

New Conditions for F&V Imports into the EU EU Plant Health & Official Controls Legislation

Freshfel Fact Sheet Update

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PURPOSE

The purpose of this Fact Sheet is to provide Freshfel members with a broad overview of the main 2019 changes in EU legislation on plant health and official controls affecting fruit and vegetables imports. The document is a summary of the information & analysis that have been conducted by the Freshfel Secretariat so far and communicated to members since the start of the Plant Health & Official Controls reform. It is based on the information available until 31 July 2019 and subject to future revision pending on legislative developments.

CONTENTS

1. Implementing Directive 2019/523 on new protective measures against pests of concern, to be applied as of 1 September
2. Regulation (EU) 2016/2031 introducing a new EU Plant Health Framework, to be applied as of 14 December 2019
3. 2019 Emergency measures
4. Regulation (EU) 2017/625 introducing a new EU Official Controls Framework, to be applied as of 14 December 2019

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1. Implementing Directive 2019/523 amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

On 28 March, the European Commission published in the Official Journal the [amended Annexes I to V to Council Directive 2000/29/EC](#). The update's objective is to introduce new protective measures for the introduction of plants and plants products into the EU. These new requirements shall apply as on 1 September 2019.

When it comes to fruit and vegetables, the new Annexes introduce three main relevant changes:

A) Amendments of Annex IV, Part A

A number of points have been modified introducing new obligations for third countries' NPPOs and operators importing F&V into the EU, in relation to a number of pests & commodities combinations:

NON EUROPEAN FRUIT FLY - New Point 16.5/6 affecting Fruits of *Citrus L.*, *Fortunella Swingle*, *Poncirus Raf.*, and their hybrids, *Mangifera L.* and *Prunus L.*:

- The exporting country will have to choose among four options to import into the EU, namely (a) „country free of“, an (b) „area free of“, if (c) „no signs of Tephritidae (non-European), to which those fruits are known to be susceptible, have been observed at the place of production and in its immediate vicinity (...) on official inspections carried out at least monthly during the three months prior to harvesting, and none of the fruits harvested at the place of production has shown, in appropriate official examination, signs of the relevant organism“ or if the fruits (d) have been subject to an „effective treatment“ to ensure freedom of Tephritidae.
- NPPOs of exporting countries should send a written notification statement to DG SANTE before 1 September on their status in relation to non-European fruit fly (*tephritidae* family) if they choose to export under options (a), (b) or (d). There is notification obligation if the country "chooses" to conduct exports under option (c). In this case, however, the traceability information should appear in the phyto certificates.
- „Effective treatment“ should be understood as „any official procedure for the killing, inactivation or removal of pests, or for rendering pests infertile or for devitalization“ (ISPM 5). Therefore, this definition includes the application of a systems approach, as described in ISPM 14.
- The different options communicated by third countries' NPPOs create different obligations for operators. Under option (b) the freedom status shall be indicated in the „Additional Declaration of the phyto certificate accompanying the goods. In option (c) traceability information should also feature in the phytos. If option (d) is used, the term „post-harvest treatment“ or alternatively „systems approach“ shall be mentioned in the box „Additional Declaration“. Moreover, under the latter option, details of the treatment used (e.g. cold treatment temperature, time, etc.) should be indicated in the box „treatment“ of the phytosanitary certificate.

FALSE CODLING MOTH - New point 16.6 affecting Fruits of *Capsicum (L.)*, *Citrus L.*, other than *Citrus limon (L.) Osbeck.* and *Citrus aurantiifolia (Christm.) Swingle*, *Prunus persica (L.) Batsch* and *Punica granatum L.* originating in countries of the African continent, Cape Verde, Saint Helena, Madagascar, La Reunion, Mauritius and Israel:

- Obligation of exporting NPPOs to notify their status to the Commission in relation to *thaumatotibia leuctreta*, namely (a) - free country, (b) – free area and (d) – effective cold treatment or another effective treatment. There is no obligation to notify in advance option (c) – official inspections in place of production.
- The functioning of this provision is similar to point 16.5 (see above for more details). In short, this means that the option ‘selected’ by an exporting country shall be notified in advance by the NPPO (except for option c) and feature in the phytosanitary certificates of operators.
- Importantly for this provision, those NPPOs which already notified a mitigation treatment to the Commission under the previous measure shall now provide additional information on the “effectiveness” of said treatment or measure, as this justification was not asked before.

ENARMONIA PRUNIVORA WALSH, GRAPHOLITA INOPINATA HEINRICH AND RHAGOLETIS POMONELLA (WALSCH) – New point 16.7 affecting fruits of *Malus Mill.*:

- The 4 options outlined are also similar to the ones under point 16.5 (see details above).
- Therefore, notification by NPPOs concerned is needed before 1 September (except for option c), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-d).

GUIGNARDIA PIRICOLA (NOSA) YAMAMOTO – New point 16.8 affecting Fruits of *Malus Mill.* and *Pyrus L.*:

- The 4 options outlined are also similar to the ones under points 16.5 (see details above).
- Therefore, notification by NPPOs concerned is needed before 1 September (except for option c), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-d).

TACHYPTERELLUS QUADRIGIBBUS SAY– New point 16.9 affecting fruits of *Malus Mill.* and *Pyrus L.*:

- The 4 options outlined are also similar to the ones under points 16.5 (see details above).
- Therefore, notification by NPPOs concerned is needed before 1 September (except for option c), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-d).

