

SCIENTIFIC OPINION

ADOPTED: 28 March 2019

doi: 10.2903/j.efsa.2019.5668

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 (high risk plants, plant products and other objects). The commodity risk assessment performed by EFSA will be based on the information provided by the National Plant Protection Organisations of non-EU countries 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 risk mitigation 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.

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

Requestor: European Commission

Question number: EFSA-Q-2018-00117

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Acknowledgements: The EFSA Panel on Plant Health wishes to thank Svetla Kozelska and Maria Rosaria Mannino for the information and suggestions provided and Emanuela Tacci for the administrative and technical support provided to this scientific output.

Suggested citation: EFSA PLH Panel (EFSA Panel on Plant Health), Bragard C, Dehnen-Schmutz K, Di Serio F, Gonthier P, Jacques M-A, Jaques Miret JA, Fejer Justesen A, MacLeod A, Magnusson CS, Milonas P, Navas-Cortes JA, Parnell S, Reignault PL, Thulke H-H, Van der Werf W, Vicent Civera A, Yuen J, Zappalà L, Jeger MJ, Gardi C, Mosbach-Schulz O, Preti S, Rosace MC, Stancanelli G and Potting R, 2019. Guidance on commodity risk assessment for the evaluation of high risk plants dossiers. *EFSA Journal* 2019;17(4):5668, 16 pp. <https://doi.org/10.2903/j.efsa.2019.5668>

ISSN: 1831-4732

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background as provided by the European Commission.....	4
1.2. Terms of Reference as provided by the European Commission.....	4
1.3. Interpretation of the Terms of Reference.....	4
2. Data and methodologies.....	5
3. Evaluation of commodity data.....	6
4. Evaluation of the identification of pests potentially associated with the commodity in the country of origin.....	7
5. Description and assessment of the efficacy of risk mitigation measures.....	12
6. Uncertainty.....	14
7. Conclusions.....	14
8. Recommendations.....	14
References.....	14
Glossary.....	15
Abbreviations.....	15
Appendix A – List of potential pests not further assessed.....	16

1. Introduction

1.1. Background as provided by the European Commission

The new Plant Health Regulation (EU) 2016/2031¹, 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 list of 'high risk plants, plant products and other objects' has been published (EU) 2018/2019². 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. 178/2002³, 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, paragraphs 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 the applicant 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 Organisation of the country of origin⁴ (hereinafter referred in this Guidance as the applicant).

In January 2018, the European Commission requested EFSA to provide scientific assistance in standardising the information requirements for dossiers to support applicants (countries of origin) 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,⁵ following the international standard for pest risk assessment (ISPM 11, FAO, 2013a). The objectives of the commodity risk assessment are to: (1) identify pests that may require risk mitigation measures;⁶ and (2) evaluate the overall efficacy of the measures currently applied.

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) 228/2013, (EU) 652/2014 and (EU) 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, pp. 4–104.

² Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation C/2018/8877. OJ L 323, 19.12.2018, pp. 10–15.

³ 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, pp. 1–24.

⁴ Commission Implementing Regulation (EU) 2018/2018 of 18 December 2018 laying down specific rules concerning the procedure to be followed in order to carry out the risk assessment of high risk plants, plant products and other objects within the meaning of Article 42(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council. C/2018/8876, OJ L 323, 19.12.2018, pp. 7–9.

⁵ Issues outside of the remit of the EFSA Plant Health panel (e.g. economic and social impact, invasive plants that do not pose a plant health threat, genetically modified organisms, pesticide compliances) are not assessed in the commodity risk assessment of high risk plants, plant products and other objects.

⁶ The term 'risk mitigation measure' is used in this guidance as synonym of 'risk reduction option'.

2. Data and methodologies

It should be noted that the text in green italics throughout this Guidance aims to provide practical guidance to the assessors to conduct the commodity risk assessment.

The Panel performs its commodity risk 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, 2013a). It should be noted that the Panel's conclusions are formulated to respect 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 contained in the Technical Report (EFSA, 2018).

Guidance is provided on the methodology to be 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 risk mitigation measures.

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

- *EPPO Global Database* (<https://gd.eppo.int/>)
- *CABI Plant Protection Compendium* (<https://www.cabi.org/cpc/>)
- *The Plant List* (<http://www.theplantlist.org/>)
- *Index Fungorum* (<http://www.indexfungorum.org/>)
- *MycoBank* (<http://www.mycobank.org/>)
- *NEMAPLEX* (<http://plpnmweb.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.

