article 88 of the Regulation by introducing an empowerment for the Commission to list specific commodities to be exempted from the obligation to attach the plant passport on them, and to determine the modalities for the application of such an exemption.

(ix) The alignment of the possibility to accept alternative official attestations issued by third countries with the international state of play.

According to Article 99 of the Regulation, the Commission is empowered to adopt delegated acts setting out the elements to be contained in official attestations issued by third countries for specific imported plants, plant products and other objects, other than wood packaging material, which are required by the applicable international standards. However, no international standards so far exist for such attestations. This is because such official

attestations usually refer to very specific types of commodities and countries of origin, while the international standards usually are of a more general nature. This restricted possibility to accept official attestations, only when they are drawn up in accordance with relevant international standards, also affects Commission Implementing Decisions applicable since many years ago.

The proposal therefore amends Article 99 of the Regulation to broaden the requirement concerning ‘the applicable international standards’, by including other criteria as an alternative to the existence of international standards, and to empower the Commission to adopt delegated acts setting out the elements of those attestations without the need for international standards to be adopted.

(x) *Rationalisation of reporting obligations*

The proposal amends the relevant Articles of the Regulation regarding the following reporting obligations:

- (a) removal of annual reporting of the number and locations of the demarcated areas established, the pests concerned, and the respective measures taken during the preceding calendar year (Article 18);
- (b) rationalisation of reporting by decreasing its frequency and prolonging the duration of the multiannual survey programmes (i.e., period during which Member States have to survey all quarantine pests) from 5-7 years to 10 years (Article 23).
- (c) digitalisation of the following reporting measures:
 - (i) ad-hoc reporting of demarcated areas (Article 18);
 - (ii) annual reporting of results of surveys for quarantine pests (Article 22);
 - (iii) reporting of the multiannual survey programmes (Article 23);
 - (iv) annual reporting of results of surveys for priority pests (Article 24);
 - (v) annual reporting of results of surveys for protected-zone quarantine pests (Article 34);

This initiative also includes the establishment of an electronic system for the submission of reports (Article 103).

(xi) *Relevant amendments in other Union acts and final provisions*

Not applicable.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2016/2031 of the European Parliament and of the Council as regards multiannual survey programmes, notifications concerning the presence of regulated non-quarantine pests, temporary derogations from import prohibitions and special import requirements and establishment of procedures for granting them, temporary import requirements for high risk plants, plant products and other objects, the establishment of procedures for the listing of high risk plants, the content of phytosanitary certificates, the use of plant passports and as regards certain reporting requirements for demarcated areas and surveys of pest

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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, it is important to streamline those requirements in order to ensure that they fulfil the purpose for which they were intended and to limit the administrative burden.
- (2) Regulation (EU) 2016/2031 of the European Parliament of the Council² sets out rules on protective measures against pests of plants. Those rules include the classification and listing of regulated pests, requirements concerning the introduction into, and movement within, the Union territory of certain plants, plant products and other objects, surveys, notifications of outbreaks, measures to eradicate pests if found present in the Union territory and certification.

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....

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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 (OJ L 317, 23.11.2016, p. 4).

- (3) Moreover Regulation (EU) 2016/2031 contains a number of reporting requirements in the fields of establishment of demarcated areas and surveys of Union quarantine pests, priority pests and protected zones quarantine pests, which should be simplified in line with the Commission's Communication on 'Long-term competitiveness of the EU: looking beyond 2030'³.
- (4) In accordance with Article 18(6) of Regulation (EU) 2016/2031, Member States are to 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 in this regards during the preceding calendar year.
- (5) As experience has shown during the application of Regulation (EU) 2016/2031, it is more effective, for the purpose of co-ordination of phytosanitary policy at Union level, to notify the demarcated areas immediately after their establishment. Immediate notification of demarcated areas by a Member State to the other Member States, the Commission and the professional operators helps to become aware about the presence and spread of the pest concerned and to decide on next measures to be taken. Therefore, Article 18(6) of Regulation (EU) 2016/2031 should establish an obligation for Member States to notify the Commission and the other Member States of the demarcated areas immediately after their establishment, together with the pests concerned and the respective measures taken. Such obligation does not add any new administrative burden, because the immediate notification of demarcated areas is an existing obligation set out in Annex I, point 7.1, to Commission Implementing Regulation (EU) 2019/1715⁴ and is currently practised by all Member States. Setting out that obligation in Article 18(6) of Regulation (EU) 2016/2031 will further enhance clarity about the applicable rules concerning demarcated areas, while the respective obligation in Implementing Regulation (EU) 2019/1715 should be removed to avoid overlaps of the respective provisions.
- (6) Moreover, and as experience from the application of Article 18(6) of Regulation (EU) 2016/2031 has shown, the obligation for Member States to 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, only adds administrative burden, and no practical value, to the obligation of immediate notification of demarcated areas. It should therefore be removed from that Article.
- (7) In accordance with Article 22(3), Article 24(2) and Article 34(2) of Regulation (EU) 2016/2031, Member States are to report to the Commission and the other Member States, by 30 April of each year, the results of the surveys, which were carried out in the preceding calendar year, concerning the presence of certain pests within the Union territory. Those are Union quarantine pests, pests subject to the measures adopted pursuant to Articles 29 and 30 of Regulation (EU) 2016/2031, priority pests and protected zone quarantine pests respectively. Moreover, and in accordance with Article 23(2) of Regulation (EU) 2016/2031, Member States are, on request, to notify

