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Guidance on commodity risk assessment for the evaluation of high risk plants dossiers

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Abstract

Article 42 of the European Regulation (EU) 2016/2031, on the protective measures against pests of plants), introduces the concept of "high risk plants, plant products and other objects" that are identified on the basis of a preliminary assessment to be followed by a commodity risk assessment. Following a request of the European Commission, this Guidance was developed to establish the methodology to be followed when performing a commodity risk assessment for high risk commodities. Any commodity risk assessment performed by EFSA will be based on the information provided by the applicant requesting a lifting of import prohibition of a high risk commodity. Following international standards on pest risk analysis this Guidance describes a two-step approach for the assessment of pest risk associated with a specified commodity. In the first step, pests associated with the commodity that require phytosanitary measures are identified. In the second step, the overall efficacy of proposed risk reduction options for each pest is evaluated. A conclusion on the pest-freedom status of the commodity is achieved. The method requires key uncertainties to be identified.

Keywords: European Union, commodity risk assessment, plant health, plant pest, quarantine, evidence-based assessment

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1. Introduction

1.1. Background as provided by the European Commission

Regulation (EU) 2016/2031[1], on the protective measures against pests of plants, will be applying from December 2019. Provisions within the above Regulation are in place for the listing of "high risk plants, plant products and other objects" (Article 42) on the basis of a preliminary assessment, and to be followed by a commodity risk assessment. A first list of "high risk plants, plant products and other objects" is to be adopted by end 2018. Scientific opinions are therefore needed to support the European Commission and the Member States in the work connected to Article 42 of Regulation (EU) 2016/2031, as stipulated in the terms of reference.

1.2. Terms of Reference as provided by the European Commission

In view of the above and in accordance with Article 29 of Regulation (EC) No 178/2002[2], the Commission asks EFSA to provide scientific opinions in the field of plant health.

In particular, EFSA is expected to prepare and deliver risk assessments for commodities that shall be listed in the relevant Implementing Acts as "High risk plants, plant products and other objects". Article 42, paragraph 4 and 5, establishes that a risk assessment is needed as a follow-up to evaluate whether the commodities will remain prohibited, removed from the list and additional measures will be applied or removed from the list without any additional measures. This task is expected to be on-going, with a regular flow of dossiers being sent by third countries required for the risk assessment.

Therefore, to facilitate the correct handling of the dossiers and the acquisition of the required data for the commodity risk assessment, a format for the submission of the required data for each dossier is needed.

Furthermore, a standard methodology for the performance of "commodity risk assessment" based on the work already done by Member States and other international organizations needs to be set.

1.3. Interpretation of the Terms of Reference

As a result of the classification of commodities as "High risk plants, plant products and other objects" their import into the EU will be prohibited. Requests for lifting the import prohibition can be sent to the European Commission by the National Plant Protection Organization of the exporting country.

In January 2018, the European Commission (EC) requested EFSA to provide scientific assistance in standardizing the information requirements for dossiers to support applicants (third countries) requests for lifting the import prohibition of high risk plants, plant products and other objects as specified in Regulation (EU) 2016/2031. In a Technical Report (EFSA, 2018), EFSA specified information and data required to perform a commodity risk assessment.

In this document, guidance on a standard methodology for the performance of "commodity risk assessment" is given dealing with plant health[3], following the international standard for pest risk assessment (FAO, 2013 - ISPM 11). The objectives of the commodity risk assessment are to (1)

[1] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. OJ L 317, 23.11.2016, p. 4–104.

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

[3] Issues outside of the remit of the Plant Health panel, e.g.. economic and social impact, invasive plants, GMO organisms, pesticide compliances, are not assessed in the commodity risk assessment.

identify pests that may require phytosanitary mitigation measures, and (2) evaluate the overall efficacy of the measures currently applied.

2. Data and Methodologies

It should be noted that the text in italics aims to provide some guidance to the assessors. The advisory text should be removed before publication of the opinion.

