Q & A from the Webinar "How to prepare dossiers to support demands for import of high-risk plants and plant products"

Abbreviations:

CRA = Commodity Risk Assessment

EPPO = European and Mediterranean Plant Protection Organization

EC = European Commission

EU = European Union

NPPO = National Plant Protection Organization

PRA = Pest Risk Assessment

TR = Technical Report

1. **Question: Where can the list of high risk plant be found?**

Answer: The list of high risk plants was published in the Official Journal of the European Union in December 2018 in Commission Implementing Regulation (EU) 2018/2019 and it is also available in the EC website in the Plant Health and Biosecurity section. For others plants and plant products the current import requirements detailed in Council Directive 2000/20/EC will continue applying.

2. **Question: A big challenge for applicant countries is to be able to prepare dossier of high risk plants or plant products at an earlier stage. Do we need guidelines to identify plants or plant products that could be on your high risk list?**

Answer: The list of high risk plants, plant products and other objects was published in the Official Journal of the European Union in December 2018 (Commission Implementing Regulation (EU) 2018/2019).

3. **Question: After the applicant country submits the dossier, how long it will take for the EC/EFSA to provide feedback or decision?**

Answer: We cannot provide specific time-scales. The checking of the completeness of the dossiers and the CRA will be carried out in a reasonable period of time. The submission of complete dossiers, containing all the requested information, is very important to avoid unnecessary delays. In case of missing information, delays will occur since they will be requested to the country of origin.

After receiving the risk assessment from EFSA, the Commission will proceed in due time.

4. **Question: If a technical dossier is submitted, and EFSA requires extra information, is the file accepted under conditions, or do we need to send it in again?**

Answer: When the European Commission forwards the application and the scientific dossier to EFSA, EFSA registers the application in the Register of Questions platform under the status of "Under consideration". This status is shown during the completeness and suitability check (CC/SC) phase of the application. If in this phase EFSA identifies that there is information missing in the dossier, EFSA will issue a letter of missing information to the applicant specifying the information needed to declare the dossier valid. The applicant should integrate the missing information requested in the dossier and submit a consolidated version of the entire dossier to EFSA via CD-ROM/USB key. This consolidated version of the dossier will be used as reference for the risk assessment. Once the application is considered valid it is moved to the risk assessment phase.

5. **Question: Which are the steps the dossiers will follow after submission?**

Answer: As explained in Commission Implementing Regulation (EU) 2018/2018, the dossier shall be submitted to the EC, who carries out a first completeness check. The file is then transferred to EFSA that will carry out the risk assessment.

The outcome of the risk assessment will be published in the EFSA Journal (available online) and after this publication, the EC will proceed with the modification of the list of high risk plants, establishing a permanent prohibition if the risk is too high, or establishing specific import requirements. This modification will be done per country and commodity.

6. **Question: With the number of dossiers expected to be received by EFSA, how will you prioritize? Are there any criteria?**

Answer: The risk assessment will be done following the order of submission of the dossiers, once their completeness has been verified.

7. **Question: How can we follow the different stages dossiers will follow during CRA?**

Answer: This information will not be available, but the Minutes of the meeting of the working group in charge of the commodity risk assessment will be publicly available on the EFSA website. The applicant country will receive an acknowledgement of receipt from the EC after submitting the demand of import accompanied by the technical dossier. If the information provided is sufficient, the EC will transmit the dossier to EFSA to carry out the risk assessment. In case there is information missing, the EC or EFSA will contact the applicant to request the missing information. Once the risk assessment by EFSA is finalised, it will be published in the EFSA website and the EC will proceed with the modification of the list of high risk plants by publishing an implementing regulation. You can find in Commission Implementing Regulation (EU) 2018/2018 all the details about the procedure to submit the demand of import accompanied by a technical dossier of plants listed as high risk plants.

8. **Question: If the dossier provided passes the assessment, does the EU allow imports by issuing an import license?**

Answer: After the risk assessment is completed, the EC will proceed to the modification of the list of high risk plants and the establishment of specific import requirements or a permanent prohibition, depending on the conclusions of the risk assessment. All the procedures are detailed in Commission Implementing Regulation (EU) 2018/2018.

