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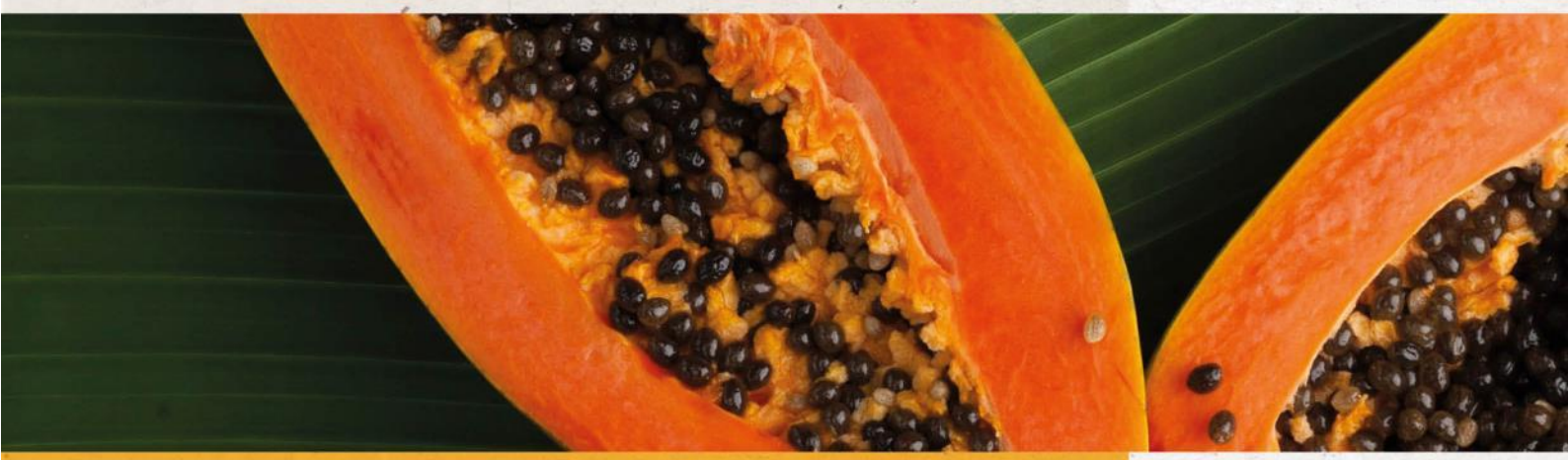
COLEACP GUIDELINES

THE EXPORT OF FRESH GUAVA, PAPAYA, AND ANNONA



NEW PLANT HEALTH RULES FROM THE EUROPEAN UNION

COLEACP

DISCLAIMER:

Note that this document is not a regulatory reference. The elements included within it are not exhaustive or exclusive, and they may or may not be relevant, depending on the situation of each country. The content of each national action plan, and any dossiers submitted to the EU, remain the sole responsibility of the NPPO and industry stakeholders in the countries concerned.

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This publication is an integral part of a COLEACP collection, which is made up of educational and technical tools and materials. All of them are suited to different types of operators and levels of education found in agricultural supply chains, production and sales, and support services.

This collection is available online for COLEACP partners.

FIT FOR MARKET SPS

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PART 1

Background and guidelines on meeting EU requirements covering the regulated pest *Bactrocera spp.* on fresh guava, papaya, and Annona from 11 April 2022

1. BACKGROUND

The European Union is overhauling its plant health (phytosanitary) regulations. On 14th December 2019, the new EU Plant Health Law (Regulation (EU) 2016/2031) came into operation, bringing rigorous new rules to prevent the introduction and spread of harmful pests and diseases in the EU.

Under the new regime, special measures have been introduced for crops that are a known pathway into the EU of serious pests that could damage EU agriculture or the environment. These include new requirements covering the export of fresh guava, papaya, and Annona to prevent the introduction of the Oriental fruit fly *Bactrocera dorsalis* (Hendel) and in addition, in the case of guava, the peach fruit fly *Bactrocera zonata* (Saunders).

The new requirements stipulate certain conditions that exporting countries must meet before exports of these fruits are allowed. Some of these conditions refer to International Standards for Phytosanitary Measures (ISPMs), and exporting countries must be familiar with the relevant ISPMs in order to fully understand and comply with the EU rules.

National action plans and stakeholder engagement

Meeting these new rules requires immediate and concerted action from producers, exporters and the National Plant Protection Organisations. If there are continued interceptions of these fruit fly species in exported produce, the EU is expected to react and impose more stringent measures.

Experience has shown that meeting the new EU rules requires effective dialogue and engagement between public and private sectors. All stakeholders must agree on the actions needed to ensure that the exported produce is free of these fruit fly species. This means identifying and agreeing on actions to be taken by private sector operators at all stages, from production to export. It also means agreeing to the responsibilities of the public sector authorities, in particular the National Plant Protection Organisation (NPPO).

COLEACP recommends the establishment of platforms that bring all major stakeholders around the table to develop and implement a national plant health action plan for the crops concerned. It is essential that all stakeholders agree to and implement the national action plan; if only one exporter sends infested produce to the EU, the repercussions will affect the entire sector. This national action plan must be appropriate to the local context, and usable by the range of different producers and exporter concerned (large and small).

COLEACP Support

This document was prepared by COLEACP for national authorities and the export sector to help orientate the development of a national action plan and dossier to meet the new requirements. It provides a framework to guide the process, and outlines the various elements that can be incorporated into a national approach to manage *Bactrocera spp.*. It identifies the information needed and actions to be taken at all stages, from production to export, by both public and private sectors.