The Panel performed the assessment following the relevant guiding principles and steps presented in the EFSA Guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018), in the Guidance on evaluation of the effectiveness of risk-reducing options (EFSA PLH Panel, 2012) and in the International Standard for Phytosanitary Measures No 11 and No 21 (FAO, 2004, 2013). It should be noted that the Panel's conclusions are formulated respecting its remit and particularly with regard to the principle of separation between risk assessment and risk management (EFSA founding regulation (EU) No 178/2002).

The data and supporting information provided in the dossier submitted by the applicant form the basis of the commodity risk assessment. In evaluating the dossier provided, EFSA PLH Panel assumes that the applicant followed the instructions in the Technical Report (EFSA 2018))

Examples of databases that could be used for checking the completeness of the information provided are listed below:

- *EPPO Global Database (EPPO, online)*
- *CABI Plant Protection Compendium (CABI, online)*
- *The Plant List (The Plant List, online)*
- *Index Fungorum (http://www.indexfungorum.org/)*
- *MycoBank (http://www.mycobank.org/)*
- *NEMAPLEX (http://plpnemweb.ucdavis.edu/)*
- *Fauna Europaea (https://fauna-eu.org/)*
- *Europhyt*
- *USDA Agricultural Research Services (https://nt.ars-grin.gov/)*
- *Bibliographical databases*
- *Statistical databases*

When performing a commodity risk assessment, the databases used to check the completeness of the information provided should be explicitly mentioned.

Guidance is provided on the methodology used in the commodity risk assessment and concerns the evaluation of commodity data, identification of pests potentially associated with the commodity and evaluation of the phytosanitary mitigation measures.

At several points in the risk assessment process additional information may be required. Figure 1 gives an overview of the points in the assessment process where this may be the case. This could include requests for clarifications or additional documentation from the applicant.

156 **Figure 1:** Figure 1: Critical decision points that may affect the progress of the assessment.

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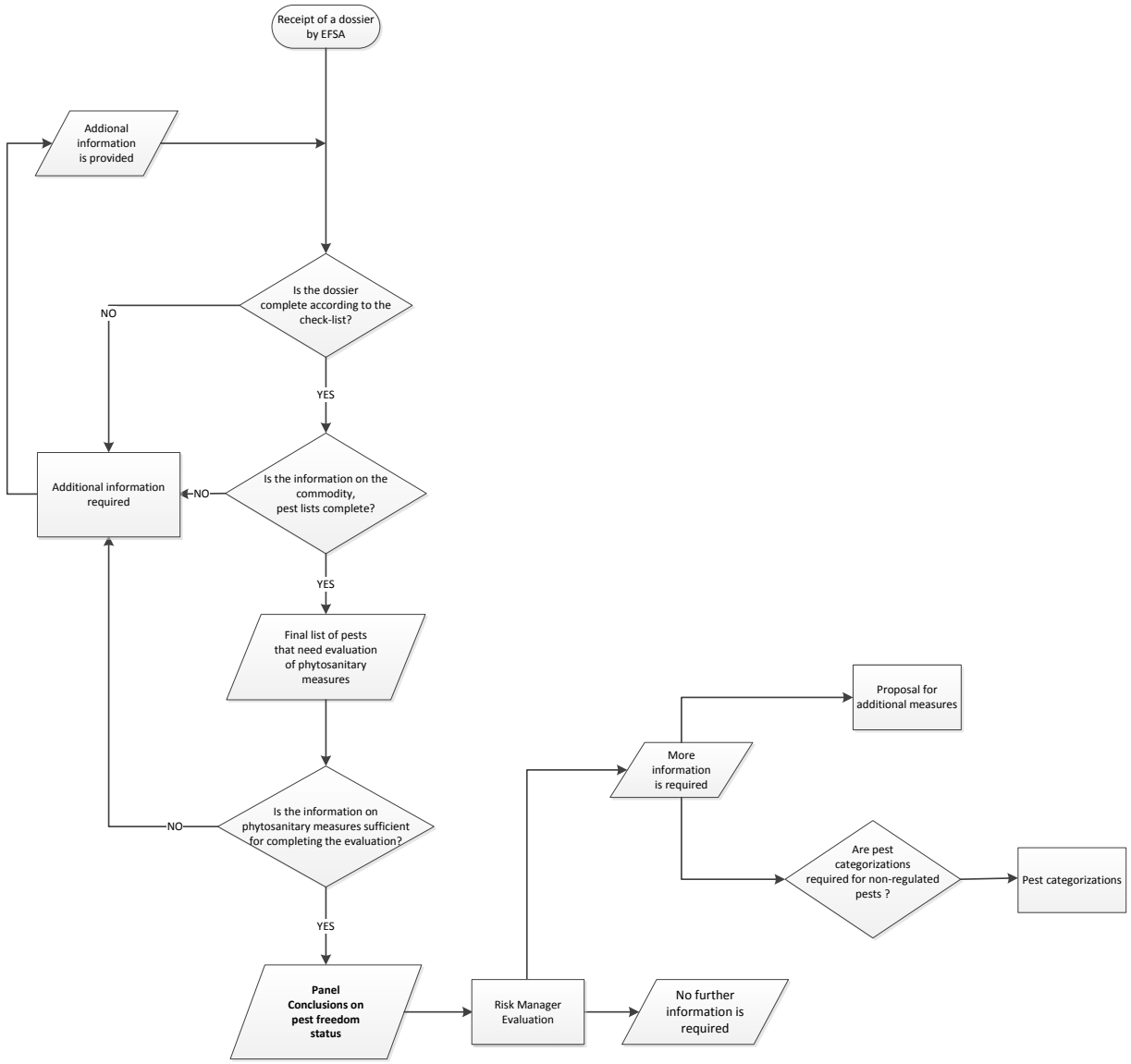