9. **Question: If a particular pest has already undergone PRA by EFSA or EPPO, should the country of origin still provide all the information listed in section 4.4 of the TR?**

Answer: Yes, the country of origin still need to provide all the information required in section 4.4 of the TR. This will speed up the review process. You can use the Pest Risk Assessment by EFSA and EPPO as a source. The most recently available information on the pests needs to be provided.
In case an already existing PRA is not present for that particular pest you do not need to develop a new PRA at this stage.

10. **Question: Does the list include products which applicant countries are already exporting in the EU with phytosanitary certificate like citrus, tomatoes, etc.? And are *in vitro* plants excluded?**

Answer: All plants listed in the list of high risk plants, plant products and other objects (Commission Implementing Regulation (EU) 2018/2019) will require that a risk assessment is carried out before they can be introduced into the EU from 14 December 2019. This list does not contain citrus, tomatoes or *in vitro* plants. For these fruits and for *in vitro* plants, the current import requirement will continue applying as today.

11. **Question: Do you have specific measures for tubers that are intended to be for consumption?**

Answer: *Ullucus tuberosus* is listed as a high risk plant and after 14 December 2019 its introduction into the EU will not be permitted until a risk assessment will be completed.

12. **Question: What would happen to the export of a product if the dossier will not be submitted by the end of 2019? Will these dossiers be evaluated in parallel with the ongoing exportations or the current exports be cut to the end of the process? Also, if the country of origin submits the dossiers in time but EFSA has not yet finished the CRA, can the planned export continue?**

Answer: Dossiers can be prepared and submitted as soon as all the necessary information is compiled. Once the new Regulation (Regulation (EU) 2016/2031) will entry into force, on 14 December 2019, the plants listed as high risk plants will be provisionally prohibited pending a complete risk assessment. However, until the date above the planned export can be realized.

If a country exporting a plant listed as high risk plant has not submitted the demand of import accompanied by the technical dossier (or if the information has been submitted but the risk assessment has not yet been completed), the export of that plant from that specific country will not be permitted until the country sends a demand for import accompanied by a technical dossier, the risk assessment is concluded and the list of high risk plants accordingly modified in the form of a Commission Implementing Regulation voted by Member States.

13. **Questions:**

a. **What do you mean by "certified" nursery. Is it a registered nursery in a country or is it a nursery that produce only certified plants for planting, or something else?**

Answer: A certified nursery is a nursery under supervision of the NPPO following an agreed protocol of plant material certification. All the exporting nurseries should be listed and it should be specified if any of them is certified.

b. If the reproductive material is imported from the EU but grafting and growing of seedlings is done outside of the EU, will this be accepted as a "certified" seedling and nursery? Should a list of all certified nurseries be listed?

Answer: All the exporting nurseries should be listed and it should be specified if any of them is certified.

c. Could you explain the term regarding point 3.8 of the TR?

Answer: This point requires the description of the general sanitary status and phytosanitary management in the production areas designated for export and the identification of possible differences among these production areas, providing reasons.

14. Question: How do you plan to provide measure from your request to countries who are in process to integrating to the EU?

Answer: The countries which are in process of integration to the EU will need to follow the same procedure as the rest of non-EU countries.

15. Question: If nurseries from EU have cooperation with nurseries in non-EU country and the production of wood is in a non-EU country, are they obliged to follow all instructions and submit dossiers?

Answer: Yes. If the plants are not produced in the EU and they are listed in Commission Implementing Regulation (EU) 2018/2019, a dossier has to be submitted for the risk assessment to be carried out. If your question refers only

to wood, please note that only the wood of *Ulmus* L. from countries where the pest *Saperda tridentata* is known to occur is listed as a high risk product.

16. **Question: Because we have a lot of signature contracts, with buyers from EU, do we have the possibility, with specific control measures, to realise that contracts in future?**

Answer: The control measures will only be available after the risk assessment has been completed. We encourage you to contact the NPPO of your country to prepare and submit a demand of import accompanied by a technical dossier (as explained in Commission Implementing Regulation (EU) 2018/2018) as soon as possible for the risk assessment to be initiated. Please note that if the risk assessment has not been completed and the list of high risk plants has not been modified for the specific plants originating in your country, the trade of these plants will not be permitted from 14 December 2019, until these requirements are met (risk assessment completed and list of high risk plants accordingly modified).

17. **Question: Will historical safe trade data (with any phytosanitary problem or ban of any delivery) be taken into consideration by EFSA analysts when developing the risk assessment?**

Answer: The history of safe trade can be included in the dossier as supporting material and will be evaluated as part of the risk assessment. However, complete dossiers, including all the required information, have to be submitted for the risk assessment to be carried out. Please note that, as indicated in Commission Implementing Regulation (EU) 2018/2018 the dossier shall be submitted by the NPPO of the applicant country, and not by a company.