Part 1 of this document gives an overview of the new requirements; the measures

that need to be taken; important details on filling out the phytosanitary certificate; and an explanation of the options for pest-free status. **Part 2** gives guidelines for preparing dossiers for submission to the EU, which will be necessary for some exporting countries. References and links to the relevant ISPMs are provided.

2. REGULATORY CHANGES AFFECTING EXPORTS OF ANNONA, PAPAYA AND GUAVA TO THE EU

In recent years there have been several interceptions in Europe of imported fruits of Annona species (*Annona* L.) and papaya/pawpaw (*Carica papaya* L.) due to the presence of the Oriental fruit fly *Bactrocera dorsalis* (Hendel). There have been similar interceptions of Oriental fruit fly, as well the peach fruit fly *Bactrocera zonata* (Saunders) on guava (*Psidium guajava* L.).

B. dorsalis is a highly invasive species native to Asia and is now found in at least 65 countries including most of sub-Saharan Africa[1]. *B. zonata* is also native to Asia, and found in more than 20 countries in Asia and Africa[2]. The risk of introduction and establishment of both pests in Europe is facilitated by trade, and by changes in climate and land use. Both species can spread rapidly due to their high reproductive potential, rapid dispersal ability, and broad host range. They cause serious economic impact due the loss of export markets as well as costly quarantine restrictions and eradication measures.

EPPO (the European and Mediterranean Plant Protection Organization) recommends member countries to regulate both species as quarantine pests. *B. zonata* is classified on the EPPO A2 List of pests (pests that are locally present in the EPPO region); and *B. dorsalis* on the EPPO A1 List (pests that are absent from the EPPO region)[3].

In December 2019, Regulation (EU) 2019/2072[4] entered into force, containing details on the implementation of the new EU Plant Health Law. ANNEX VII of the regulation stipulates additional requirements for the introduction into the European Union of certain plants and plant products from third countries.

Amendments to these requirements were introduced in December 2021 in Commission Implementing Regulation (EU) 2021/2285[5]. These include special requirements for the import of plants that are likely hosts of *B. dorsalis* and *B. zonata*. This decision was based on evidence that included a pest risk analysis conducted by EPPO, and EU interception data. The products affected include fresh Annona, papaya and guava from listed third countries.

New EU rules for imports of Annona and papaya from 11 April 2022

Annex VII, Point 72.2 of Regulation (EU) 2021/2285 introduces certain requirements concerning imports of Annona and papaya into the EU from (among others) the following countries:

[1] https://www.cabi.org/isc/datasheet/17685

[2] https://www.cabi.org/isc/datasheet/17685#tosummaryOfInvasiveness

[3] https://www.eppo.int/ACTIVITIES/plant_quarantine/A1_list

[4] 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

[5] COMMISSION IMPLEMENTING REGULATION (EU) 2021/2285 of 14 December 2021 amending Implementing Regulation (EU) 2019/2072 as regards the listing of pests, prohibitions and requirements for the introduction into, and movement within, the Union of plants, plant products and other objects, and repealing Decisions 98/109/EC and 2002/757/EC and Implementing Regulations (EU) 2020/885 and (EU) 2020/1292

Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Réunion, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Tanzania, The Democratic Republic of the Congo, Togo, Uganda, Zambia, and Zimbabwe.

According to Annex VII, Point 72.2 of Regulation (EU) 2021/2285, all fruits of *Annona* L. and *Carica papaya* L. exported to the EU must conform with **one** of the following special requirements (options a to d). Note that this is the original text from the regulation (with additions in green from COLEACP):

a. the fruits originate in a **country recognised as being free** from *Bactrocera dorsalis* (Hendel) in accordance with the relevant International Standards for Phytosanitary Measures (ISPM 4; see Chapter 4), provided that this freedom status has been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned,

   or

b. the fruits originate in an **area** established by the national plant protection organisation in the country of origin as being free from *Bactrocera dorsalis* in accordance with the relevant International Standards for Phytosanitary Measures (ISPM 4), which is mentioned on the phytosanitary certificate (under the rubric 'Additional declaration'), provided that this freedom status has been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned,

   or

c. no signs of *Bactrocera dorsalis* have been observed at the **place of production** and in its immediate vicinity since the beginning of the last complete cycle of vegetation, 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 examinations, signs of *Bactrocera dorsalis* (ISPM 10; see Chapter 4), and **information on traceability** is included in the phytosanitary certificate

   or

d. the fruits have been subjected to an **effective systems approach** or an effective post-harvest treatment to ensure freedom from *Bactrocera dorsalis* and the use of a systems approach or details of the treatment method are indicated on the phytosanitary certificate, provided that the systems approach or the post-harvest treatment method have been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned

In practical terms, Option (d) is the most accessible to the majority of the exporting countries listed, especially in supply chains involving smallholders. Details on how to apply this option are given in Part 2 of this document.

Options (a) and (b) require pest-free countries or areas, which are challenging because of the widespread distribution of *B. dorsalis* in sub-Saharan Africa.
Option (c) requires a place of production designated as free from *B. dorsalis*. This could be attempted where pest pressure is low, but resources are needed to ensure areas of low pest prevalence in the locality, and the place of production must be designated as pest-free through a series of inspections by the NPPO, conducted strictly according to procedures specified in ISPM 10. These options are not described in detail in this document, but general information is provided in Chapter 4 "Pest Free status".