GRAPHOLITA PACKARDI ZELLER– New point 16.10 affecting fruits of *Malus Mill.*, *Prunus L.*, *Pyrus L.* and *Vaccinium L.*, originating in Canada, Mexico and the USA:

- 3 options are outlined, similar to the ones under points 16.5 (see details above) but omitting one option („country free“). In this case, the options are the following: (a) „area free of“, (b) „no signs of the pest in the place of production as per official inspections carried out, and (c) fruits subject to an „effective treatment“ to ensure freedom from the pest.
- Therefore, notification by NPPOs concerned is needed before 1 September (except for option b in this case), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-c).

NEOLEUCINODES ELEGANTALIS (GUENÉE) – New point 25.7.3 affecting fruits of *Capsicum annuum* L., *Solanum aethiopicum* L., *Solanum lycopersicum* L. and *Solanum melongena* L.:

- 4 options are outlined. The first three options are the same as the ones applying under point 16.5: (a) - free country, (b) – free area or (c) – official inspections in place of production (see details on each above). The fourth option (d) is however different, and applies to those fruits that “originate in an insect proof site of production established by the NPPO as free”.
- Notification by NPPOs concerned to the Commission is required before 1 September only for options (a) and (b), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-d). Under options (c) and (d), information on traceability should be included in the certificates.

BACTERICERA COCKERELLI (SULC.) – New point 25.7.4 affecting fruits of Solanaceae originating in Australia, the Americas and New Zealand

- 4 options are outlined. The first three options are the same as the ones applying under point 16.5: (a) - free country, (b) – free area or (c) – official inspections in place of production (see details on each above). The fourth option (d) is however different, and applies to those fruits that “originate in an insect proof site of production established by the NPPO as free”.
- Notification by NPPOs concerned to the Commission is required before 1 September only for options (a) and (b), and relevant operators shall fill the boxes as appropriate depending on the option selected (a-d). Under options (c) and (d), information on traceability should be included in the certificates.

NPPO NOTIFICATIONS EXPLAINED:

All newly introduced measures require the filing of notifications by third countries’ NPPOs concerned. In this regard, the following must be highlighted:

- Outreach to third countries: The Commission has notified third countries of the new obligations by a communication to WTO in April 2019. Moreover, Commission services have sent a notice on 1 July to all IPPC contact points reminding third countries of the need to file notifications.
- Procedure and timeline: Notifications have to be sent to SANTE-G1-PLANT-HEALTH@ec.europa.eu. If the Commission has not received a notification by the 1st of September 2019, import of the commodities targeted will be preliminary banned from entering the EU until the NPPO notified its status in relation to the pests. Please also note that if a third country has not provided communication on a certain option (e.g. "country free" (a) or "effective treatment (d)), import under these options would not possible until such communication is made by the NPPO.
- Progress report: The European Commission has made available an overview of the notifications required/received [HERE](#). Freshfel strongly encourages European operators to check the status notice of the countries they are importing from, and to liaise with the country’s NPPO with a matter of urgency if the notification has not been sent to the Commission yet. The Freshfel Secretariat is also available to help operators concerned to liaise with competent authorities in Brussels (e.g. third country missions to the EU). Members are invited to alert Freshfel’s Secretariat of the lack of notifications filed by third countries of interest.

Infographic summary of new requirements under Annex IV - Part A



→ *Tephritidae*







→ *Thaumatotibia leucotreta*






→ *Enarmonia prunivora, Grapholita inopinata & Rhagoletis pomonella*

→ *Guignardia piricola & Tachypterellus quadrigibbus*




→ *Grapholita packardi*







→ *Neoleucinodes elegantalis*






→ *Bactericera cockerelli*






B) Amendments of Annex V, Part B, Section I

Under the Implementing Directive, a range of fruits have been added to Plant Health Directive 2000/29, Annex V, Part B, Section I. The fruits concerned are the following:

- Fruits of *Solanaceae* family (extending existing legislation, which previously only included *Solanum lycopersicum* - tomato and *Solanum melongena* -eggplant)
- Kiwi (*Actinidia Lindl.*), Strawberry (*Fragaria L.*), Grapes (*Vitis L.*), Papaya (*Carica papaya L.*), Avocado (*Persea americana Mill.*), Raspberry/Blueberry/Blackberries (*Rubus L.*)

The main implication of their inclusion in this section is that these fruits, regardless of the origin, will need to be accompanied by a **phytosanitary certificate** to enter the EU as of the 1st of September.

Moreover, it is worth noting that the fruits under the first bullet point, together with the rest of fruits which were already listed in the same part of the legislation (see paragraph below) will require a phyto certificate for all origins. This extends the scope of the previous provisions, which only required this for „ fruits originating in non–European countries“ (e.g. fruits coming from the Balkans, Norway or Ukraine would now require the phyto certificate too).

Actinidia Lindl., Annona L., Carica papaya L., Cydonia Mill., Diospyros L., Fragaria L., Malus L., Mangifera L; Passiflora L., Persea americana Mill., Prunus L., Psidium L; Pyrus L., Ribes L., Rubus L., Syzygium Gaertn., Vaccinium L., and Vitis L. 'originating in non-European countries

Please note that the obligation to carry a certificate will be extended to all F&V on 14th December, although with a lower degree of 1% of controls for those commodities to which the obligation extends on that date (see section 2.A for more details).

IMPORT CONTROLS FOR NEWLY LISTED COMMODITIES IN ANNEX V EXPLAINED

Newly listed commodities will be subject to 100% documentary checks and a minimum of 5% of consignments to be physically checked upon entry into the Union. The level of these checks (between 5 and 100%) will depend on the Member State of entry of the fruits: each Member State can decide at national level whether they will stick to the minimum required by EU law or apply checks in more consignments. This degree of controls will also be subject to change depending on inspection results (e.g. potential interceptions). Changes will be notified on an annual basis by the Commission's notification of reduced plant health checks. The last notification, including the 5% controls for the newly listed commodities, is valid from 01.01.2019 to 31.12. 2019. It can be found [HERE](#).

