



Información requerida en los dossiers para solicitar la importación de vegetales de alto riesgo

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TECHNICAL REPORT

APPROVED: 26 October 2018

doi:10.2903/sp.efsa.2018.EN-1492

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

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Abstract

Article 42 of the new Plant Health Law (Regulation (EU) 2016/2031 on protective measures against pests of plants), introduce a concept of "high risk plants, plant products and other objects" in relation



INTRODUCCIÓN

El objetivo del documento es facilitar que los países solicitantes puedan proporcionar la información requerida sobre:

- 1) la **mercancía** (caracterización del producto y la descripción de los procesos de producción)
- 2) Las **plagas potencialmente asociadas** con la mercancía en el país potencial exportador
- 3) la **información sobre las medidas de mitigación y las inspecciones**

Propocionar instrucciones sobre cómo presentar la información



PROCEDIMIENTO

El expediente técnico debe enviarse a la Comisión Europea.

La Comisión Europea lo recepcionará y examinará su contenido y puede solicitar al solicitante información o aclaraciones,

Una vez la Comisión Europea concluye que se cumplen los requisitos, enviará el expediente a la EFSA.



PROCEDIMIENTO

EFSA verificará el dossier y podrá pedir información adicional y/o aclaraciones

Una vez verificado procederá a hacer la evaluación del riesgo



PROCEDIMIENTO

Si los dossiers son remitidos en inglés el tiempo se acortará, frente a si se envían en otra lengua oficial de la Unión.

Deberán ser legibles y el check list que se proporciona en el “Apéndice A”, debe estar en la portada del dossier



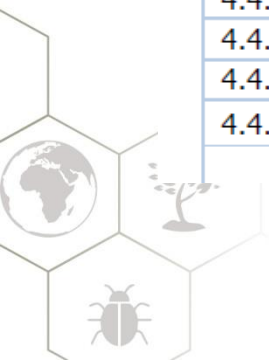
INFORMACIÓN EN LA PRIMERA PÁGINA

	Provided	Not provided	EFSA agrees	EFSA comments
3 COMMODITY DATA				
3.1 Taxonomic information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.2 Plants for planting specification (ISPM 36 – FAO, 2012)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.3 Seeds specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.4 Fruit and vegetable specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.5 Wood specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.6 Other commodities specification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.7 Production period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.8 Phytosanitary status and management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.9 Intended use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.10 Production area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.11 Separation of production areas				
3.12 Climatic classification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3.13 Pictures and description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



INFORMACIÓN EN LA PRIMERA PÁGINA

4 PESTS LIST				
4.1 List of all the pests potentially associated with the commodity plant species or genus in the exporting country	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.2 List of EU regulated pests (Table D1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.3 List of non-regulated pests (Table D2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4 Summary table of relevant pests associated with the commodity (Table D3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Details of the literature search according to Appendix B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
OPTIONAL- Additional information or evidence (e	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Data for each pest of Table D3				
4.4.1 Scientific name	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.2 Taxonomic classification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.3 Geographical distribution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.4 Prevalence of the pest during the season	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.5 Biology of the pest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.6 Main hosts				
4.4.7 Arthropods and nematodes description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.8 Pathogens description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.9 Other living organisms description	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.10 Impact of the pest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4.11 Information from other pest risk assessment(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



INFORMACIÓN EN LA PRIMERA PÁGINA

5 DATA ON PHYTOSANITARY MITIGATION MEASURES				
5.1 Description of phytosanitary mitigation measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.2 Description of phytosanitary regulations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.3 Description of surveillance and monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.4 Trade volumes and frequencies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5.5 Description of post-harvest procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Appendix E tables				



INFORMACIÓN EN LA PRIMERA PÁGINA

Table E1 - Details of pesticide treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E2 - Details of other treatments/measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E3 - Calendar including relevant crop phenology data, pest presence in the crop and timing of treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Table E4 - Assessment of the overall efficacy of phytosanitary mitigation measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



RESPONSABILIDAD

Con independencia de los controles que pueda hacer EFSA, el solicitante tiene la plena responsabilidad de la integridad, exactitud y corrección de los datos facilitados.

En caso de que se requiera información adicional, EFSA puede ponerse en contacto con el solicitante.

La compilación de las listas de plagas debe estar respaldada por referencias bibliográficas.



CONFIDENCIALIDAD

Se deberá indicar la parte del dossier que se considera confidencial y los motivos, por ejemplo un tratamiento...