New EU rules for imports of guava from 11 April 2022

Annex VII, Point 72.3 of Regulation (EU) 2021/2285 introduces certain requirements concerning imports of fruits of guava (*Psidium guajava* L.) into the EU from (among others) the following countries:

Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Réunion, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Tanzania, The Democratic Republic of the Congo, Togo, Uganda, Zambia, Zimbabwe

According to Annex VII, Point 72.3 of Regulation (EU) 2021/2285, all fruits of *Psidium guajava* L. exported to the EU must conform with one of the following special requirements (Options):

a. the fruits originate in a **country recognised as being free** from *Bactrocera dorsalis* (Hendel) and *Bactrocera zonata* (Saunders) in accordance with the relevant International Standards for Phytosanitary Measures (ISPM 4; see Chapter 4), provided that this freedom status has been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned,

   or

b. the fruits originate in an **area** established by the national plant protection organisation in the country of origin as being free from *Bactrocera dorsalis* and *Bactrocera zonata* in accordance with the relevant International Standards for Phytosanitary Measures (ISPM 4), which is mentioned on the phytosanitary certificate (under the rubric 'Additional Declaration'), provided that this freedom status has been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned,

   or

c. no signs of *Bactrocera dorsalis* or *Bactrocera zonata* have been observed at the place of production and in its immediate vicinity since the beginning of the last complete cycle of vegetation, 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 examinations, signs of *Bactrocera dorsalis* and *Bactrocera zonata* (ISPM 10; see Chapter 4), and information on traceability is included in the phytosanitary certificate

   or

d. the fruits have been subjected to an effective systems approach or an effective post-harvest treatment to ensure freedom from *Bactrocera dorsalis* and *Bactrocera zonata* and the use of a systems approach or details of the treatment method are indicated on the phytosanitary certificate, provided that the systems approach or the post-harvest treatment method have been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned

As in the case of Annona and papaya, in practical terms, Option (d) is the most accessible to the majority of the exporting countries listed, especially in supply chains involving smallholders. Details on how to apply this option are given in Part 2 of this document.

Options (a) and (b) require pest-free countries or areas, which are challenging because of the widespread distribution of *B. dorsalis* and *B. zonata* in sub-Saharan Africa.

Option (c) requires a place of production designated as free from *B. dorsalis* and *B. zonata*. This could be attempted where pest pressure is low, but resources are needed to ensure areas of low pest prevalence in the locality, and the place of production must be designated as pest-free through a series of inspections by the NPPO, conducted strictly according to procedures specified in ISPM 10. These options are not described in detail in this document, but general information is provided in Chapter 4 “Pest Free status”.

Other Quarantine Pests

Under national plant health legislation, a number of plant pests and diseases are classified as quarantine organisms. These are pests that are mainly or entirely absent from a country, but which could have a potentially serious economic, environmental or social impact if they were to be introduced. Most countries have a quarantine list that identifies the most dangerous harmful organisms whose introduction must be prohibited.

The new EU Plant Health Law ((EU) 2016/2031) classifies all plant pests according to the following four categories:

- Union quarantine pests: Not present at all in the EU territory or, if present, just locally and under official control. Strict measures must be taken to prevent their entry or further spread within the EU. Union Quarantine Pests are listed in Directive 2000/29/

EC[6].

- Protected zone quarantine pests: Present in most parts of the Union, but still known to be absent in certain 'protected zones'. These pests are not allowed to enter and spread within these protected zones.
- Regulated non-quarantine pests: Widely present in the EU territory but since they have an important impact should be guaranteed free or almost free from the pest.
- Priority Pests: Those with the most severe impact on the economy, environment and/ or society. The EU Commission released a list of 20 priority pests in October 2019 (Regulation EU 2019/1702).

It is important to note that this document is not exhaustive. There are other quarantine pests affecting these crops, whose introduction into the EU is prohibited or controlled. **It is essential to monitor and avoid the presence of <u>all</u> harmful organisms in export crops.**

In particular, Point (5) of Regulation (EU) 2021/2285 highlights the importance of Tephritidae (fruit flies) in general. Some individual species and genera are already named as Union quarantine pests (including *B. dorsalis* and *B. zonata*). However, due to the lack of methods to identify many fruit flies at species level, notably at larval stages, the EU has taken a pragmatic approach. Several entire genera are listed as Union quarantine pests, which allows protective measures to be taken against them while the diagnostic methods are being addressed. **This means, in effect, that all fruit flies are subject to the very strict measures outlined in this document.**

[6] Directive 2000/29/EC lists EU quarantine pests in annexes I and II (Part A, Section I and II). Commission Implementing Directive (EU) 2017/1279, Commission Implementing Directive (EU) 2019/523 and Commission Implementing Regulation (EU) 2019/2072 have amended and updated Directive 2000/29/EC

3. COMPLETING THE PHYTOSANITARY CERTIFICATE

All plants and plant products imported into the EU from non-EU countries are subject to compulsory plant health checks. These include:

- a review of the phytosanitary certificate and associated documents to ensure that the consignment meets EU requirements;
- an identity check to make sure that the consignment corresponds with the certificate;
- an inspection of the produce to ensure that it is free from harmful organisms.

According to Regulation (EU) 2019/2072, Annona, papaya and guava exported fresh to the EU must be accompanied by a phytosanitary certificate and there are strict requirements on how this should be filled.

It is critically important to complete the certificate correctly as there is a low tolerance of mistakes by European importing countries. Consignments entering Europe can be rejected and destroyed if the phytosanitary certificate is filled incorrectly.

According to ISPM 12, if the space provided in the phytosanitary certificate is not sufficient to insert all the necessary information (e.g. in the additional declaration), it is permitted to add an attachment. If you do so, it is very important to adhere to the following:

- Each page of any attachment must bear the number of the phytosanitary certificate and be dated, signed and stamped in the same manner as required for the phytosanitary certificate itself.
- You must state in the relevant section of the phytosanitary certificate if there is an attachment.
- If an attachment has more than one page, the pages must be numbered, and the number of pages indicated on the phytosanitary certificate.