18. **Question: How precise information of volume, frequencies and seasonal timing planned for export to the EU (point 5.4 of the TR) you need, because it is very difficult to predict?**

Answer: Please provide information as accurate as possible, also according to an average of volume, frequencies and timing related to previous years.

19. **Question: Can the dossiers (or other evidences) be submitted in a language different than English? What if the pesticide label is not written in English?**

Answer: Yes, dossiers can be submitted in any EU languages, but no other language that are not European. However, dossiers (or evidences, including for example the pesticide labels) submitted in a language other than English, will be first translated into English.

20. **Question: Will food safety be considered in the CRA?**

Answer: We do not assess food safety issues, but we do expect you to follow all the requirements regarding food safety.

21. **Question: On the page 22 of the TR regarding ANNEX A and B, we cannot access the provided weblink.**

Answer: Please use the following link: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2018.EN-1492

In case of further issues, we invite you to submit your query to the EFSA Animal and Plant Health Unit (ALPHA) at the following email address: ALPHA@efsa.europa.eu

22. How can we prove or give evidence on pest status? Can you give us an example?

Answer: The pest status in your country (e.g. absent, confirmed by survey; present, limited distribution, confirmed by survey) should be specified according to ISPM-8 by the NPPO. The NPPO should submit the dossier.

For non-regulated pests, an official pest status may not be available; in this case you should consider and provide sources of scientific, technical and grey literature. This information should show the presence/absence of the non-regulated pest in your country.

23. Question: How do we decide on the status of a pest in the EU (i.e., Absent/Present/Restricted) if it is not on the official EU lists, and in particular, how do we assess the "Restricted" category?

Answer: You can check and provide evidences in available databases (e.g. EPPO, online and CABI, online) or literature.

This information will be completed, when necessary, by EFSA during the risk assessment, because in some cases the applicant countries may not have access to this detailed information.

24. Question: Can EUROPHYT's balance sheet be used as a source of data to complete the verification of the situation of countries of origin?

Answer: The data of EUROPHYT interceptions may be submitted as part of additional information, however, this information will not be used as source of information for the pest status of a country of origin, because the absence of interceptions does not mean that the pest is not present in that country.

25. Question: As for apple fruit trees, what about washing the roots? Is it a relevant measure? For example, if roots are washed, can export be done beside this regulation?

Answer: Even if the root system is washed (which can be considered as a phytosanitary mitigation measure against targeted pests), countries of origin are still required to provide a complete dossier including all the phytosanitary mitigation measures used to produce the commodity.

26. Question: What are the rules around export of plants/trees with soil parts?

Answer: If the plants/trees are included in the list of high risk plants, a risk assessment has to be carried out for its introduction into the EU from 14 December 2019, and you should provide all the information listed in the EFSA TR "Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031" available at http://www.efsa.europa.eu/en/supporting/pub/en-1492. If the plants/tress are not listed as high risk plants, then the current import requirements listed in Directive 2000/29/EC will continue applying.

27. Question: Why *Momordica* L. is listed as a high risk plant with identified pest of concern (*Thrips palmi*)?

Answer: Fruits of *Mormordica* are listed as high risk plants in relation to the pest *Thrips palmi* because despite there are currently import requirements for this commodity in relation to this pest, there are recurrent interceptions, and therefore it is necessary that the mitigation measures are evaluated by EFSA to ensure they are sufficient to ensure pest freedom. After the publication of the list of high risk plants, the EU has notified to its trade partners via WTO-SPS the procedures and information that applicant countries shall submit in relation to *Momordica* (G/SPS/N/EU/272/Add.3, available at: http://spsims.wto.org/en/ModificationNotifications/View/147666?FromAllNotifications=True

If your country is free from *Thrips palmi* you need an official declaration of the NPPO. In this case *Momordica* is not considered as a high risk plant. If *Thrips*

palmi is present in your country, you should provide the information about the mitigation measure following the relevant section in the TR.

28. Question: Can the EU provide any ideas on what contributes to "effective mitigation measures" for *Thrips palmi* on *Momordica*? What kind of dossier should we submit to export *Momordica* to the EU?