CONFIDENCIALIDAD

De conformidad con el artículo 38 del Reglamento (CE) 178/2002, **los dictámenes de la EFSA, así como los antecedentes de información** en la que se basen los dictámenes, excluyendo la información confidencial, **se pondrá a disposición al público.**

Según la misma disposición, todos los documentos en poder de la EFSA están sujetos al Reglamento (CE) No 1049/2001 sobre el **acceso del público a los documentos en poder de las instituciones de la UE.**

Además, la información en poder de EFSA está sujeta al Reglamento (CE) no 1367/20065 sobre la aplicación de la disposiciones del Convenio de Aarhus sobre el **acceso a la información, la participación del público en la toma de decisiones y el acceso a la justicia en materia medioambiental a las instituciones y organismos comunitarios.**



ACCESO PÚBLICO A LA INFORMACIÓN

Todo lo que no se declare como confidencial podrá tener libre acceso público



DATOS DE LA MERCANCIA

3.1 Proporcione nombre científico (género y especie), sinónimos y, en su caso, nombre(s) común(es) y clasificación taxonómica pertinente, incluyendo cultivar o variedad, si corresponde, del (producto) que se importará a la UE.

www.theplantlist.org



DATOS DE LA MERCANCIA

3.2 En el caso de las plantas destinadas a la plantación (incluidas las semillas) indicar el tipo y la edad de las plantas y el condiciones de crecimiento, tal como se definen en el Anexo 1 de la NIMF 36 (FAO, 2012) (reportado en el Apéndice C de este documento). Especificar el cultivo, la descripción del cultivar de los productos o subproductos de la planta origen que se importará a la UE. Describa los medios de cultivo utilizados en la producción y en el de exportación según ISPM 40 (FAO, 2017a).

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?



DATOS DE LA MERCANCIA

Appendix C – Classification of plants for planting

1. meristem tissue culture
2. in vitro culture
3. budwood/graftwood
4. unrooted cuttings
5. rooted cuttings
6. root fragments, root cuttings, rootlets or rhizomes
7. bulbs and tubers
8. bare root plants
9. rooted plants in pots



DATOS DE LA MERCANCIA

Appendix C – Classification of plants for planting

Examples of growing conditions ranked from lowest to highest pest risk:

1. growth chamber
2. greenhouse
3. screen house
4. field grown in containers (pots, tubs etc.)
5. field grown
6. plants collected from the wild



DATOS DE LA MERCANCIA

3.3 Si procede, indique si la planta se cultiva a partir de semillas certificadas y/o en un vivero. En el caso de las semillas, especifique el tipo de certificación en relación con la ausencia de la plagas.



DATOS DE LA MERCANCIA

3.4 En el caso de las frutas o hortalizas, describa la parte/s de la planta, así como la presentación (es decir, la presencia de hojas, sépalos o frutos, etc.).



DATOS DE LA MERCANCIA

3.5 En el caso de la madera, describa el tipo de madera según ISPM 39 (FAO, 2017b) (es decir, tipo de mercancía, nivel de procesamiento, presencia/ausencia de corteza, etc.)



DATOS DE LA MERCANCIA

3.6 En el caso de otros productos básicos, proporcione descripciones detalladas.



DATOS DE LA MERCANCIA

3.7 Indique el período del año en que se produce el producto y la fenología del cultivo (incluidos los períodos de siembra/plantación, floración, fructificación y cosecha).



DATOS DE LA MERCANCIA

3.8 Describe the general sanitary status and phytosanitary management of the crop in the production area designated for export.

If there are differences with other production areas within the country, describe these differences and the reasons for them.



DATOS DE LA MERCANCIA

3.9 Indicate the intended use of the commodity (i.e., direct distribution to final consumers, repacking for consumption, propagation, milling, transformation, etc.).



DATOS DE LA MERCANCIA

3.10 Include a map of the exporting country highlighting the production areas and the production areas designated for export.



DATOS DE LA MERCANCIA

3.11 Indicate how you ensure separation between production areas designated for export and other production areas, if adjacent to the first ones.



DATOS DE LA MERCANCIA

3.12 Provide the Köppen-Geiger climate classification (sub-group level) relevant for the production areas (<http://koeppen-geiger.vu-wien.ac.at/>)

3.13 Attach colour pictures with a brief description of the commodity intended to be exported into EU and of the main stages/steps of production, handling and shipping processes.



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.1 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country supported by evidence (Appendix B).

Sources of information

Developing search strategies

“Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety” (Glanville et al., 2014)

Reporting the search in the technical dossier submitted by third countries



BASES DE DATOS

For database searches, the following information should be reported for each result:

- The name of the database and the service provider used;
- The URL of the database (internet address);
- The justification for choosing the database:
- The date on which the search was conducted;



BASES DE DATOS

- The date of the most recent update of the bibliographic database (when available);
- The date span of the search;
- Any limits applied to the search (e.g. publication types)
- The complete search strategy or strategies used (as run in the database), and the number of results retrieved.



WEBSITES

- a) For websites or tables of contents of journals:
- The name of the resource (i.e. website name, journal name in case of searching in a specific table of content).
 - The URL of the resource (internet address);
 - The justification for choosing the website or journal:



WEBSITES

- The date on which the search was conducted, and the date range of the search, or the dates, volumes and issues searched in the case of table of contents.
- The method of searching (e.g. browsing, using the search engine included in the website, scanning in the case of tables of contents).
- The search terms used to search, and the number of relevant records retrieved.