Exporting under Option (c): pest free production site

If exporting countries are using Option (c) to export these fruits, it is essential to include the following words in the phytosanitary certificate:

- In the Additional Declaration write:
  - For Annona and papaya: "The consignment complies with Option (c) of Annex VII, Point 72.2 of Regulation (EU) 2021/2285: no signs of *Bactrocera dorsalis* (Hendel) have been observed at the place of production and in its immediate vicinity since the beginning of the last complete cycle of vegetation, 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 examinations, signs of *Bactrocera dorsalis* (Hendel),".

- For Guava: "The consignment complies with Option (c) of Annex VII, Point 72.3 of Regulation (EU) 2021/2285: no signs of *Bactrocera dorsalis* (Hendel) and *Bactrocera zonata* (Saunders) have been observed at the place of production and in its immediate vicinity since the beginning of the last complete cycle of vegetation, 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 examinations, signs of *Bactrocera dorsalis* (Hendel) and *Bactrocera zonata* (Saunders)

- Information on traceability must be provided: In the phytosanitary certificate, alongside the description of the product, you must write the unique identification number or name of the approved production site from which the produce was sourced.

Exporting Option (d): Systems Approach

If exporting countries are using Option (d), a dossier must submitted in advance to the European Commission (See Part 2 of this document). Once this submission has been accepted by the Commission, exports can take place, but it is essential to include the following words in the phytosanitary certificate:

- in the Treatment Box/section write: "Systems approach".
- in the Additional Declaration write:
  - For Annona and papaya: "The consignment complies with Option (d) of Annex VII, Point 72.2 of Regulation (EU) 2021/2285 and a systems approach for *Bactrocera dorsalis* (Hendel) has been applied. Measures applied have been communicated to the EU on the (insert date)".
  - For guava: "The consignment complies with Option (d) of Annex VII, Point 72.3 of Regulation (EU) 2021/2285 and a systems approach for *Bactrocera dorsalis* (Hendel) and *Bactrocera zonata* (Saunders) has been applied. Measures applied have been communicated to the EU on the (insert date)".

4. PEST FREE STATUS

International standards for phytosanitary measures (ISPMs) describe what needs to be done in order for an area, country, place of production or production site to be officially recognised as pest free. In each case the process must be led by the officially designated NPPO in each country, and it must follow closely the methodology outlined.

Establishing pest free area (PFA) status requires data to be collected so that the presence or absence of the pest can be verified. Establishing pest free status needs to follow strictly the guidelines described in the relevant ISPM, and requires the NPPO (and their designated agents) to have the necessary training, resources and capabilities in data collection and pest risk analysis.

The following documents and guides from IPPC/FAO provide further information:

- ISPM 30 on "Establishment of Areas of Low Pest Prevalence for Fruit Flies (Tephritidae)";
- ISPM 4 on "Requirements for establishing pest free areas" in general, and ISPM 26 on "Establishment of pest free areas for fruit flies (Tephritidae)";
- ISPM 10 on the "Establishment of pest free places of production and pest free production sites";
- Guide for Establishing and Maintaining Pest Free Areas on requirements for pest free areas, pest free places of production, pest free production sites and areas of low pest prevalence;
- ISPM 6 (Guidelines for surveillance) and ISPM 2 (Framework for pest risk analysis) provide further details on general surveillance and specific survey requirements;
- ISPM 35 gives guidance on a "Systems approach for pest risk management of fruit flies (Tephritidae)".

Pest free areas and countries

Pest free area or country status is difficult to obtain in the case of fruit fly as these pests are highly mobile and widely dispersed. This option would only be worth pursuing in areas that are geographically distinct or isolated from the main areas of pest distribution. Establishing and maintaining an area of low pest prevalence may be a possibility (where the capacity and resources are available nationally) and can be part of the systems approach.

Pest or disease free area:	An area in which a specific pest or disease does not occur. This can be an entire country; an un-infested part of a country in which a limited area is infested; or an un-infested part of a country within a generally infested area.

An area of low pest or disease prevalence: An area, whether all of a country, part of a country, or all or parts of several countries (as identified by the competent authorities) in which a specific pest or disease occurs at low levels and is subject to effective surveillance, control or eradication measures.

There are three main stages to establish and maintain a PFA:

- systems to establish freedom;
- phytosanitary measures to maintain freedom;
- checks to verify freedom has been maintained.
- The work needed in each case varies according to factors such as the biology of the pest, the characteristics of the PFA, and the level of phytosanitary security required.
- The work involved in establishing and maintaining pest free area/country status is detailed and time consuming and involves:
- data collection (pest surveys for delimiting, detection, monitoring);
- regulatory controls (protective measures against the introduction into the country; including listing as a quarantine pest);
- audits (reviews and evaluation);
- documentation (reports, work plans).

Pest free place of production and production site

Pest free place of production: Place of production in which a pest is absent (demonstrated by scientific evidence) and generally maintained officially pest free for a defined period.

A place of production is "any premises or collection of fields operated as a single production or farming unit".

Pest free production site: Place of production in which a pest is absent (demonstrated by scientific evidence) and generally maintained officially pest free for a defined period.

A production site is "a defined part of a place of production, that is managed as a separate unit for phytosanitary purposes".

A place of production can only be designated as pest free by the NPPO.

The NPPO and producers/exporters are required to conduct surveillance and inspections according to the international guidelines. The guides from IPPC/FAO (see links above) provide further information.