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 when this may be the case. This could include requests for clarifications or additional documentation from the applicant.

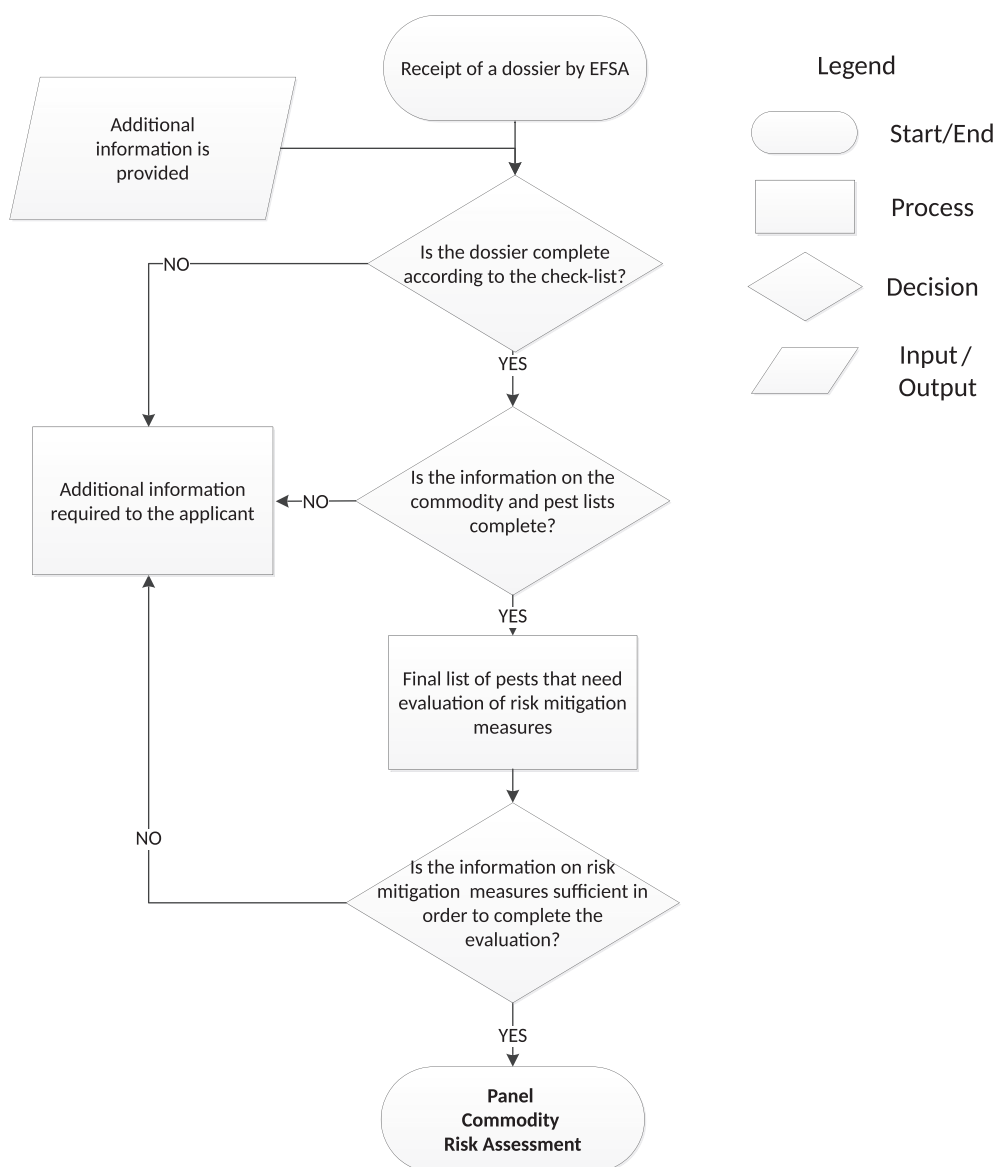


Figure 1: Critical decision points that may affect the progress of the assessment

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 3.1–3.6 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 36, FAO, 2016) and of the growing medium (according to ISPM 40, FAO, 2017a) provided according to Section 3.2 of the TR?
- Is the type of certification of the plants for planting described according to Section 3.3 of the TR?
- For 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?