3. Evaluation of commodity data

The purpose of this section is to provide an unambiguous description of the commodity and its production and handling process.

The following questions need to be answered to determine whether an unambiguous description of the commodity has been provided, as indicated in sections 3.1 to 3.6 of the Technical Report, hereafter referred as TR (EFSA 2018):

- Is the plant correctly identified as stated in section 3.1 of the TR, according to a recognised authority (e.g. The Plant List – www.theplantlist.org)?
- Is a description of plants for planting (according to Annex 1 of ISPM n. 36, FAO, 2016) and of the growing media (according to ISPM n.40, FAO, 2018) provided in section 3.2 of the TR?
- Is the propagation material described according to section 3.3 of the TR?
- In the case of fruit or vegetables, are the part/s of the plant, as well as the presentation (i.e. the presence of leaves, sepals, or fruit on the vine, etc.) appropriately described according to section 3.4 of the TR?
- In the case of wood, is the type of wood described according to ISPM n. 39 (FAO, 2018) (section 3.5 of the TR)?
- In the case of other commodities, are they appropriately described according to section 3.6 of the TR?

Based on the information required by sections 3.1 to 3.6 of the TR (EFSA, 2018) evaluate if the information provided is unambiguous and sufficient. If ambiguous or not sufficient, then further information may be required or considered as uncertainty. If unambiguous and sufficient, provide a summary of the characteristics of the commodity being evaluated.

The following questions need to be answered to determine whether the processes and places of production of the commodity have been provided (sections 3.7 to 3.13 of the TR):

- Is the timing of agronomic practices and phenology of the crop described according to section 3.7 of the TR?
- Is the general sanitary status and phytosanitary management of the crop described according to section 3.8 of the TR?
- Is the intended use of the commodity described according to section 3.9 of the TR?
- Are production areas clearly specified and described (including map/s) according to sections 3.10 and 3.11 of the TR?
- Is the climate classification for the production area provided according to section 3.12 of the TR?
- Are colour pictures and the descriptions informative and provided according to section 3.13 of the TR?

Based on the information required in sections 3.7 to 3.13 of the TR evaluate if the information provided is unambiguous and sufficient.

If sufficient and unambiguous, provide a description of the commodity and a summary of the relevant processes and places of production, including the assessment of uncertainties.

Otherwise further information may be required.