PART 2

Guideline for preparing a dossier for submission to the EU on management of:

- *Bactrocera dorsalis* in Annona and papaya
- *B. dorsalis* and *B. zonata* in guava

How to use a systems approach according to Option (d) of Annex VII, Points 72.2 and 72.3 of Regulation (EU) 2021/2285

BACKGROUND TO THE DOSSIER

Part 2 of this document addresses the development of a dossier to meet Option (d) of Annex VII, Points 72.2 (for **Annona and papaya**) and 72.3 (for **guava**) of Regulation (EU) 2021/2285. If a country listed under these points in the regulations opts to export these fruits under Option (d), then they are required to ensure that:

d. " the fruits have been subjected to an **effective systems approach or an effective post-harvest treatment** to ensure freedom from *Bactrocera dorsalis* (and *B. zonata* in the case of guava) and the use of a systems approach or details of the treatment method are indicated on the phytosanitary certificate, provided that the systems approach or the post-harvest treatment method have been communicated in advance in writing to the Commission by the national plant protection organisation of the third country concerned"

To comply with Option (d), the NPPO must submit a dossier to the European Commission (EC). This must describe in detail the systems approach or post-harvest treatment that will be applied to all exports to ensure that they are free from *Bactrocera* spp. After 11th April 2022, no exports of these fruits will be permitted from the listed countries unless and until a dossier has been received. After 11th April, the systems approach or post-harvest treatment described in the dossier must be applied by everyone involved in exports of these fruits to the EU.

Note: It is recommended that the NPPO submit one dossier covering Annona and/or papaya for the management of *B. dorsalis,* and a separate dossier for the management of *B. dorsalis* and *B. zonata* in guava. If an NPPO is considering combining into a single dossier, they should first check with the EC.

There are very limited options for post-harvest control of *Bactrocera* spp. on these fruits that can guarantee they are pest free, while maintaining quality and shelf-life. In recognition of this, the new EU Directive allows for the use of a systems approach. This means developing an action plan that combines several different pest management measures that, used together, will significantly reduce pest risk (see ISPM 14[5]). These measures may include surveillance, cultural practices, crop treatment, post-harvest disinfestation, inspection.

In their dossier, the exporting country must provide sufficient information to the EU to enable the evaluation and approval of the proposed systems approach to managing *Bactrocera* spp.. Once the dossier is submitted, its receipt by the EC can be checked using the following link: Déclarations on pest status from non-EU countries; (PDF files attached to each country show the status of their pest dossiers and declarations).

Introduction to this Guide

This document was prepared by COLEACP as a guide for national authorities and export sectors to help orientate the development of a dossier in the context of Regulation (EU) 2021/2285. It provides a framework to guide the process and outlines the various elements that can be incorporated into a systems approach to manage *Bactrocera spp.*. It identifies the information to be provided, and actions to be taken, at all stages from production to export, by both public and private sectors.

Note that the elements included here are not exhaustive. The dossier could include all or a selection of these measures, as well as any others that may be available and appropriate locally.

1 Article 13(1)(ii) of Implementing Directive 2019/523

2 ISPM 14: "The use of integrated measures in a systems approach for pest risk management". http://www.fao.org/3/a-y4221e.pdf

This guide covers the following sections that should be included in the dossier:

- general information on the national Annona, papaya or guava sectors;
- phytosanitary measures taken before, during and after harvest to reduce and control *Bactrocera* spp;
- phytosanitary inspection and certification system;
- quality management system put in place by the NPPO to ensure that the dossier is effectively implemented and monitored.

According to ISPM 14, the characteristics of a systems approach are as follows:

A systems approach requires two or more measures that are independent of each other, and may include any number of measures. An advantage of the systems approach is the ability to address (local) variability and uncertainty by modifying the number and strength of measures (needed) to meet phytosanitary import requirements.

Measures used in a systems approach may be applied pre- and/or post-harvest wherever national plant protection organizations (NPPOs) have the ability to oversee and ensure compliance with phytosanitary procedures.

A systems approach may include measures applied in the place of production, during the post-harvest period, at the packing house, or during shipment and distribution of the commodity.

Risk management measures designed to prevent contamination or re-infestation are generally included (e.g. maintaining the integrity of lots, pest-proof packaging, screening of packing areas, etc.).

Procedures such as pest surveillance, trapping and sampling can also be components of a systems approach.

Measures that do not kill pests or reduce their prevalence but reduce their potential for entry or establishment (safeguards) can be included in a systems approach. Examples include designated harvest or shipping periods, restrictions on the maturity, colour, hardness, or other condition of the commodity, the use of resistant hosts, and limited distribution or restricted use at the destination.

ISPM 35 provides specific guidance for the development, implementation and verification of a systems approach for the management of Tephritidae.

Effective engagement between stakeholders

Experience has shown that engagement between public and private sector stakeholders is essential during development of the dossier to ensure that it is adapted to the local context, and to secure the buy-in of all involved. After a dossier has been submitted to the European Commission, it must be rigorously followed by all stakeholders that are involved in exports to the EU. It is very important therefore that the dossier is appropriate for the context, and is usable by the range of different producers and exporters concerned (large and small).

Useful tool to help implement a systems approach

The Decision Support for Systems Approach (DSSA) tool has been developed to allow users in importing or exporting countries to identify, potential options for pest risk management that could help with the formulation of pest risk management plans. The DSSA supports evaluation and development of a Systems Approach to pest risk management, as defined in ISPM 14.