³ COM(2023)168.

⁴ Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).

their multiannual survey programmes upon their establishment to the Commission and the other Member States.

- (8) In accordance with Article 23(1), third subparagraph, the multiannual survey programmes are to be established for a period of five to seven years. As experience has shown since the date of application of Regulation (EU) 2016/2031, Member States need more time to properly design and develop those programmes. Therefore, and also in order to reduce administrative burden for the competent authorities, that period should be extended to 10 years. For reasons of legal clarity, it should be specified that those programmes are to be established again for consecutive periods of 10 years thereafter, and the first period is to expire on 14 December 2029, namely 10 years after the date of application of Regulation (EU) 2016/2031.
- (9) Article 30(1), second subparagraph, of Regulation (EU) 2016/2031 sets out that, where the Commission concludes that the criteria as regards pests not listed as Union quarantine pests, set out in Subsection 2 of Section 3 of Annex I to that Regulation, are fulfilled, it is to immediately, by means of implementing acts, adopt measures for a limited time as regards the risks posed by that pest.
- (10) During the implementation of that provision, certain Member States expressed their doubts concerning the precise scope of the term ‘measures’, and in particular whether it concerns actions taken in the context of imports or internal movement of goods, in order to prevent the entry and spread of the respective pest in the Union territory. Therefore, and for reasons of legal clarity and completeness, Article 30(1) should be amended to specifically indicate that those measures may include the prohibition of the presence of the respective pest in the Union territory, and requirements concerning the introduction into, and movement within, the Union of plants, plant products and other objects.
- (11) Article 41(4) of Regulation (EU) 2016/2031 sets out that, 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 of that Article, Member States are to adopt the necessary measures, as referred to in Union legislation on official controls, and to notify the Commission and other Member States through the electronic notification system under Article 103 of that Regulation. That Article sets out the requirement to prevent the presence of Union quarantine pests on those plants, plant products or other objects.
- (12) However, no requirement to notify violation of the respective rules exists in Article 37 of Regulation (EU) 2016/2031, which concerns measures to prevent the presence of regulated non-quarantine pests (‘RNQPs’) on plants for planting.
- Therefore, Article 37 of Regulation (EU) 2016/2031 should be amended, by providing that in case of non-compliance with the requirements on RNQPs, Member States adopt the necessary measures, as referred to in Regulation (EU) 2017/625, and notify the Commission and other Member States through the electronic notification system referred to in Article 103 of Regulation (EU) 2016/2031.
- (13) Consequently, Article 104 of Regulation (EU) 2016/2031, which concerns notifications in the case of presence of pests, should also include a reference to Article 37(1).