4. Evaluation of the identification of pests potentially associated with the commodity in the exporting country

The purpose of this section is to identify and list the pests associated with the commodity in the country of origin. Distinction is made between pests that are regulated in the EU (EU-regulated) and those that are not regulated in the EU (non EU-regulated). For the group of non EU-regulated pests a decision has to be made whether a pest categorisation is needed to confirm if the pest fulfils the criteria to be considered for Union quarantine pest status (see Figure 1). The end result is a list of pests for which phytosanitary mitigation measures may be required.

The following questions need to be answered to determine whether the two pest lists (sections 4.1 to 4.4 of the TR) are complete and correctly classified and if the additional information on the selected pests is provided (sections 4.5 and sub-sections 4.5.1 to 4.5.11 of the TR):

- Is the list of all pests potentially associated with the plant species or genus of the commodity in the exporting country compiled according to section 4.1?

  If applicable, indicate the pest species that are missing from the above list. These species should be further evaluated and considered for addition to table D1 and D2, as submitted. If necessary at this stage the applicant could be asked to provide further information.

- Are all the EU regulated pests included in table D1, according to section 4.2 of the TR?

  For each pest species:

  - Is the most recent valid scientific name provided?
  - Is the pest status (presence or absence) provided and correctly classified?

    Check the reliability of surveillance/monitoring system and results.
  - If applicable, is sufficient evidence for the pest-free areas status in the country of export given according to ISPM 4 (FAO, 1995)?

    Check the reliability of surveillance/monitoring system and results.
  - Is the regulatory status (e.g. quarantine pests, regulated non-quarantine pests) in the country provided?
  - Is the evidence given on the association of the pest with the commodity satisfactory? *Based on the host range, biology and life cycle of the pest, conclude whether one or several stages may be associated with the commodity at origin. Check if the Europhyt records of interceptions, or information from literature searches, support the statement provided by the applicant.*
  - Are all pests identified that may need phytosanitary mitigation measures? *Identify EU-regulated pests that may need phytosanitary mitigation measures: the pest is present in the applicant third country and known to use the plant species or genus of the commodity as host (copy these species to Table 1)*

  Create the final table with the list of EU-regulated pests (Table 1). Indicate and justify any changes made to the original table D1 of the TR.

  If necessary at this stage the applicant could be asked to provide further information.

- Are all the non-regulated pests in EU included in table D2, according to section 4.3 of the TR?

  For each pest species:

  - Is the most recent valid scientific name provided?

- Is the pest status (presence or absence) in the EU provided and correctly classified?

  Check if the information provided is correct and updated. Are there any of these pests present in the EU and under official control?

- If applicable, is sufficient evidence for the pest-free area status in the country of export given according to ISPM 4 (FAO, 1995)?

  Check the reliability of surveillance/monitoring system and results.

- Is the regulatory status in the applicant third country provided?

- Is the evidence given on the association of the pest with the commodity satisfactory?
  Based on the biology and life cycle of the pest, conclude whether one or several stages may be associated with the commodity at origin. Check if the Europhyt records of interceptions, or information from literature searches, support the statement provided by the applicant.

- Is the evidence given on the impact of the pest satisfactory?
  An important risk element to decide for potential pest categorisation is the possible impact of the pest in the EU. Evidence of the impact of the pest nside and outside~~and outside~~ the exporting country should be considered. Elements that may increase the possible impact in the EU are:
  - climate matching
  - host range including important plant species for the EU
  - evidence of the pest as vector of plant disease
  If there is no evidence of impact, the pest is excluded from the assessment and moved to the list of "pests not further assessed" (see Appendix A). If evidence about potential impact of these pests becomes available, they could be reassessed.

- Are all pests identified that may need phytosanitary mitigation measures?

  Identify all other pests (not regulated in the EU) that may need phytosanitary mitigation measures: the pest is present in the applicant third country, is absent in the EU, known to use the plant species or genus of the commodity as host and having potential impact in the EU (copy these species to Table 2)

Create the final table with the list of pests not regulated in the EU (Table 2 in assessment).

If necessary at this stage the applicant could be asked to provide further information.

Indicate and justify any difference compared to table D2, of the TR.

- In table D3 of the TR all pests, present in the applicant third country, associated with the commodity and that may need phytosanitary mitigation measures or/and pose a potential risk for the EU are identified and summarised by the applicant.