The requirements for the handling of phytosanitary documents can vary depending on the EU Member State of entry. For instance, the acceptance of an original document vs. the acceptance of a certified copy of the phytosanitary certificate is in the hands of each EU national inspection authority. Please get in touch with the respective authorities, where you conduct import inspections, to clarify whether they will require a phytosanitary certificate with a „wet“ signature as of 1 September for these commodities, or if a copy/print of the file will be accepted. Please note further, that this procedure is limited to the time between the 1st of September 2019 until the 14 of December 2019, when the EU Official controls Regulation 2017/625 will start to be applied, thus harmonising inspections & control procedures throughout MSs (see section 3 of this fact sheet on „Official Controls“).

2. Regulation (EU) 2016/2031 on protective measures against pests of plants, introducing a new EU Plant Health Framework

On 14 December, the new EU Plant Health Law ([Regulation \(EU\) 2016/2031](#)) enters into application. This modernised legislative framework has the overarching objective of implementing effective measures for the protection of the Union's territory and its plants, as well as ensuring safe trade from a biosecurity point of view, and helping the mitigation of the impacts of climate change on the health of crops and forests.

These new rules will bring several main changes when it comes to imports of fresh produce:

A) Phytosanitary certificate obligation for all F&V, with a few exceptions and different degrees of checks in Border Control Posts

From 14 December 2019, all plants (including living parts of plants eg. fruit and vegetables) will need to be accompanied by a phytosanitary certificate to enter into the EU, unless they are listed in [Commission Implementing Regulation \(EU\) 2018/2019](#) as exempted from this general requirement (not requiring to be accompanied by a phytosanitary certificate).

Currently, the list of plants exempted from the obligation to carry a phytosanitary certificate as of 14 December 2019 includes five fruits:

- Pineapples (*Ananas comosus (L.) Merrill*),
- Coconuts (*Cocos nucifera L.*),
- Durians (*Durio zibethinus Murray*),
- Bananas (*Musa L.*),
- Dates (*Phoenix datylifera L.*).

When it comes to phytosanitary checks at the border, it is important to note that, for those fruits and vegetables covered by this „extended obligation“ to carry a phyto as of 14 December, but having no additional requirements (i.e. not covered by the Annexes I to V of the Plant Health Directive 2000/29 of the previous section), this obligation will entail documentary controls (100%), and a 1% minimum physical checks.

Please note, that phytosanitary certification will become mandatory as of the 14th December 2019 sharp. So what matters in the transition is not the shipment date, but the date of entry into the Union. Therefore, it is recommended to alert traders and third country partners to have PCs prepared for consignments which will be shipped already before the 14th of December 2019 and arriving on 14th December 2019 or after. Other practical requirements to be taken into account:

- Additional Declarations: While in the past the box „Additional Declaration“ has been handled differently, as of the 14th of December 2019 a uniform approach will be introduced. The full wording of the treatment/system approach defined in Annex VII of [„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, an](#) needs to be inserted document.
- Signatures: Currently there is no legal basis governing the conduct of signatures on phytosanitary certificates. Therefore, it is up to the MS to decide their code of conduct with that regard, resulting in different approaches by MS authorities. DG SANTE is currently discussing with the MS on a common approach on wet signatures vs. copy. Therefore, it is highly recommended that traders carry the original document with a wet signature, to ensure smooth documents checks as of the 14th of December 2019.
- Delay in possibility for electronic transmission of PCs: Opposite to announcements made earlier, no electronic transmission opportunity for phytosanitary certificates will be available as of the 14th of December 2019. That has the following causes:
 - No third country partner has yet agreed, to conduct the transmission of PC's to the EU via TRACES;
 - Connection to the IPPC ePhyto Hub is scheduled for the course of 2020.

Therefore, the following operational possibilities will be available on 14 December:

1. Paper format
2. Creation of the phytosanitary certificate in TRACES by third country NPPO and printing
3. Information from the PC can be added manually into TRACES to support the data gathering.

According to the Commission, the second and third options are preferred, as they would allow operators to start using both paper & electronic transmission, a sort of „transition“, to get used to TRACES and be ready for the moment when electronic transmission of PCs will be made available. Moreover, the Commission mentioned the easier identification of potential fraud in PCs as a positive side effect of this „duplication“, together with the fact that any information included in TRACES will contribute building the Commission's database.

Key take aways for traders:

- Shipments leaving the third country before the 14th of December but entering the EU on 14th of December or after will need a PC as of the due date. No transition period is foreseen. Third country partners should prepare PC's already.
- Additional declarations: Exact wording will need to be copied from Annex VII of [„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, an](#)
- Mode of transmission: Paper format and original signatures. Ideally, operators should start integrating PCs in TRACES too.

B) an from entry for ,High Risk’ plants, until PRA is conducted

In order to increase the prevention against the introduction of new pests via imports, [Commission Implementing Regulation \(EU\) 2018/2019](#) establishes in its Annex I a list of high risk plants, the introduction of which into the EU territory will be provisionally prohibited from 14 December 2019 onwards until a full risk assessment (PRA) has been carried out.

The rules concerning the procedure to be followed in order to carry out said risk assessment for high risk plants are detailed in [Commission Implementing Regulation \(EU\) 2018/2018](#).