SECTION 1. EXECUTIVE SUMMARY OF THE DOSSIER

It is recommended that the dossier should begin with a general statement. This will help the European Authorities to understand the approach taken. This statement may be along the following lines:

A systems approach has been developed to guide producers so that they can integrate a combination of measures that together help to manage the risk of Bactrocera spp. and ensure that fruit of Annona, papaya or guava exported to the European Union are free from this regulated pest.

Risk management of *Bactrocera spp.* is maintained throughout the supply chain from production, harvesting, handling, packaging, phytosanitary inspections, certification and transportation through to export. This is achieved through the application of a series of measures and interventions in a systems approach that includes the following components (please list whichever are relevant for the national dossier):

- registration of plantations and packhouses;
- risk profiling of operators;
- *Bactrocera spp.* surveillance in production areas using traps, scouting and record keeping to monitor infestation levels;
- application of cultural control and strict crop hygiene at all production sites;
- implementation of pre-harvest control measures, guided by surveillance data;
- post-harvest inspections for pest infestation, on delivery at the packhouse;
- establishment of biosecurity measures to minimise introduction of the pest into packaging and handling areas;
- packhouse grading of fruit for export;
- effective functioning of the national administrative and regulatory framework;
- phytosanitary inspections by the NPPO during production, harvesting, and at port and/or airport of exit;
- issuance of phytosanitary certificates for pest free consignments;
- application of an internal audit system by the NPPO to ensure the effective implementation of the plant health inspection and certification system.

SECTION 2. GENERAL OVERVIEW OF THE NATIONAL EXPORT SECTOR ANNONA, PAPAYA AND/OR GUAVA

According to ISPM 14, the following information is important for the evaluation of pest risk:

- the crop, place of production, expected volume and frequency of shipments;
- production, harvesting, packaging/handling and transportation;
- the crop/pest dynamics;
- plant health risk management measures that will be included in the systems approach, and relevant data on their efficacy;
- relevant references.

Background information on the export sector may include the following information:

- Crop details. Varieties grown for export:
- scientific name;
- common name;
- characteristics of each variety;
- sensitivity or resistance to *Bactrocera spp.*

Production zones

- describe and map the main production zones for export;
- describe the production seasons (timeframe), by zone;
- describe the climate in each production zone, assessed according to risk of *Bactrocera spp.* infestation.

Production and export statistics for the last 2 to 3 years, specifying if possible:

- destination country;
- method of shipment (sea, air, land).

Presence and distribution of *Bactrocera spp.* in the country:

- species present, prevalence, period of infestation;
- other host plants in production areas for these export crops.

SECTION 3. INTEGRATED PRE-HARVEST AND POST-HARVEST MEASURES FOR THE PREVENTION AND CONTROL OF *BACTROCERA SPP.*

According to ISPM 14, the following pre- and post-harvest measures may be integrated into a systems approach:

- surveillance and monitoring (traps);
- treatment, including the use of plant protection products;
- post-harvest disinfestation;
- inspection;
- others.

An effective systems approach will reduce the risk of any fruit that is exported to the EU being infested with *Bactrocera spp.*.

Reference to **ISPM 35** is recommended as it provides specific guidance a systems approach for the management of Tephritidae.

The measures described below are general recommended good practices for production of these fruit crops. During development of the dossier, stakeholders should agree and select which of these measures are appropriate locally, and describe how they will be adapted and applied by all those involved in exports.

1. Measures at plantation level to monitor and control *Bactrocera spp.*

Pre-harvest, growers producing Annona/papaya/guava for export to the EU should:

i. Apply cultural control of *Bactrocera spp.*. Good plantation management and crop hygiene are critical. For example, all fruits and fruit waste should be collected and buried, or otherwise disposed of; they should never be left to rot in the open field.

ii. Conduct surveillance and monitoring. Traps should be used by individual companies, as well as national surveillance programmes, to monitor the presence of *Bactrocera spp.*.

- The national authorities should be able to specify the type of trap and

attractant to use under local conditions (according to availability and effectiveness), as well as the frequency of collection.

- The authorities should agree with industry the thresholds of intervention. For example, what number of trapped flies of *Bactrocera spp.* will trigger a decision to spray, or to stop harvesting for export.
- FAO/IAEA give guidelines on the most widely used trapping systems, including traps and attractants, trapping applications, as well as procedures for assessment of trap layouts and trap densities based on pest risk, data recording and analysis.

iii. Control *Bactrocera spp.* using plant protection products. The national authorities should be able to provide guidance on which products to use, and how to use them (including application method, dose rate, pre-harvest interval). These must be in accordance with the registration status in the country of origin, and the maximum residue level (MRL) of the active ingredient in the EU.

iv. Be trained. Growers and workers should be trained (and updated) in good practice on the identification, prevention, surveillance, and control of *Bactrocera spp.*.

During harvest, growers producing Annona/papaya/guava for export to the EU should:

i. monitor closely the maturity/ripeness of the fruit as this is closely linked to the risk of Bactrocera spp. infestation and attack;

ii. use strict crop hygiene measures at the harvest site, with collection and disposal of all fruit waste;

iii. during harvest, ensure that procedures are in place for sorting, isolating and disposing of all damaged fruit and safeguarding activities to prevent infestation at harvest;

iv. ensure that handling and transport conditions are managed carefully to reduce the risk of *Bactrocera spp.* gaining access to harvested fruit;

v. operate a traceability system that allows for the identification of plantations, and strict separation of harvest lots;

vi. ensure that all people involved in harvesting are trained so that they are aware of and apply good practices to reduce the risk of Bactrocera spp. damage; this includes good practice for prevention, control, crop hygiene, and traceability.