- For wood, is the type of wood described according to ISPM 39 (FAO, 2017b) (Section 3.5 of the TR)?
- For other commodities, are they appropriately described according to Section 3.6 of the TR?

Based on the information required by Sections 3.1–3.6 of the TR (EFSA, 2018), assessors should 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, assessors should 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 3.7–3.13 of the TR):

- Is the timing of agronomic practices/production processes 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 the 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 3.7–3.13 of the TR, assessors should evaluate if the information provided is unambiguous and sufficient.

If sufficient and unambiguous, assessors should 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 country of origin

The purpose of this section is to identify and list the relevant 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 risk mitigation measures may be required.

The following questions need to be answered to determine whether the two pest lists (Sections 4.1–4.4 of the TR) are complete and correctly classified and if the additional information on the selected relevant pests is provided (Sections 4.4 and Subsections 4.4.1–4.4.11 of the TR):

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

If applicable, assessors should indicate the pest species that are missing from the above list. These species should be further evaluated and considered to be added to Tables 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 according to ISPM 8 (FAO, 1998)?

Assessors should check the reliability of surveillance/monitoring system and results.

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

Assessors should check the reliability of surveillance/monitoring system and results.

- Is the regulatory status (i.e. quarantine pests, regulated non-quarantine pests, non-regulated pest) in the country of origin 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, assessors should conclude whether one or several stages may be associated with the commodity at origin. Assessors should 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 risk mitigation measures?

Assessors should: identify EU regulated pests that may need risk mitigation measures: the pest is present in the country of origin and known to use the plant species or genus of the commodity as host (these species need to be copied to Table 1); create the final table with the list of relevant 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 the 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?

Assessors should check if the information provided is correct and updated: e.g. are 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 origin given according to ISPM 4 (FAO, 1995)?

Assessors should check the reliability of surveillance/monitoring system and results.

- Is the regulatory status in the country of origin provided?
- Is there sufficient evidence given on the association of the pest with the commodity?

Based on the biology and life cycle of the pest, assessors should: conclude whether one or several stages may be associated with the commodity at origin; and check if the EUROPHYT records of interceptions, or information from literature searches, support the statement provided by the applicant.

- Is there sufficient evidence of the impact of the pest?

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 inside and outside the applicant 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*
- records of significant damage, outbreaks and official control measures*
- 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 in the future, they could be reassessed.*

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

Assessors should identify all other pests (not regulated in the EU) that may need risk mitigation measures: e.g. the pest is present in the country of origin, is absent or not widely distributed in the EU, known to use the plant species or genus of the commodity as host and having potential impact in the EU (these species need to be copied to Table 2).

Assessors should 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.

Assessors should indicate and justify any difference compared with Table D2, of the TR.

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

Assessors should provide a summary table (Table 3) with the list of pests that may need risk mitigation measures based on Tables 1 and 2.

- For each of the identified relevant pests listed in Table D3 of the TR, check that the following information is provided (according to Section 4.4 of the TR):

Note that, if additional pests are included in Table 3 (compared with 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. subspecies, pathovar, etc.).
- Geographical distribution of the pest in the country: provide if applicable, pest distributions/ pest-free areas maps for each pest, considering a map as stated in Section 3.10. of the TR as a background layer.
- Prevalence of the pest during the season (e.g. percentage of infested plants/fruit during the different phenological stages indicated in Section 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 pathogen.
- For 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 is 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, snails), describe their association with the commodity.
- Indicate the impact caused by the pest in the country of origin.
- If available provide any pest risk assessments or pest risk analysis already performed on the pest.
- 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 the EU regulated pests, present in the applicant country and known to be associated with the plant species or genus of the commodity

Pest species	Taxonomic information	Pest status in the country of origin	Pest-free area (s) in the country of origin	Evidence and uncertainty on pest status and pest-free area(s)	Regulatory status in the country of origin	Can the pest be associated with the commodity?	Evidence and uncertainty on association with the commodity	Pest for which risk mitigation measures may be required
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>

Table 2: List of pests not regulated in the EU, present in the applicant country and known to be associated with the plant species or genus of the commodity

Pest species	Taxonomic information	Status in the EU (present/absent)	Pest-free area(s) in country of origin	Evidence and uncertainty on pest status and pest-free area(s)	Regulatory status in applicant country	Can the pest be associated with the commodity?	Evidence and uncertainty on association with the commodity	Does the pest have impact in applicant country	Evidence and uncertainty on the level of impact	Pest of potential risk for EU
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>			<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>

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

Pest species associated with the commodity	Regulated pests in EU
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>
	<input type="checkbox"/>

5. Description and assessment of the efficacy of risk mitigation measures

The purpose of this section is to evaluate if the risk mitigation measures described in the dossier are sufficient in order to achieve pest freedom of the consignment for each pest identified in Section 4 (Table 3) of this Guidance.