- (14) In certain cases, it is appropriate to allow the introduction into the Union territory of certain plants, plant products or other objects, from certain third countries, by way of derogation from the respective prohibition established pursuant to Article 40(1) of Regulation (EU) 2016/2031 or the special and equivalent requirements established by the implementing act adopted in accordance with Article 41(2). The respective plants, plant products and other objects are currently listed respectively in Annexes VI and VII to Implementing Regulation (EU) 2019/2072⁵. Such cases are those in which a third country has made a request for such a temporary derogation and has provided written guarantees that the measures it is applying on its territory are effective in reducing the respective risk from these plants, plant products or other objects and a provisional risk assessment has shown that the risk for the Union territory can be reduced to an acceptable level by application of certain temporary measures set out in points 2 and 3 of Section 1 of Annex II to Regulation (EU) 2016/2031.
- (15) For purposes of clarity and transparency, the Commission should be empowered to adopt implementing acts providing for such derogations. For reasons of completeness, those acts should also set out the temporary measures[which are necessary to reduce the respective phytosanitary risk to an acceptable level and which allow the appropriate time for the full assessment of all pest risks, which are not yet fully assessed in relation to the particular plants, plant products or other objects. This will allow, once the respective assessment is completed, in accordance with the principles of Section 2 of Annex II to Regulation (EU) 2016/2031, those plants, plant products or other objects to be kept in or removed from the list of commodities in accordance with Article 40(3) or Article 41(3) of Regulation (EU) 2016/2031.
- (16) In accordance with Article 42(4) of Regulation (EU) 2016/2031, a plant, plant product or other object is to be removed from the list of high-risk plants, plant products and other objects, if it is concluded, on the basis of a risk assessment, that their introduction into the Union territory is to be subject to prohibition, special requirements or no requirements at all. However, as the experience of the application of that Article has shown, in certain cases the introduction of those commodities into the Union territory could be subject to special measures that reduce the respective phytosanitary risk to an acceptable level, while for some of the pests they host a full assessment is still pending. For this reason, the Commission should be empowered to adopt an implementing act to remove plants, plant products or other objects from the list of high-risk plants, plant products or other objects adopted pursuant to Article 42(3), if they present a phytosanitary risk which is not yet fully assessed and no implementing act has yet been adopted for them pursuant to Article 42(4). In order to reduce any phytosanitary risk to an acceptable level, those acts should set out temporary measures concerning the introduction of those plants, plant products and other objects into the Union territory.
- (17) In order to ensure a proportionate approach and the swiftest possible conclusion of the respective risk assessments, the application period of all those implementing acts should be such as to reasonably allow to fully assess all phytosanitary risks and the

⁵ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1–279).

measures applied by the third countries concerned, and should not be longer than 5 years.

- (18) Moreover, the Commission should be empowered to adopt a delegated act, supplementing Regulation (EU) 2016/2031 with elements concerning the procedure to be followed in order to grant temporary derogations from Article 40(2) and Article 41(2). This is necessary because, the experience since the adoption of Regulation (EU) 2016/2031 has shown that a standardised procedure in respect of granting such temporary derogations is necessary to guarantee transparency and consistency to Member States, third countries and the professional operators concerned.
- (19) The Commission should be empowered to adopt a delegated act, supplementing this Regulation by setting out procedures to be complied with for the listing of high risk plants, plant products and other objects. That procedure should include all of the following elements: the preparation, content and submission of the respective dossiers by the third countries concerned; the actions to be taken following the reception of those dossiers; the procedures on the performance of the respective risk assessment; the handling of dossiers concerning confidentiality and data protection. This is necessary because, experience has shown that a specified procedure in respect of listing high risk plants could guarantee transparency and consistency to Member States, third countries and the professional operators concerned.
- (20) In accordance with Article 44(1), point (a), of Regulation (EU) 2016/2031, the Commission is to set out equivalent requirements, by means of implementing acts, on request of a particular third country, if 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.
- (21) Experience with the implementation of that provision has shown that setting out requirements equivalent only to the special requirements in respect of the movement of plants, plant products and other objects within the Union territory, is neither adequate nor possible in the case where such requirements for movement do not exist. This is a frequent case in practice, where the Union rules concern pests which are only present in third countries and not in the Union territory and where only requirements for the introduction of commodities into the Union territory have been adopted.
- (22) For this reason, the requested level of phytosanitary protection on the part of the respective third country should be also equivalent to the applicable special requirements in respect of the introduction into the Union territory of the plants, plant products and other objects concerned, from all or certain third countries.
- (23) In accordance with Article 71(2) of Regulation (EU) 2016/2031, the phytosanitary certificate is to specify under the heading 'Additional Declaration' which specific requirement is fulfilled, whenever the respective implementing act, adopted respectively 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), provides for several options for such requirements. That specification is to include the full wording of the relevant requirement.