2. Measures at the packhouse level to prevent the introduction, infestation and spread of Bactrocera spp.

On receiving the fruit, packhouse managers must:

i. have procedures in place to record the condition and phytosanitary status (pest presence) of the fruit when it arrives at the packhouse;
ii. have a system in place to record all Bactrocera spp. control treatments applied pre- and post- harvest to each lot;
iii. have a traceability system in place to ensure that each lot is identified and maintained separately through all post-harvest operations.

Measures post-harvest to monitor and control Bactrocera spp.

i. ensure that all operators involved in harvest and post-harvest activities can recognise damage by this pest, and know what to do when they find it;
ii. have procedures in place in the field and packhouse to inspect for presence and damage of *Bactrocera spp.* at all fruit handling, packing and storage sites;
iii. put intervention and isolation procedures in place when damage from Bactrocera spp. is identified;
iv. have systems for washing, drying, and waxing harvested fruit;
v. ensure practices and facilities are in place for the management of all fruit waste, including fruit damaged by *Bactrocera spp.;*
vi. use refrigerated storage facilities where possible;
vii. apply post-harvest treatments when necessary using plant protection products;
viii. as in the case of field applications, the national authorities should be able to provide guidance on which products to use, and how to use them (application method, dose rate);
ix. these must be in accordance with the registration status in the country of origin, and the maximum residue level (MRL) of the active ingredient in the EU;
x. ensure that harvested fruit is never exposed to *Bactrocera spp.* attack during packing, storage (including temporary storage), or transport (road, port or airport). This includes physical screening of transported consignments and packing areas to prevent pest entry. Use of pest-proof packaging is also an option;
xi. train all people involved in post-harvest handling so they are aware of and apply good practice at all times to reduce the risk of damage from *Bactrocera spp.*.

SECTION 4. INSPECTION AND CERTIFICATION SYSTEM

According to ISPM 14, the exporting country authorities are responsible for:

- monitoring, auditing and reporting on the effectiveness of the system;
- taking appropriate corrective measures;
- keeping the relevant documentation up to date;
- use of phytosanitary certificates in accordance with requirements.

The measures included in a Systems Approach should be implemented in accordance with the approved procedures and should be monitored by the NPPO of the exporting country to ensure the system achieves its objectives.

The measures described below are general recommendations outlining the administrative and regulatory framework that needs to be in place, with an emphasis on the official control system and its enforcement by the competent authorities. The NPPO and associated stakeholders must select which of these measures will be included in the dossier, and describe how they will be adapted/applied in the context of the national export sectors of the fruits in question.

Administrative and regulatory framework governing export of Annona/papaya/guava to the EU

i. there should be a system in place to register and identify all individual operators in the production and export chain (e.g. with a unique number);
ii. there should be a system for the identification and traceability of all orchards/ plantations producing these products for export;
iii. authorities should conduct risk categorization of exporters (high, medium and low risk);
iv. authorities should conduct risk categorisation of exports (late season, airfreight,...);
v. the opening and closing dates of the export season should be stipulated by

competent authorities (with provision under national pant health regulations for this to be legally enforced) according to the risk of *Bactrocera spp.* presence. This should be guided by national *Bactrocera spp.* surveillance data and monitoring of the production cycle (fruit maturation).

National surveillance system for monitoring *Bactrocera spp.* populations

This includes:

i. **Surveillance**. Monitoring of *Bactrocera spp.* populations (using traps) in and near areas where the fruit in question is produced for export. This needs to be accompanied by a system to compile and analyse the data.
ii. **Risk mitigation measures.** According to the results of the monitoring, measures may need to be taken to reduce the risk of infested fruit entering the export supply chain.
iii. **Alert system**. An alert system needs to be in place to inform stakeholders of any increased risk of *Bactrocera spp.* infestation, and any mitigation measures they must take.

The document "Trapping guidelines for area-wide fruit fly programmes" from FAO/IAEA is a valuable resource. Fruit fly surveillance using traps is a highly specialized and this guideline provides detailed information for trapping under different pest situations for different fruit fly species (Tephritidae) of economic importance.

Control and certification system

The NPPO will be active at all stages of the export value chain. This includes providing advice and training, as well as monitoring and the implementation of plant health measures (that may include specific controls and certification). In brief:

i. at the production level, the NPPO must provide advice and training, and ensure the application of good practice by private sector operators;
ii. at the packhouse level, the NPPO may control infrastructure and packing conditions. Training of private sector operators will be provided in identification of *Bactrocera spp.* damage, crop waste management, among others;
iii. at the point of export (ports, airports, road borders), procedures must be in place, and implemented effectively, for the inspection of produce, issuing of plant health certificates, and preparation of all necessary documentation.

Action to be taken by the NPPO at producer level in Annona/papaya/guava for export to the EU

i. Confirming exporter registration.

ii. Checking traceability of all plantations that supply fruit for export.
iii. Assessing and documenting the application of good practice by producers covering:
    - cropping practices;
    - crop hygiene and crop waste management;
    - *Bactrocera spp.* monitoring system using approved traps;
    - implementation of control methods;
    - others.
iv. System to verify the training of operators in good practices for the prevention and control of Bactrocera spp..

Action to be taken by the NPPO at all packhouses supplying Annona/papaya/guava for export to the EU

The NPPO will conduct an assessment of:

i. premises and equipment, to ensure the prevention of *Bactrocera spp.* entry and spread;
ii. the implementation of good hygiene practices, and measures to prevent the risk of *Bactrocera spp.* infestation;
iii. the implementation of inspection/monitoring by packhouse personnel at all handling and storage sites to check for the presence of *Bactrocera spp.;*
iv. the effectiveness of sorting and isolation systems, and the suitability of infrastructure, to deal with fruit that shows the presence of and/or damage from *Bactrocera spp.;*
v. the facilities and procedures for disposal of damaged fruit and fruit waste;
vi. the effectiveness and implementation of the traceability system;
vii. the effectiveness of the system in place for the isolation of lots;
viii. the frequency and effectiveness of staff training.