  Provide a summary table (Table 3) with the list of pests that may need phytosanitary mitigation measures based on Tables 1 and 2

- For each pest listed in table D3 of the TR check that the following information is provided (according to section 4.4 of TR) :

  Note that if additional pests are included in Table 3 (compared to the ones listed in the table D3 of the dossier), the applicant may be asked to provide information for the additional pests.

- Scientific name, synonyms and if applicable, common name(s) in English

- Taxonomic classification, including at least class, order, family, genus, species and information below species level if relevant (e.g. sub-species, pathovar, etc.).
- Geographical distribution of the pest in the country, providing if applicable, pest distributions/pest-free areas maps for each pest, considering map provided under 3.10. of the (TR) as background layer.
- Prevalence of the pest during the season (e.g. percentage of infested plants/fruit during the different phenological stages indicated in paragraph 3.7 of the TR).
- Relevant biological characteristics (e.g., life cycle, association with the pathway, thermal requirements, environmental conditions for symptom / disease expression) of the pest.
- Main hosts of the pest, including alternate hosts if relevant, vector(s) required.
- In the case of arthropods and nematodes, for each stage (e.g., egg, larva/nymph, pupa, adult), indicate the part of the plant where it can be found, describe the type of damage. Provide information whether any latent phase or asymptomatic infestation/infection stages are known for the pest species. Indicate also if the pest can be a vector of any plant disease.
- In the case of fungi, bacteria, viruses, phytoplasmas, describe the symptom(s) in the commodity and the part of the plant where it can be found, describe the type of damage. Provide information whether any latent phase or asymptomatic infestation/infection stages are known for the pest species. Indicate also if the pest can be a vector of any plant pathogens.
- In the case of any other living organism (e.g., parasitic plants), describe their association with the commodity.
- Indicate the impact caused by the pest.
- If available provide pest risk assessments or pest risk analysis
- Additional information or evidence (optional)

If there is incomplete information for the above listed items the applicant may be asked to provide the missing information.

Table 1: List of EU regulated pests List of EU regulated pests, present in the applicant third country and known to use the plant species or genus of the commodity as a host

Pest species	Taxonomic information	Pest status in the applicant third country	Pest-free area(s)	Evidence and uncertainty on pest status and pest-free area(s)	Regulatory status in the applicant third country	Can the pest be associated with the commodity?	Evidence and uncertainty on association with the commodity	Pest for which phytosanitary mitigation measures may be required
		☐	☐			☐		☐
		☐	☐			☐		☐
		☐	☐			☐		☐
		☐	☐			☐		☐
		☐	☐			☐		☐
		☐	☐			☐		☐

Table 2: List of pests not regulated in the EU and present in the country of origin. List of pests not regulated in the EU, present in the applicant third country and known to use the plant species or genus of the commodity as host

Pest species	Taxonomic information	Status in EU	Pest-free area(s) in applicant third country	Evidence and uncertainty on pest status and pest-free area(s)	Regulatory status in applicant third country	Can the pest be associated with the commodity?	Evidence and uncertainty on association with the commodity	Does the pest have impact in applicant third country	Evidence and uncertainty on the level of impact	Pest of potential risk for EU
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐
			☐			☐		☐		☐

Table 3: Summary table of pest species associated with the commodity and that may have a potential risk for EU (selected from tables 1 and 2)

Pest species associated with the commodity	Regulated pests in EU
	☐
	☐
	☐
	☐
	☐
	☐
	☐
	☐

5. Evaluation of the data on phytosanitary mitigation measures

The purpose of this section is to evaluate if the phytosanitary measures described in the dossier achieve pest freedom of the commodity for each pest identified in section 4 (Table 3) of this Guidance.

The following questions need to be answered to evaluate the phytosanitary mitigation measures as indicated in sections 5.1 to 5.5 of the TR:

- Is the description of the phytosanitary mitigation measures of the commodity provided according to section 5.1 and Appendix E of the TR?
- Is the information on phytosanitary regulations and inspection systems relevant and complete for the crop of interest or associated quarantine pests (section 5.2 of the TR)?
- Is the description of the surveillance and monitoring systems sufficiently detailed according to section 5.3 of the TR?
- Is the information on trade provided according to section 5.4 of the TR?
- Is the information on post-harvest processes and transport provided according to section 5.5?