Worth noting, within the realm of F&V, the list only includes *Momordica L.* originating from third countries or areas of third countries where *Thrips palmi Karny* is present.

C) Draft ,Phytosanitary Conditions Regulation’

[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, an](#) whose aim is to transfer the Annexes I to V of previous Council Directive 2000/29/EC to the new regulatory framework, represents in principle a ‘technical step’ which should in principle not bring any substantial change in conditions for import. .

The secondary act includes the following:

| Article | Content |
|-----------|--|
| Article 3 | List of Union quarantine pests (Annex II) |
| Article 4 | List of protected zones and the respective protected zone quarantine pests (Annex III) |
| Article 5 | List of Union regulated non-quarantine pests and specific plants for planting with and thresholds (Annex IV) |
| Article 6 | Measures to prevent the presence of RNQPs on specific plants for planting (Annex V) |
| Article 7 | List of plants, plant products and other objects whose introduction into the Union from third countries is prohibited (Annex VI – only plants for planting like citrus are included, as well as tubers, bark and soil) |
| Article 8 | List of plants, plant products and other objects originating from third countries, or in the Union territory and the corresponding special requirements for their introduction into or movement within the Union territory |
| Annex VII | Includes the special requirements for the introduction of plant products, including |

| | |
|------------|--|
| | fruits, from third countries. The requirements for fruits are covered in points 57 to 72 of this annex, whose substance has not suffered changes in principle (pages 115 to 132 of the pdf annex enclosed). |
| Annex VIII | Compiles the special requirements for movement within the union. |
| Article 9 | List of plants, plant products and other objects, whose introduction into certain protected zones is prohibited (Annex IX). |
| Article 10 | List of plants, plant products and other objects to be introduced into, or moved within protected zones and corresponding special requirements for protected zones (Annex X). In this Annex, points 37 and 38 are related to fruits (37 on conditions for citrus, fortunella, poncirus and their hybrids originating in BU, GR, ES, FR, HR, IT, CY, PT and SV with peduncles to enter protected zone Malta, and 38 on vitis, which shall be free from leaves to enter Cyprus). |
| Article 11 | List of plants, plant products and other objects for which a phyto certificate is required for their introduction into the Union (part A of Annex XI). These will be the ones covered by the “phyto obligation” under article 72(1) of the new plant health law. On top of this, Article 11(2) states that all other plants, other than the ones listed in part B of Annex XI, shall be accompanied by a phyto certified (under the “extension of the obligation” to carry a phyto). This exception covers the commodities already included in previous legislation published in December (pineapple, coconut, durian, banana, and dates). |
| Article 12 | List of plants for which a phyto is requirement for their introduction into a protected zone from certain third countries (Annex XII – no F&V) |
| Article 13 | List of plants for which a plant passport is required for movement within the union (Annex XIII – no F&V). |
| Article 15 | List of plants for which a plant passport with the designation ZP is required (Annex XIV- no F&V). |

The Freshfel Secretariat reviewed and discussed the draft text of this act with members when it was published for public consultation in August. From our understanding and the discussion with members, no substantial changes were identified compared to the previous provisions, in line with the Commission’s announced approach.

It is also worth reiterating that, as indicated in the previous section, this regulation shall provide further clarification in Annex VII regarding the wording on ‘Additional Declarations’ in PCs.

ONGOING APPLICATION OF EXISTING MEASURES FOCUS:

Please be reminded that, despite the “re-shape” of this measure, all existent provisions in the Annexes I to V of Council Directive 2000/29/EC will remain valid and applicable (including those already introduced in previous years and the ones to be applied as of 1 September). This includes, among other, the measures regulating citrus entry into the Union under point 16 of Annex IV (obligation to be free from peduncles, treatment vs. citrus canker, *Cercospora angolensis*, CBS, and non-European fruit flies), as well as the provisions to mitigate *Keiferia lycopersicella* (Walsingham) for tomatoes and aubergines, under point 25.7.2. Please check the consolidated version of [Annexes I to V of Council Directive 2000/29/E](#) if you need more information on existing measures.

3. 2019 Emergency measures

As it can be seen throughout this document, the new EU plant health & official controls framework is not made out of a „stand alone“ regulation, but is rather an evolving exercise comprising a wide range of secondary legislation.

Some of these changes having implications for imports can come relatively fast upon the identification of new biosecurity risks, particularly the so-called “emergency measures”. These are usually adopted for a short/medium period, subject to changes depending on the development of the risk identified.

In 2019, two reviews have been conducted in existing emergency measures affecting F&V.

A) Renewal and extension of the scope of the emergency measure on citrus black spot – March 2019

On 20 March, the [Commission Implementing Decision \(EU\) 2016/715](#) setting out emergency measures to prevent the introduction of *Phyllosticta citricarpa* (McAlpine) Van der Aa (citrus black spot) was published in the EU Official Journal. The decision renewed the previous Commission Implementing Decision 2019/449, which was due to expire on 31 March 2019, until the end of March 2022.

The new decision introduced additional measures on citrus black spot for the main Southern Hemisphere suppliers:

- a) Extension of the scope of the measures to Brazil, in addition to Argentina, South Africa and Uruguay.
- b) Specific growing and inspection requirements for citrus fruits originating in the countries targeted above, notably:
 - A statement that the specified fruits originate in a field of production which has been subject to treatments against CBS carried out at the appropriate time since the beginning of the last cycle of vegetation;
 - A statement that an appropriate official inspection has been carried out in the field of production during the growing season, and no CBS symptoms have been detected in the specified fruit since the beginning of the last cycle of vegetation;
 - A statement that a sample has been taken along the line between arrival and packaging in the packing facilities of at least 600 fruits of each species per 30 tonnes, or part thereof, selected as much as possible on the basis of any possible CBS symptom, and all sampled fruits showing symptoms have been tested and found free of that harmful organism;
 - In the case of *Citrus sinensis* (L.) Osbeck ‘Valencia’, an additional statement that a sample per 30 tonnes, or part thereof, has been tested for latent infection and found CBS free.