The issuing of phytosanitary certificates

The NPPO must operate a system of controls and certification according to the method of shipment (road, air, sea). This must address:

i. the implementation of document checks;
ii. physical inspection;
iii. identity checks;
iv. sampling method, according to ISPM 31 requirements;

v. the NPPO must have in place a system for tracking and archiving inspection data;

vi. the NPPO must have a system for the tracking and archiving of phytosanitary certificates.

Important Note: See Part I, Chapter 3 for instructions on the correct completion of the phytosanitary certificate according to the regulatory changes.

SECTION 5. NPPO QUALITY MANAGEMENT SYSTEM

The measures described below are general recommendations outlining the NPPO quality management system that needs to be in place. The NPPO and associated stakeholders must select which of these measures will be included in the dossier, and describe how they will be adapted/applied in the context of the national Annona/papaya/guava export sector.

Internal audit

This should describe the monitoring and internal audit system in place to ensure the effective implementation of the plant health inspection and certification system including:

- training of NPPO managers and technical personnel (inspectors, enforcement officers);
- designing and implementing effective procedures for the inspection of plantations and packhouses.

Management of interceptions/notifications

This should describe the system in place for tracking notifications and communicating with stakeholders including:

- statistics on *Bactrocera spp.* notifications;
- information on processing, tracking and communicating official notifications.

SECTION 6. GENERAL RECOMMENDATIONS ON PREPARATION AND SUBMISSION OF THE DOSSIER

According to Regulation (EU) 2021/2285, each country exporting Annona, papaya and guava to the EU must select the option/s they will use to ensure that the fruit is free from *Bactrocera spp.* These options are listed in Annex VII of the regulation, and they specify the strict conditions that apply in order that the fruit can be exported to the EU.

Countries that chose to export under Option (d) of Annex VII (Points 72.2 for Annona and papaya; 72.3 for guava) must submit a dossier to the European Commission. This dossier must describe in detail the system or post-harvest treatment that will be applied to ensure that all fruit exported to the EU is free from *Bactrocera spp.*.

After 11th April 2022, no exports will be permitted from a country unless and until a dossier has been received. The system described in the dossier must then be followed by all stakeholders involved, including growers, private operators, and the NPPO. The dossier in effect becomes a national *Bactrocera spp.* action plan.

The NPPO of the exporting country has the responsibility for submitting the dossier to the European Commission. However, it is essential that the NPPO works hand-in-hand with the private sector to develop the content of the dossier, and subsequently to ensure that it is implemented effectively.

If private sector operators are not involved in developing the dossier, and the NPPO does not secure their buy-in (agreement), it is less likely that they will understand its importance and implement it effectively.

Feedback from the private sector is essential to ensure that the dossier is adapted to local conditions, and is appropriate and usable by the range of different producers and exporter concerned (large and small).

The following steps are recommended for the preparation and submission of the dossier.

Step 1: Setting up a Technical Working Group (TWG)

The TWG will bring stakeholders together (private and public sector) to consider and agree the elements that should be included in the national dossier/action plan.

The Group will be convened by the NPPO. The composition of the group may vary according to the local Annona/papaya/guava industry and public authorities. As a general rule, a small group will be more effective than a large one but, as a minimum, it is important for the group to ensure that the membership:

- contains representatives of the NPPO with sound knowledge and experience

in the relevant phytosanitary official controls and enforcement;

- is acceptable to organisations representing the private sector;
- is representative of the export sector, representing both large and small- scale operators, and including members who have a sound knowledge of Annona/papaya/guava production and export;
- contains members with a strong scientific and technical expertise. This is essential to document in a clear and precise manner the phytosanitary measures that will be included in the dossier.

Step 2: Preparing the first draft of the dossier

The first draft of the dossier will be prepared by the NPPO with the support and agreement of the TWG. This COLEACP guide can be used as a framework for the dossier, which is adapted and customised according to the local circumstances

Step 3: Validating the dossier with stakeholders

Consultation with the key public and private stakeholders is essential to ensure that the dossier is fit-for-purpose, locally appropriate, and accepted by all the major stakeholders that will be involved in implementing it.

This consultation will give the wider industry a chance to obtain clarification, and to recommend changes. The aim is to use feedback from the consultation to develop a final version of the dossier that is approved and recognised by all.

If resources are available, consultation is best achieved through the organisation of a national workshop where the dossier can be presented and discussed to a large group. If this is not possible, the draft may be presented to smaller meetings/groups, or circulated via industry associations or other representative bodies.

Step 4: Submitting the Dossier to the European Commission

The dossier must be submitted to the EC by the National Plant Protection Organization; only an NPPO is authorized to submit the official documentation to their counterparts in the European Union.

The dossier should be forwarded by the designated Contact Point at the NPPO to the following e-mail address: SANTE-G1-PLANT-HEALTH@ec.europa.eu

Preparing and implementing a national systems approach for the management of *Bactrocera spp.* according to ISPM 14 is a significant challenge. The private sector and the NPPO may therefore identify the need for technical assistance.

Where this is the case, it is important to identify and secure the support needed as soon as possible in order to ensure that all necessary action has been taken before the start of the next export season.

Requests for technical support can be made to COLEACP.

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