Use the information provided in section 4.5 (biology of the pests) of the TR and the information above (section 5.1 to 5.5 of the TR) for the evaluation of the phytosanitary mitigation measures.

Pest freedom is assessed at the consignment level. Pest freedom is defined by the International Plant Protection Convention (ISPM 5, FAO, 2017) as the absence of a specific pest in a consignment in numbers or quantities that can be detected by the application of official phytosanitary procedures. These phytosanitary procedures include the performance of inspections, tests, surveillance or treatments (ISPM 5, FAO, 2017).

The assessors identify for each pest the relevant risk reduction options (RROs) acting on the pest, based on section 5.1, Table E1 to E4 of the TR and summarize this in Table 4 reported below. If the RRO can act as a standalone measure (SA, e.g. heat treatment of wood) this is indicated. For each identified RRO it is assessed if there are limiting factors that may reduce the effectiveness of the RRO (e.g. implementation in production processes). These limiting factors are documented (see also section 2.2.2.3. of the EFSA (2018) guidance on quantitative risk assessment – EFSA PLH Panel et al., 2018).

Based on this information, for each identified pest, an expert judgement is given by the assessors for the probability (0-1) that pest freedom of a consignment is achieved by the RRO combination acting on the pest under consideration (according to Table 5. It is a subjective probability, taking into account practical limitations in finding pests at very low densities. At the level of a flow of consignments, this probability would translate in a proportion of consignments being pest free.

The related uncertainties deriving from the limiting factors are documented.

Table 4: Example of a table that can be used to evaluate the efficacy of RROs for each pest/likelihood terms.

Pest species	RRO1	RRO2	RRO3	RRO4	RRO5	RROn	Limiting factors	Pest freedom ratings
Pest 1	x	x	x					*Likely*
Pest 2			x	SA	x			*Extremely likely*
Pest n								

.								

SA= Stand Alone RRO for the pest

X = RRO is acting on the pest

As an aid in documenting the evidence the assessors can use a table format as provided in Table 5 Following the EFSA Guidance on uncertainty (EFSA, Scientific Committee 2018), the likelihood of pest freedom can be expressed as a percentage: where a probability value approaching 0(=0%) probability means that the answer is almost certainly no, and a probability approaching 1(=100%) means it is almost certainly yes. To aid the expert judgement the EFSA (2014) Guidance on Expert Knowledge Elicitation can be used (EFSA, 2014). Table 5 reports an adaptation of the likelihood expressions of EFSA, Scientific Committee (2018, Table 2), which are appropriate for this application. To distinguish high probabilities a translation in repeated consignments is given.

The approach of repeated consignments enables the risk assessor to answer the more quantitative questions, expressed in different units.

Table 5 - Likelihood classes and corresponding subjective probability ranges for the evaluation of probability to realise pest-free consignments given the RROs acting on the pest under consideration

Probability term	Probability of one consignment being "pest free"	Explanation using repeated consignments
Almost certain	*99.95% - 100%*	*More than 9995 of 10000 consignments are on average pest free.* *(Less than 5 of 10000 are infested; on average at most one of every 2000 consignments is infested)*
Extremely likely	*99.90% - 99.95%*	*Between 9990 and 9995 of 10000 consignments are on average pest free.* *Between 5 and 10 of 10000 are infested; on average at most one of every 1000 consignments is infested.*
Very likely	*99.5% - 99.9%*	*Between 995 and 999 of 1000 consignments are on average pest free.* *(Between 1 and 5 of 1000 are infested; on average at most one of every 200 consignments is infested*
Likely	*99.0% - 99.5%*	*Between 990 and 995 of 1000 consignments are on average pest free.* *(Between 5 and 10 of 1000 are infested; on average at most one of every 100 consignments is infested*
Moderate likely	*95% - 99%*	*Between 95 and 99 of 100 consignments are on average pest free* *(Between 1 and 5 of 100 are infested; on average at most one of every 20 consignments is infested)*
Unlikely	*90% - 95%*	*Between 90 and 95 of 100 consignments are on average pest free.* *(Between 5 and 10 of 100 are infested; on average at most one of every 10 consignments is infested)*
Very unlikely	*50% - 90%*	*Between 5 and 9 of 10 consignments are on average pest free.* *(Between 1 and 5 of 10 are infested; on average at most one out of two consignments is infested)*