B) Revision and extension of the scope of the emergency measure on Fall Armyworm –ongoing

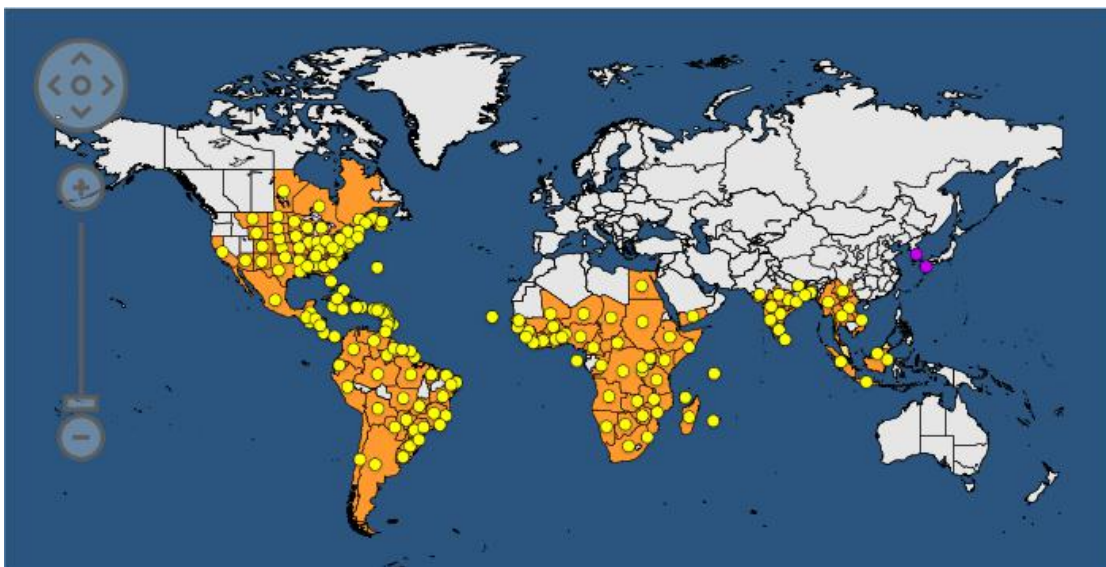
In 2018, the European Commission implemented emergency measures against the fall armyworm, or *Spodoptera frugiperda* (Smith), through [Commission Implementing Decision \(EU\) 2018/638](#). The measure would apply until 31 May 2020.

The provisions affected imports of fruits of *Capsicum L.*, *Momordica L.*, *Solanum aethiopicum L.*, *Solanum macrocarpon L.* and *Solanum melongena L.* originating in Africa or in the Americas, where the pest was known to occur. Under the measure, these imports had to:

- Originate in a “country free” (a) or “area free” (b)
- Be produced in a production site supervised by the NPPO, with official inspections, and with complete physical protection against the pest (c)
- Comply with conditions under point (c) and be subject to an „effective treatment“ (d), which is indicated in the phyto certificate (e)

In September, the Commission reviewed this emergency measure, together with Member States. The result was [Commission Implementing Decision \(EU\) 2019/1598](#) of 26 September 2019 amending Implementing Decision (EU) 2018/638 establishing emergency measures to prevent the introduction into and the spread within the Union of the harmful organism *Spodoptera frugiperda* (Smith). As previously announced by Freshfel, the new measure meant an extension in the scope, as it now applies to all third countries. The reasoning behind is the worrying and rapid spread of the pest, particularly in Asia (see EPPO map below). The measure shall apply until 30 June 2021.

EPPO DATABASE: Global Distribution of *Spodoptera frugiperda*



4. Regulation (EU) 2017/625 introducing a new EU Official Controls Framework, to be applied as of 14 December 2019

The new [Official Controls Regulation 2017/625](#) will come into force as of the 14th of December 2019. It will provide the framework for Member States to verify that businesses comply with agri-food chain rules, and will encompass all those activities that range from plants and animals production to food manufacturing and supply, including activities that take place at farm level, processing and distribution to the consumer. Therefore, the new regulation will also cover import controls on fruit and vegetables entering the EU from third countries (to note, that fruit and veg. were out of the scope of the previous Official Controls Regulation). Besides, the regulation introduces a strong component of digitalisation of official controls operations under the umbrella of the so-called Information Management System for Official Control (IMSOC), which aims at facilitating the transmission of documents and certification & at enhancing traceability in the supply chain.

The Regulation and most of the numerous delegated & implementing acts accompanying it enter into force on 14 December 2019, at the same time as the new EU Plant Health Law. For F&V imports, there are two main implications to take into account:

A) Key changes as of the 14th of December 2019 on plant health controls

With the coming into force of the Official Control Regulation (EU) 2017/625) new rules for the plant health controls will apply.