- (24) The practical implementation of Regulation (EU) 2016/2031 has shown that the phytosanitary certificates should also indicate reference to the requirements adopted pursuant to Article 37(4) of the Regulation, namely measures to prevent the presence of RNQPs on the plants for planting concerned, as referred to in point (f) of Article 36 of that Regulation, in the case where the respective provision provides for several different options for such requirements. This is consistent with the approach concerning the Union quarantine pests, as Article 71(2) of that Regulation refers to the implementing act adopted pursuant to Article 41(2) and (3). It will also offer more clarity and certainty to the competent authorities, the professional operators and the third countries, with regards to the application of the rules concerning RNQPS and the respective plants for planting.
- (25) For this reason, Article 71(2) of Regulation (EU) 2016/2031 should include a reference to the implementing acts adopted pursuant to Article 37(4). Moreover, the reference to Article 37(2) should be removed, as it is not relevant to the content of the Additional Declaration of a phytosanitary certificate.
- (26) In accordance with Article 88 of Regulation (EU) 2016/2031, plant passports are to 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 of Regulation (EU) 2016/2031. Where such plants, plant products or other objects are moved in a package, bundle or container, the plant passport is to be attached to that package, bundle or container.
- (27) Trade practises based on Regulation (EU) 2016/2031 have shown that, in certain cases, it is not practically feasible to attach plant passports to trade units of particular plants, plant products or other objects due to their size, shape or other specific characteristics, or due to the speed of its transfer from one professional operator to another. Instead, the trade units of those plants, plant products or other objects should be allowed to be moved within the Union territory with a plant passport associated with them in way other than by physical attachment. The requirements of Regulation (EU) 2016/2031 for the issuance of plant passports for the respective plants, plant products and other objects are to remain as applicable.
- (28) Therefore, the Commission should be empowered to adopt a delegated act allowing certain plants, plant products and other objects to be moved without a plant passport attached to their trade units, due to their size, shape, speed of their trade or other specific characteristics that make that attachment impractical. In this regard, it is necessary to determine the modalities ensuring that the plant passport remains in use, although not attached, and still refers to the respective plants, plant products and other objects, in order to make sure that a plant passport always remains connected to its respective commodity by means of a special mark, chip, database or other appropriate elements.
- (29) In accordance with Article 99(1) of Regulation (EU) 2016/2031, the Commission is empowered to adopt delegated acts supplementing that 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. Since the adoption of Regulation (EU) 2016/2031, no such international standards have been adopted, and no preparatory work is

currently being carried out by any international organisation to produce such standards. As a result, and in the absence of such international standards, it is not possible, based on Article 99 of Regulation (EU) 2016/2031, to adopt a delegated act setting out the necessary elements for the respective official attestations. Due to the lack of such a delegated act, the introduction into the Union territory of the relevant plants, plant products or other objects cannot take place with those official attestations as alternatives to phytosanitary certificates.

- (30) Moreover, and in accordance with certain implementing acts adopted pursuant to Council Directives 77/93/EEC⁶ and 2000/29/EC⁷, plants, plant products and other objects are still being introduced into the Union territory accompanied by official attestations, other than phytosanitary certificates, issued in several third countries. Those acts are, in particular, Commission Decisions 93/365/EEC⁸, 93/422/EEC⁹, 93/423/EEC¹⁰, and Implementing Decision 2013/780/EU¹¹. Those Decisions have been adopted in the absence of any respective international standards.
- (31) The experience gained from the application of Regulation (EU) 2016/2031 and those Decisions, which are still in force, indicates that those official attestations offer adequate guarantees for the phytosanitary protection of the Union territory, despite the fact that no respective international standards have ever existed. For this reason, and in order to ensure the continued use of official attestations under Regulation (EU) 2016/2031, the condition that the elements of that delegated act are required by the applicable international standards should be removed from Article 99(1).
- (32) In accordance with Article 103 of Regulation (EU) 2016/2031, the Commission is to establish an electronic system for the submission of notifications by the Member States. In order to ensure that such electronic system could be applicable also for the submissions of reports, such as the reports for the surveys of Union quarantine pests, priority pests and protected zones quarantine pests, the first sentence of that Article should be amended in order to also include the submission of reports by the Member

⁶ Council Directive 77/93/EEC of 21 December 1976 on protective measures against the introduction into the Member States of harmful organisms of plants or plant products (OJ L 26, 31.1.1977, p. 20).

⁷ 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).

⁸ Commission Decision 93/365/EEC of 2 June 1993 authorizing the Member States to provide for derogations from certain provisions of Council Directive 77/93/EEC in respect of heat-treated coniferous wood, originating in Canada, and establishing the details of the indicator system to be applied to the heat-treated wood, (OJ L 151, 23.6.1993, p. 38).