Extremely unlikely	*0% - 50%*	*Between 0 and 5 of 10 consignments are on average pest free.* *(Between 5 and 10 of 10 are infested; on average at most every consignments is infested)*

If the assessors want to express the uncertainty in a more quantitative way they can refer to section 3.5.3 of the EFSA guidance on quantitative risk assessment (EFSA PLH Panel et al., 2018).

It should be noted that it is not within the remit of EFSA to decide if the appropriate level of pest freedom is reached given the combination of RROs acting on the relevant pests that can be associated with the commodity. Instead of a yes or no answer, the risk manager is provided with a judgement of the probability (or with a range of probability values in case of the more quantitative approach) that pest freedom is reached for the pests under consideration for the evaluated commodity.

Summarize the results in Table 6.

Table 6: Concluding table

Pest species	Likelihood of pest-freedom	Justification	Key uncertainties
Pest 1			*List key uncertainties that affect the final conclusion. If no key uncertainties, insert "none"*
Pest 2			
Pest n			

6. Uncertainty

Describe in the narrative form the main sources of uncertainty only when they may affect the conclusion about the pest freedom status of the commodity.

7. Conclusions

The conclusion of the commodity risk assessment can be:

There are XX pests associated with the commodity in the exporting country that may require phytosanitary mitigation measures.

The phytosanitary mitigation measures indicated in the dossier may/may not achieve pest-freedom of the commodity. If commodity pest-freedom is not achieved, list the pest species for which pest-freedom is not achieved (Table 6).

8. Recommendations

As with all EFSA guidance, this Guidance should be regularly reviewed (EFSA Scientific Committee, 2015) to take into account the experiences of the Panel and the needs of those requesting pest risk assessments.

References

EFSA (European Food Safety Authority), 2014. Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. EFSA Journal 2014;12(6):3734. [278 pp.] doi:10.2903/j.efsa.2014.3734

EFSA (European Food Safety Authority) Scientific Committee, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Craig P, Hart A, Von Goetz N, Koutsoumanis K, Mortensen A, Ossendorp B, Martino L, Merten C, Mosbach-Schulz O and Hardy A, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp.https://doi.org/10.2903/j.efsa.2018.5123

European Food Safety Authority (EFSA), Dehnen-Schmutz K, Jaques Miret JA, Jeger M, Potting R, Corini A, Simone G, Kozelska S, Munoz Guajardo I, Stancanelli G and Gardi C, 2018. 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.EFSA supporting publication 2018:EN-1492, 22pp. doi:10.2903/sp.efsa.2018.1492

EFSA PLH Panel (EFSA Panel on Plant Health), 2012. Guidance on methodology for evaluation of the effectiveness of options for reducing the risk of introduction and spread of organisms harmful to plant health in the EU territory. EFSA Journal 2012;10(6):2755, 92 pp. https://doi.org/10.2903/j.efsa.2012.2755

EFSA PLH Panel (EFSA Panel on Plant Health), Jeger M, Bragard C, Caffier D, Candresse T, Chatzivassiliou E, Dehnen-Schmutz K, Gregoire J-C, Jaques Miret JA, MacLeod A, Navarro MN, Niere B, Parnell S, Potting R, Rafoss T, Rossi V, Urek G, Van Bruggen A, Van der Werf W, West J, Winter S, Hart A, Schans J, Schrader G, Kozelska S, Mosbach-Schultz O, Vos S and Gilioli G, 2018. Guidance on quantitative pest risk assessment. EFSA Journal 2018; 16(8):5350, 86 pp. https://doi.org/10.2903/j.efsa.2018.5350