- All fruit and vegetables, which will need a phytosanitary certificate as of the 14th December 2019 and fall under the provision of Article 73 of the Plant Health Regulation (EU) 2016/2031 will be controlled in line with Article 44 (OCR 2107/625), following a risk-based approach. For the commodities falling under Article 73, a minimum frequency of controls of 1% minimum has been set. This control can be conducted at designated control points other than the border control post of entry. Also the 5 excepted products fall under Article 44.
- All fruit and vegetables, which are already regulated within the current Annexes of Plant Health Directive 2000/29 and will fall under Art. 72 of the new Plant Health Regulation 2016/2031, will be controlled in line with Art. 47.1 of the OCR Regulation (EU) 2017/625 directly at the border control point. These products will have 100% of controls unless they are in the reduced frequency check lists published annually by the Commission.
- Implementing Regulation 103/2004 on specific rules for identity checks will be repealed by „*Commission Implementing Regulation XXX establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts.*“ The new rules will impose monitoring and reporting obligations for the MS on the results of sampling, in order to further harmonise control operations. This will include some guidance on including on dormant pests.

KEY TAKE AWAYS FOR TRADERS:

- F&V, which already require a PC will be controlled at the Border Control Posts on 100% frequency rate, if not otherwise defined within the reduced checks' list.
- F&V, which require a PC as of the 14th of December 2019 will be controlled on risk-basis with 1% minimum checks frequency.

B) Scope of operations at Border control posts (BCP'S) and points

The reform also includes the revision of conditions for the designation of border control posts (first entry points) as well as border control points. Article 47 to 64 of the 2017/625 define the framework of control operations and conditions for the designation of border control posts and points. This includes:

- Definition of goods subject to controls (Art. 47)
- Provision to conduct official controls (Art.49)
- Definition of certificates and documents accompanying consignments and split consignments (Art. 50)
- Specific rules for official controls at border control posts (Art 51)
- Details of documentary checks, identity checks and physical checks (Art. 52)
- Definition of documentary checks, identity checks and physical checks (Art.54)
- Decisions on consignments (Art. 55)
- Rules on the usage of the CHED (Art. 56-58)
- Rules for the designation of border control posts & points (Art. 59 - 64)

The new rules for the designation of border control posts and points require a revision and assessment of the current list of border control posts by the MS in line with provisions of Art. 64 (Conditions: sufficient number of staff, premises appropriate to nature and volume of the consignment, equipment to perform the controls, equipment to extend controls in case of non-compliance, contingency arrangements to smoothen controls, technology necessary to operate within IMSOC, access to service of official laboratories, measures in place to avoid cross-contamination and to comply with relevant biosecurity standards).

These conditions apply to border control posts and border control points equally. This may result in a change of accessible border control posts and points for fruit and vegetable controls. The list of BCP'S and points is available in TRACES. It is strongly advised, if not yet available, to get in touch with your respective national authority to clarify the entry points as of the 14th December 2019. With regard to control points other than BCP's and the conditions, under which controls can be transferred to control points, this will be governed by " Commission Delegated Regulation XXX as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts" (to be published in Mid-December). As border control points have to fulfill the conditions of Art. 64 of the OCR, current border control points in particular on company premises could lose their designation. For controls at border control points, a transitional period until the 14th December 2020 was given with regard to (1) Identity checks and physical checks as well as (2) documentary checks and (3) the conditions for the performance of controls at border control points. Border control points may still operate with the rules laid down in Commission

Directive (EC) 103/2004 until next year. For the transfer of the consignment a second CHED will be needed. The first CHED can be cloned and changed accordingly.

KEY TAKE AWAYS FOR TRADERS:

- MS should publish the newly designated BCP's in TRACES asap;
- Operators are encouraged to check the availability of the new BCP-lists within TRACES;
- If not available, operators should get in touch with MS authorities to understand the state of play of the national designations and possibly push for swift publication;
- Current border control points at company premises may lose their control point status if not complying with the conditions of Art. 64. Of the new ORC. Operators concerned are advised to check with the respective national authorities their current status of designation;
- Border control points may operate until the 14th of December 2020 still under the old provisions of Commission Directive (EC) 103/2004;
- For the transfer from border control posts to border control points a second CHED will be needed.

C) Transit, Transshipment and Onward Transportation

The supplementing Delegated Regulation on rules on official controls of consignments of animals and goods in transit, transshipment and onward transportation is expected to be published in Mid-December. The act covers rules on onward transportation and onward transportation facilities and on transit of animals and goods from the third country to another third country, passing through the Union territory. From the 14th of December 2019 goods in transit, which are regulated under Article 47.1 and Art. 44 of the OCR Regulation need to be accompanied by a Common Health Entry Document (CHED). Facilities for onward transportation need to be designated by the MS in line with Art. 9 of the Delegated Regulation XXX. A list of OT-facilities should be available in TRACES. Operators need to contact authorities at national level to know the list of registered facilities, if not yet published. Onward transportation needs to be requested by the operator within Part I of the CHED. For the onward transportation, TRACES will provide for a box within CHED to select the OT facility.

- **KEY TAKE AWAYS FOR TRADERS:**
- Goods in transit falling under Art. 47.1 and Art. 44 (all fruits and vegetables except bananas, pineapples, dates, durians and coconuts) need to be accompanied by a CHED
- Goods designated to onward transportation facilities, need to request the onward transportation in Part I of the CHED
- Onward transportation facilities are designated by the MS and should be listed in TRACES. If this not yet the case, it is recommended to get in touch with your national authorities
- Splitting consignments: each part of the splitted consignment will need a CHED with the new place of destinations. The print out will accompany the consignment.