Answer: Effective mitigation measures include all those growing conditions, treatments, inspections, etc. carried out to ensure that the fruits are free from the pest. In the case of fruits of *Momordica* originating in countries where the pest *Thrips palmi* is known to occur, the country of origin has to submit a dossier containing only the information referring to the section 5 (Data on phytosanitary mitigation measures) of the TR "Information required for dossiers to support demands for import of high risk plants, plant products and other objects as foreseen in Article 42 of Regulation (EU) 2016/2031" published by EFSA, available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1492.

29. Question: Pests inserted in table D1 of Appendix D that are placed in Table D3, are already EU-regulated. Why, then, is it required to provide all the information listed in section 4.4?

Answer: Despite the pests are already regulated, the CRA will evaluate if the measures applied for these pests are sufficient to guarantee the commodity is free from them. In this section, relevant data such as the geographical distribution of the pest in the country or the prevalence of the pest during the season have to be provided. In order to proceed with the CRA the Dossier should contain all the information required in the TR. In case of noncompliance with these requirements, EFSA may ask the applicant for additional information or clarification.

30. Question: All the proposed measures are not certain; in which case the decision approves the control measures?

Answer: The CRA will evaluate the overall efficacy of the risk reduction options applied to ensure the pest freedom of the commodity (i.e. phytosanitary mitigation measures). Once the risk assessment is completed, the EC, as risk manager, will evaluate the outcome of the risk assessment and will decide for which pest(s) additional measures may be required. This will be formalised by a Commission Implementing Regulation voted by Member States.

31. Question: Does EFSA endorse specific organizations in developing countries for document preparation?

Answer: No. The dossier needs to be submitted by the NPPO of your country. EFSA will do the risk assessment with the information provided by the country of origin but will not participate in the preparation of the dossiers.

32. Question: Who has to do the inspections?

Answer: The inspections shall be carried out under the responsibility of the official authority in the country of origin. The risk assessment will be carried out by EFSA with the information provided by the NPPO of the applicant country.

33. Question: The plants for planting are exported as different commodities (e.g. unrooted and rooted cuttings of varying age), do we need to submit separate dossiers for each commodity?

Answer: This can be done in the same dossier or in separate dossiers. However, it is very important to exactly specify the different commodity types that are traded. Because the pests associated with the commodity may differ, the different commodity types have to be dealt with in separate tables for each

commodity type. In this case, the requirements will be specified for the commodity type with the highest potential pest load (e.g. rooted cuttings).

If import requirements differ greatly between commodity types (e.g. unrooted cuttings vs potted plants) it may be better for export country to submit separate dossiers).

34. Question: Can a group of neighbouring countries submit a "joint" dossier?

Answer: No. The dossiers must be submitted by the NPPO of the country requesting to export high risk plants into the EU (Article 2 of Commission Implementing Regulation (EU) 2018/2018). This is necessary to ensure that all the necessary elements for the assessment of the risk associated with the plants, plant products or other objects to be introduced into the Union territory are certified by the responsible public authority of the country of origin. If a dossier is sent by a company, it will be automatically rejected and not transmitted to EFSA.

35. Question: What is the meaning of "Associated uncertainties" of Table E4, Appendix E of the TR?

Answer: They are uncertainties that the measure you take against a specified pest may not achieve pest-freedom of the commodity (e.g. the pest is a stem borer and the applied insecticide may not be effective against insects feeding inside the plant tissue).

36. Question: What information does EFSA require for "estimation" and "evidence" for the efficacy in the Table E1 of the TR? Can you give us an example?

Answer: In the column "estimation of the efficacy" of table E1 you may provide the specific value for efficacy of the pesticide treatment to control the target plant species as indicated in the footnote 11. You should base your estimation on

evidences. The possible evidences may include: e.g., Plant Protection Products labels, papers, TRs, experimental data, grey literature, etc. Copy of such evidence should also be provided as attachment to the technical dossier. For more details on the required information and evaluation of phytosanitary mitigation measures see EFSA PLH Panel, 2012 (footnote n.12 of Table E1 in the TR).

37. Question: Can you use other climate match systems aside from Köppen-Geiger?

Answer: According to the TR, page 7, paragraph 3.12, you need to provide the Köppen-Geiger climate classification (sub-group level) relevant for the production areas (http://koeppen-geiger.vu-wien.ac.at/). However, other climate classifications, climate matching systems or climate index can be used as long as your export country and the EU is included.