⁹ Commission Decision 93/422/EEC of 22 June 1993 authorizing the Member States to provide for derogations from certain provisions of Council Directive 77/93/EEC in respect of kiln dried coniferous wood, originating in Canada, and establishing the details of the indicator system to be applied to the kiln dried wood (OJ L 195, 4.8.1993, p. 51).

¹⁰ Commission Decision 93/423/EEC of 22 June 1993 authorizing the Member States to provide for derogations from certain provisions of Council Directive 77/93/EEC in respect of kiln dried coniferous wood, originating in the United States of America, and establishing the details of the indicator system to be applied to the kiln dried wood (OJ L 195, 4.8.1993, p. 55).

¹¹ Commission Implementing Decision 2013/780/EU of 18 December 2013 providing for a derogation from Article 13(1)(ii) of Council Directive 2000/29/EC in respect of bark-free sawn wood of *Quercus* L., *Platanus* L. and *Acer saccharum* Marsh. originating in the United States of America (OJ L 346, 20.12.2013, p. 61).

States. This is necessary to rationalise the reporting system and strengthen the process of digitalisation of phytosanitary measures.

- (33) Regulation (EU) 2016/2031 should therefore be amended accordingly.
- (34) In order to allow for the third countries and their professional operators to adapt to the new rules on the issuance of phytosanitary certificates concerning compliance with the respective RNQP rules, the amendment of Article 71(2) of Regulation (EU) 2016/2031 should apply from ... *[6 months from the entry into force of this Regulation]*,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2016/2031

Regulation (EU) 2016/2031 is amended as follows:

- (1) in Article 18(6), the first subparagraph is replaced by the following:

‘Member States shall notify the Commission and the other Member States of the demarcated areas immediately after their establishment, together with the pests concerned and the respective measures taken. Those notifications shall be made through the electronic notification system referred to in Article 103.’;
- (2) in Article 22(3), the first subparagraph is replaced by the following:

‘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. Those reports shall be submitted to the electronic system for the submission of notifications and reports referred to in Article 103, established by the Commission for that purpose;
- (3) Article 23 is amended as follows:
 - (a) in paragraph 1, the third subparagraph is replaced by the following:

‘The multiannual survey programmes shall be established for a period of 10 years, and shall be prolonged and as necessary updated thereafter for further consecutive periods of 10 years. The first period shall expire on 14 December 2029.’;
 - (b) paragraph 2 is replaced by the following:

‘2. Member States shall, on request from the Commission, notify their multiannual survey programmes. Those notifications shall be submitted to the electronic system for the submission of notifications and reports referred to in Article 103’;

- (4) in Article 24, paragraph 2 is replaced by the following:
- ‘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. Those reports shall be submitted to the electronic system for the submission of notifications and reports referred to in Article 103’;
- (5) in Article 30(1), the third subparagraph is replaced by the following:
- ‘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). They may include the prohibition of the presence of that pest in the Union territory and/or requirements concerning the introduction into, and the movement within, the Union territory of plants, plant products and other objects.’;
- (6) in Article 34, paragraph 2 is replaced by the following:
- ‘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. Those notifications shall be submitted to the electronic system for the submission of notifications and reports referred to in Article 103;
- (7) in Article 37, the following paragraph is added:
- ‘10. In the event that plants for planting 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 Article 66(3) of Regulation (EU) 2017/625 and shall notify that violation and those measures to the Commission and other Member States through the electronic notification and reporting system referred to in Article 103.
- Member States shall also notify those measures to the third country from which the plants for planting were introduced into the Union territory.’;
- (8) in Article 42(1), the following subparagraphs are added:
- ‘The Commission is empowered to adopt a delegated act, in accordance with Article 105, supplementing this Regulation by setting out the procedure to conduct the listing of high risk plants, plant products and other objects.
- That procedure shall provide for all the following elements:
- (a) the preparation of the respective evidence for the assessment of the high risk plants, plant products and other objects;
 - (b) the actions to be taken following the reception of that evidence;
 - (c) the procedures of the respective assessment;

- (d) handling of dossiers concerning confidentiality and data protection.’;
- (9) the following Article 42a is inserted after Article 42:

‘Article 42a

Temporary derogations from the prohibitions provided for in Articles 40 and 42, and from the requirements referred to in Article 41

1. By way of derogation from Article 40(1) and Article 41(1), the Commission may, by means of implementing acts, adopt temporary derogations from the prohibition provided for in Article 40(1), and from the special and equivalent requirements referred to in Article 41(2), concerning the introduction into the Union territory of specific plants, plant products and other objects originating from one or more third countries, which present a phytosanitary risk which is not yet fully assessed.