D) Information Management System for Official Control & TRACES

A key element of change of the OCR will be the transition into the Information Management System for Official Control - the IMSOC (regulation). The IMSOC is a roof, under which various technical elements of control operations will be managed digitally as of the 14th of December 2019. A first element is the monitoring and tracking of food safety and phytosanitary threats. Reporting of interceptions with regard to detection of quarantine pest will be digitally added to Europhyt - with immediate accessibility to the information for all MS BCP's. Also entries into RASFF will be done digitally as of the 14th of December 2019. This leads to a second element of the OCR: trade facilitation through better information exchange. Through the IMSOC channel all border control information will become available for all MS at the same time and will help to faster track biosecurity threats by invasive species, exceedences of MRL's and/or outbreaks of diseases. It will avoid that trade which is rejected in one harbour enters into another one in a different EU-MS.

While the new digital system will help to gather data on interceptions, there are currently no concrete plans to use the data of Europhyt and RASFF for improving the control operations. Thirdly, TRACES as an electronic creation system, will allow to create relevant certificates (CHED, phytosanitary certificates and the COI) digitally. **While TRACES allows electronic transmission of certificates with an qualified electronic signature, this is not the main purpose.** TRACES facilitates the creation of the documents and serves as a data gathering tool. Currently, „TRACES classic“ co-exists together with the new version „TRACES-NT“. All traders need to register to TRACES-NT if not done yet, as TRACES classic will cease to exist as of the 14th of December 2019 .

To transmit and release (CHED, phyto or COI) certificates electronically, inspectors will need a qualified electronic signature. The token for the signature is available and need to be requested via sante-traces@ec.europa.eu by the relevant inspectors from the MS. The availability of the electronic signature will allow MS to finally release Certificates of Inspection for Organic electronically. The transmission of eCHED's is currently in a piloting phase, and needs to be requested by the member states. While the electronic transmission of phytosanitary certificates is in planning, it will not be available as of the 14th of December 2019, as 3rd country partners are not progressing in adopting the TRACES solution. Further, the connection to the IPPC ePhyto Hub is scheduled for the course of 2020. Therefore, paper phytosanitary certificates will still be necessary at the point of inspections.

KEY TAKE AWAYS FOR TRADERS:

- Access to border control informations will be available for all MS BCP's in real-time;
- Operators who have not yet registered to TRACES, need to request access to TRACES-NT as soon as possible. The access request will be verified by the MS authorities;
- TRACES classic will stop operating as of the 14th December 2019. No information will be transferred from the old to the new system. Operators, who currently operate with TRACES classic, need to request access to TRACES-NT as soon as possible. The access request will be verified by the MS authorities;
- Qualified electronic signature is available, but has to be requested by the MS authorities via sante-traces@europa.eu. Traders are called, to raise awareness on the availability of the signature to their national authorities;

- Currently, only Certificates of Organic (COI) can be signed and transmitted electronically. Traders are called on to urge their authorities to request the signature to end laborious procedures around the COI;
- eCHED is operational, but needs to be requested by the MS
- ePhyto are still pending and will only become available in the course of 2020.

E.) COMMON HEALTH ENTRY DOCUMENT „CHED“ - CHED-PP & CHED-D

On 14 December 2019, the „Common Health Entry Document“ (CHED) will become mandatory for entry into the European Union for fruits and vegetables in need for a phytosanitary certificate. CHED has been introduced into TRACES two years ago. In particular France has made the usage of CHED mandatory already and has issued more than 100.000 CHED-PP's (for plants and plant products) in the course of the last two years.

The CHED will have to be created by operators in TRACES as a prior-notification tool and will serve to track the commodities from the origin until the customer. The document will be introduced in the system by the importer (in support of information provided by the exporter). CHED will be accessible via TRACES by several actors (sending NPPO, importer, inspection services concerned), having defined qualified access to the relevant boxes of the document. Operators will have to fill in information on Part I - Description of the consignment. Part II and III will be filled by BCP authorities. For fruit and vegetable trade, two versions of the CHED are applicable:

- CHED-PP will be covering goods entering the Union with regard to Article 47.1 and Article 44 of the OCR (2017/625).
- Second, Fruits and vegetables, which fall under emergency measures of Regulation 2019/1793 (replacing Regulation 669/2009) will need to be accompanied by CHED-D. The legal basis is provided in Article 40(1) of Regulation (2019/1715) which states, that a CHED-D is required for feed and food of non-animal origin subject to their entry into the Union to any of the measures and conditions provided for in point (d), (e) or (f) of Article 47.1 of the OCR Regulation. This means in practice, products which are subject to emergency measures under Regulation 2019/1793 (the new „669/2009“) need to be accompanied by a CHED-D, which replaces the former CED (Common Entry Document).

The scope of application for the CHED-PP leaves a grey area of interpretation due to „formulation mistake“ in the legislation. In principle, all products in need of a phytosanitary certificate will need a CHED-PP entering the EU. The OCR 2017/625 provides for a CHED-PP for products falling under Art. 72 and 74 of the Plant Health Regulation 2016/2031. Article 73, products which will only need a phytosanitary certificate as of the 14th of December 2019 are not covered in the OCR 2017/625, the so called basic-act itself, but they are within the scope of the „IMSOC“ Regulation 2019/1715. As the latter act weighs less than the basic act, this leaves a grey area of application and interpretation. The Commission is currently working on a rectification to clarify this issue & strengthen the obligation for a CHED-PP for products under Article 73 of the PHL.

However, despite this lack of clarity on the scope of application for products which will be in need of a phyto as of the 14th of December 2019 and subject to risk-based controls under Article 73 (2016/2031), it is strongly recommended to create CHED-PP's also for this product category.

To conclude, only those five products excepted from phytosanitary certification will not need a CHED to enter the EU, namely bananas, pineapples, durians, coconuts and dates.