The following questions need to be answered to evaluate the risk mitigation measures as indicated in Sections 5.1–5.5 of the TR:

- Is the description of the risk 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 regulated 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 of the TR?

Assessors should use the information provided according to Section 4.4.5 (biology of the pests) of the TR and the information above (Section 5.1–5.5 of the TR) for the evaluation of the risk mitigation measures.

Pest freedom is assessed at the consignment level. Pest freedom is defined by the International Plant Protection Convention (ISPM 5, FAO, 2018) 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, 2018).

The assessors should identify for each pest the relevant risk reduction options (RROs) acting on the pest, based on Section 5.1, Tables E1–E4 of the TR and summarise 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, 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								

RRO: Risk reduction options.

SA: Standalone RRO for the pest.

X: RRO is acting on the pest.

As an aid in documenting the evidence, the assessors should use the table format and the values 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. To aid the expert judgement the EFSA Guidance on Expert Knowledge Elicitation (EFSA, 2014) can be used. Table 5 reports an adaptation of the likelihood expressions of EFSA, Scientific Committee (2018; Table 2), which are

appropriate for this application. To distinguish the different classes of probabilities an explanation in terms of number of consignments is given.

The approach that refers to numbers of consignments enables the risk assessor to answer the more quantitative questions, expressed in 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 referring to consignments
Almost certain	99.95–100%	More than 9,995 of 10,000 consignments are on average pest free (Less than 5 of 10,000 are infested; on average at most one of every 2,000 consignments is infested)
Extremely likely	99.90–99.95%	Between 9,990 and 9,995 of 10,000 consignments are on average pest free (Between 5 and 10 of 10,000 are infested; on average at most one of every 1,000 consignments is infested).
Very likely	99.5–99.9%	Between 995 and 999 of 1,000 consignments are on average pest free (Between 1 and 5 of 1,000 are infested; on average at most one of every 200 consignments is infested)
Likely	99.0–99.5%	Between 990 and 995 of 1,000 consignments are on average pest free (Between 5 and 10 of 1,000 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, 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.

Assessors should summarise the results in Table 6.

Table 6: Concluding table

Pest species	Likelihood of pest-freedom	Justification	Key uncertainties
<i>Pest 1</i>			<i>List key uncertainties that affect the final conclusion. If no key uncertainties, insert 'none'</i>
<i>Pest 2</i>			
<i>Pest n</i>			

6. Uncertainty

Assessors should describe in the narrative form the main sources of uncertainty, only when these uncertainties 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 country of origin that may require risk mitigation measures.

The risk mitigation measures indicated in the dossier (as RROs) can achieve for each pest different probabilities of pest-freedom of the commodity. The list of the relevant pest species associated with the commodity and the likelihood of pest-freedom is summarised in Table 6.

8. Recommendations

As with all EFSA guidances, 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 and using the commodity risk assessments.

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Glossary

Commodity pest list	A list of pests present in an area which may be associated with the specific commodity (FAO, 2018)
Measures	Control (of a pest) is defined in ISPM 5 (FAO 2018) 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 RRO that do not directly affect pest abundance.
Pathway	Any means that allows the entry or spread of a pest (FAO, 2018)
Pest categorisation	The process for determining whether a pest has or has not the characteristics of quarantine pest or those of a regulated non-quarantine pest (FAO, 2018).
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 free consignment	Without pests (or specific pest) in numbers or quantities that can be detected by the application of phytosanitary procedures (ISPM 15 – FAO, 2013b).
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, 2018)
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, 2018)
Risk mitigation measures	See definition of Risk Reduction Option
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. In this Guidance the term "Risk mitigation measure" is also used as synonym of Risk reduction option

Abbreviations

EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
ISPM	International Standard for Phytosanitary Measures
PLH	EFSA Panel on Plant Health
RRO	risk reduction option (synonym of Risk mitigation measure)
SA	Standalone measure
TR	Technical Report

Appendix A – List of potential pests not further assessed

This appendix lists all the potential 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.