Those implementing acts shall:

- (a) set out temporary measures concerning the introduction of those plants, plant products and other objects into the Union territory, in accordance with the principles set out in Section 2 of Annex II; and
 - (b) amend the respective parts of the implementing act referred to in Article 40(2) and Article 41(2), by inserting a reference to the derogation concerning the respective plant, plant product or other object concerned.
2. The temporary derogations referred to in paragraph 1 may be adopted only if the following conditions have been fulfilled:
 - (a) the third country concerned has submitted to the Commission a request, containing official written guarantees for the application in its territory, prior to and at the moment of making the request, of the measures which are necessary for addressing the respective phytosanitary risk; and
 - (b) a provisional assessment has shown that those plants, plant products or other objects pose a risk that can be reduced to an acceptable level by applying one or more of the measures in respect of the phytosanitary risk concerned.
3. The Commission is empowered to adopt a delegated act, in accordance with Article 105, supplementing this Regulation as regards the procedure to be followed in order to grant the temporary derogations referred to in paragraph 1. That delegated act shall provide for the following elements of the procedure:
 - (a) the preparation, content and submission of the respective request and dossiers by the third countries concerned;
 - (b) the actions to be taken following the reception of those requests and dossiers;

- (c) handling of the requests and dossiers concerning confidentiality and data protection.
4. By way of derogation from Article 42(2), the Commission may, by means of implementing acts, adopt temporary derogations from the acts referred to in Article 42(3), if both of the following is fulfilled:
- (a) the respective phytosanitary risk of the high-risk plants, plant products or other objects is not yet fully assessed;
 - (b) no implementing act pursuant to Article 42(4) has yet been adopted as regards the plants, plant products or other objects concerned.

Those implementing acts shall set out temporary measures, which are necessary to reduce the respective phytosanitary risk to an acceptable level, concerning the introduction of those plants, plant products and other objects into the Union,.

5. The implementing acts referred to in paragraphs 1, 2 and 4 shall provide for yearly reporting from the third country concerned about the application of the respective temporary measures. In case the report concerned leads to the conclusion that the risk concerned is not appropriately addressed by the measures reported on, the act providing for those measures shall be immediately repealed or amended as necessary.
6. The application period of the implementing acts referred to in paragraphs 1, 2 and 4 shall be such as to reasonably allow a full assessment of all phytosanitary risks and the measures of the third countries concerned, and shall not be longer than 5 years.
7. The implementing acts referred to in paragraphs 1, 2 and 4 shall be adopted in accordance with the examination procedure referred to in Article 107(2).
- (10) in Article 44(1), point (a) is replaced by the following:
- ‘(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 introduction into, and/or movement within, the Union territory of the plants, plant products and other objects concerned from other third countries;’;
- (11) in Article 71, paragraph 2 is replaced by the following:
- ‘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(4), 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.’;
- (12) in Article 88, the following paragraphs are added:

‘The Commission is empowered to adopt a delegated act, in accordance with Article 105, supplementing this Regulation by:

- (a) determining the plants, plant products and other objects which, by way of derogation from the first paragraph, may be moved within the Union with a plant passport associated with them in a way other than that of a physical attachment, due to their size, shape or speed of their trade that make that attachment impossible or very difficult; and
 - (b) providing for rules to ensure that the plant passport concerned, although not attached, still refers to the respective plants, plant products and other objects by means of a special mark, chip and/or database;
- (13) in Article 99, paragraph 1 is replaced by the following:
- ‘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, 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).’;
- (14) In Article 103, the first sentence is replaced by the following:
- ‘The Commission shall establish an electronic system for the submission of notifications and reports by the Member States.’;
- (15) in Article 104, first paragraph, the first sentence is replaced by the following:
- ‘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), Article 29(3), first subparagraph, Article 30(8), Article 33(1), Article 37(10), 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).’

Article 2

Entry into force and application

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

Article 1, point (11) shall apply from ... [6 months from the entry into force of this Regulation].

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President