EFSA Scientific Committee, 2015. Scientific opinion: guidance on the review, revision and development of EFSA's cross-cutting guidance documents. EFSA Journal 2015;13(4):4080, 11 pp. https://doi.org/10.2903/j.efsa.2015. 4080

EPPO (European and Mediterranean Plant Protection Organization), online. EPPO Global Database. Available online: https://gd.eppo.int [Accessed Date]

FAO (Food and Agriculture Organization of the United Nations), 1995. ISPM (International standards for phytosanitary measures) No 4. Requirements for the establishment of pest free areas. Available online: https://www.ippc.int/en/publications/614/

FAO (Food and Agriculture Organization of the United Nations), 2004. ISPM (International Standards for Phytosanitary Measures) 21—Pest risk analysis of regulated non-quarantine pests. FAO, Rome, 30 pp. Available online: https://www.ippc.int/sites/default/files/documents//1323945746_ISPM_21_2004_En_2011-11-29_Refor.pdf

FAO (Food and Agriculture Organization of the United Nations), 2013. ISPM (International Standards for Phytosanitary Measures) 11—Pest risk analysis for quarantine pests. FAO, Rome, 36 pp. Available online: https://www.ippc.int/sites/default/files/documents/20140512/ispm_11_2013_en_2014-04-30_201405121523-494.65%20KB.pdf

FAO (Food and Agriculture Organization of the United Nations), 2017. ISPM (International standards for phytosanitary measures) No 5. Glossary of phytosanitary terms. Available online: https://www.ippc.int/en/publications/622/

FAO (Food and Agriculture Organization of the United Nations), 2016. ISPM (International standards for phytosanitary measures) No 14, The use of integrated measures in a systems approach for pest risk management FAO, Rome, xx pp Available online:

https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_14_2002_En_2017-05-25_PostCPM12_InkAm.pdf

FAO (Food and Agriculture Organization of the United Nations), 2016. ISPM (International standards for phytosanitary measures) No 36, Integrated measures for plants for planting, Rome, 22 pp Available online: https://www.ippc.int/static/media/files/publication/en/2016/01/ISPM_36_2012_En_2015-12-22_PostCPM10_InkAmReformatted.pdf

FAO (Food and Agriculture Organization of the United Nations), 2018. ISPM (International standards for phytosanitary measures) No 40, International movement of growing media in association with plants for planting, Rome, 16 pp Available online: https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_40_2017_En_2017-05-15_oI08UDw.pdf

FAO (Food and Agriculture Organization of the United Nations), 2018. ISPM (International standards for phytosanitary measures) No 39, International movement of wood, Rome, 20 pp Available online: https://www.ippc.int/static/media/files/publication/en/2017/05/ISPM_39_2017_En_2017-05-15.pdf

Abbreviations

EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
ISPM	International Standards for Phytosanitary Measures
PLH	EFSA Panel on Plant Health
PZ	Protected Zone
RRO	Risk reduction option
TR	Technical Report
SA	Standalone measure

Glossary

Commodity pest list	A list of pests present in an area which may be associated with the specific commodity
Measures	Control (of a pest) is defined in ISPM 5 (FAO 2017) as "Suppression, containment or eradication of a pest population" (FAO, 1995). Control measures are measures that have a direct effect on pest abundance. Supporting measures are organisational measures or procedures supporting the choice of appropriate Risk Reduction Options that do not directly affect pest abundance.
Pathway	Any means that allows the entry or spread of a pest (FAO, 2017)
Pest-free consignment	Without pests (or specific pest) in numbers or quantities that can be detected by the application of phytosanitary procedures (ISPM n. 15).
Pest-free area	An area in which a specific pest is absent as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained.
Pest	The process for determining whether a pest has or has not the characteristics of

categorization	quarantine pest or those of a regulated non-quarantine pest.
Phytosanitary measures	Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests (FAO, 2017)
Quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (FAO, 2017)
Risk reduction option (RRO)	A measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present. A RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager

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Appendix A – **Lists of pests not further assessed**

This appendix lists all the pests that were excluded from the assessment (e.g. there is no evidence of impact).

These pests could be considered at a later stage if further evidence becomes available, but do not form part of this assessment.