After the creation of CHED-PP/CHED-D within TRACES, the document will be printed and signed. The original CHED will remain at the border control posts and a copy will accompany the consignment to the point of destination. Eventually, the destination must be filled with the designated BCP of entry.

If the consignment needs to be split, after finalisation of the CHED for the entire consignment by the competent authority at the BCP, the operator must request the consignment to be split and submit through the IMSOC, a separate CHED for each part of the split consignment and declare therein the quantity, the means of transport and the place of destination for the relevant part of the split consignment. The competent authority at the BCP must finalise the CHEDs for the individual parts of the split consignment. Electronic transmission is in theory possible through the qualified electronic signature. This transmission option needs to be requested by the MS (see previous section), but should in the long run replace paper transmissions.

Every consignment will need one CHED. The concept of „consignment“ is defined within the OCR 2017/625, Art. 3.37 as „a number of animals or quantity of goods covered by the same official certificate, official attestation or any other document conveyed by the same means of transport and coming from the same territory or third country. This means in practice: All fruits and vegetables originating from one origin and same transport, would fall in one CHED. The various commodities can be listed within the CHED. Nevertheless, each commodity will need its own phytosanitary certificate. The point of destination within the CHED is always the Border Control Post. For onward transportation or consignment splitting, new CHEDs will be needed, which should be an easy process thanks to the „cloning“ function of TRACES, to copy easily all information from the original document and modify it within TRACES NT accordingly. A draft format of the document can already be found in [Annex II of the IMSOC Regulation](#).

The filling of this document should also be facilitated thanks to the „cloning“ option in the system.. This means that, when a new CHED-PP/CHED-D is added in TRACES-NT, this can be done from scratch, or by taking a previous CHED-PP/CHED-D and copying this one as new (allowing to retain all previous data, so only new information has to be changed/added in the template).

KEY TAKE AWAYS FOR TRADERS:

- All products which need a phytosanitary certificate, will also need to be accompanied by a CHED-PP -(despite a loophole in the formulation of the law, it is recommended to create a CHED-PP for all products which require a phytosanitary certificate);
- Bananas, pineapples, durians, dates and coconuts are excepted from this obligation, as these commodities do not need a phytosanitary certificate either
- Products which are covered by an emergency measure defined in Regulation 2019/1793 will need to be accompanied by a CHED-D replacing the former CED - Common Entry Document;
- Part I of the CHED will be filled by the traders, PART II and III by the border control authorities;
- One consignment (same means of transport and same origin) will need one CHED. The commodities can be listed in the document. Each commodity will need its own phytosanitary certificate;

- The document will be filled, printed and signed. The original remains at the BCP and a copy accompanies the consignment to the final destination. Electronic release of CHEDs is currently piloting but not yet available.
- Splitting consignments: After finalisation of the CHED for the entire consignment by the competent authority at the BCP, the operator must request the consignment to be split and submit through the IMSOC, a separate CHED for each part of the split consignment and declare therein the quantity, the means of transport and the place of destination for the relevant part of the split consignment. The competent authority at the BCP must finalise the CHEDs for the individual parts of the split consignment
- TRACES offers a cloning option, so that existing CHEDs only have to be adjusted
- For products on the water on the 14th of December 2019 and only arriving after the regime change, the notification in TRACES classic should still work.
- The option of electronic transmission needs to be requested by the MS. Traders shall alert their authorities accordingly

F.) Training and preparation in the Member States

The European Commission has invested time to inform and train the MS, in order to introduce the policy and operational changes. All MS have been trained on the usage of CHED-PP except Spain, Hungary and the U.K. (the latter however should be expected to be trained next week). All MS have been trained on the usage of CHED-D except Hungary, Malta and the U.K. Many countries have started to make first trials and to get into the usage habit already. MS are ultimately responsible for training, informing and assisting operators for the regime change on 14th of December 2019, as well as for educating about the handling of TRACES NT and CHEDs.

KEY TAKE AWAYS FOR TRADERS:

- Stakeholders are encouraged to contact their authorities to be trained and informed about the introduction of TRACES NT and the usage of CHED;
- Stakeholders shall contact BCPs to receive more information on Transitional Arrangements right before and right after the 14th of December 2019.

G.) Related implemented and delegated acts (published & still to be published acts)

- **Commission Implementing Regulation (EU) 2019/1715** of 30th September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the „IMSOC regulation“)

- **Commission Implementing Regulation (EU) 2019/1793** of 22nd October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from third countries implementing Regulation 2017/625 and (EC) No 178/2002 of the EP and the Council and repealing Commission Regulations (EC) No. 669/2009, (EU) No 884/2014, (EU) 2017/186 and (EU) 2018/1660
- **COMMISSION DELEGATED REGULATION (EU) 2019/1602** of 23 April 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination
- **Commission Delegated Regulation XXX** as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts (to be published in December 2019)
- **Commission Delegated Regulation XXX** supplementing Regulation (EU) 2017/625 of the EP and the Council as regards rules for official controls of consignments of animals and goods in transit, transshipment and onward transportation through the Union and amending Commission Regulations (EC) No. 798/2008, (EC) No 1251/2008, (EC) No. 119/2009, (EU) No. 206/2010, (EU) No 605/2010, (EU), No. 142/211, (EU) No. 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777(EC)
- **COMMISSION IMPLEMENTING REGULATION (EU) .../... of XXX** establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts
- **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

The Freshfel Secretariat remains available to respond to any questions regarding the new system and the transmission of certificates as of 14 December 2019, and will continue reporting updates on the matter via the newsletter or ad hoc alerts, when relevant.