LISTA DE REFERENCIAS

b) For reference lists:

- The bibliographic details of the documents whose reference lists were scanned;
- The number of relevant bibliographic references retrieved.



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.2 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country **that are EU regulated** and provide information as indicated in Table D1 (Appendix D).



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.3 List all the pests potentially associated with the plants species or genus of the commodity in the exporting country **that are not regulated in the EU**, and for these pests provide information as indicated in Table D2 (Appendix D).



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4 For each pest listed in the summary Table D3 (see Appendix D) submit the following information (substantiate this information with the appropriate references, which should be provided together with the technical dossier):

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



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4.2 Taxonomic classification, including at least class, order, family, genus, species and information below species level if relevant (e.g. sub-species, pathovar, etc.).

4.4.3 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 as background layer.



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4.4 Prevalence of the pest during the season (e.g. percentage of infested plants/fruit during the different phenological stages indicated in paragraph 3.7).

4.4.5 Relevant biological characteristics (i.e., life cycle, association with the pathway, thermal requirements) of the pest.

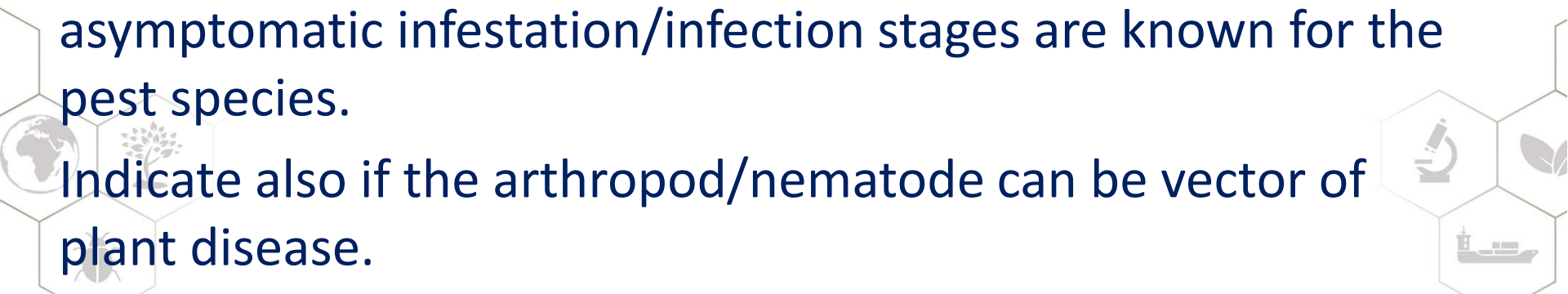


Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4.6 Main hosts of the pest, including alternate hosts if relevant.

4.4.7 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 arthropod/nematode can be vector of plant disease.



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4.8 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.

4.4.9 In the case of any other living organism (e.g. parasitic plants), describe their association with the commodity.



Identificación de todas las plagas potencialmente asociadas con la mercancía

4.4.10 Indicate the impact caused by the pest on the commodity and/or relevant hosts other than the commodity.

4.4.11 If available provide pest risk assessment(s).



Identificación de todas las plagas potencialmente asociadas con la mercancía

Please note that the applicant is invited to submit any additional information or evidence that is considered useful in supporting the risk assessment (e.g. list of all pests known to use the plant species or genus of the commodity as hosts at the global level, records of interceptions on the exported commodity, etc.).



Identificación de todas las plagas potencialmente asociadas con la mercancía

Please also note that EFSA reserves the right to request the information referred to in points from 4.4.1 to 4.4.11 and in section 5, also for other pests than those listed in Table D3 (e.g., other pests listed in Table D1 and/or Table D2 or other pests found by EFSA in its review).



Data on phytosanitary mitigation measures

5.1 Describe phytosanitary mitigation measures (including the ones intended to be applied when exporting the commodity into the EU) of the commodity and their effectiveness, supported by evidences (i.e. probit 9, average survival time, etc.) following Appendix E.



Data on phytosanitary mitigation measures

5.2 Indicate phytosanitary regulations and inspection systems related to the crop of interest or associated quarantine pests in the country of origin.



Data on phytosanitary mitigation measures

5.3 Describe surveillance and monitoring systems of the pests associated with the commodity as detailed as possible (e.g. sampling and inspection strategies, frequencies, intensities, diagnostic protocols, etc.).

5.4 Indicate volume, frequencies and seasonal timing planned for export to the EU.



Data on phytosanitary mitigation measures

5.5 Describe the post-harvest processes and transport system (from farm to processing and from processing to point of export), including type of packaging material, size of packaging, shipping capacity. Likewise, indicate temperature and relative humidity of the containers, if applicable.

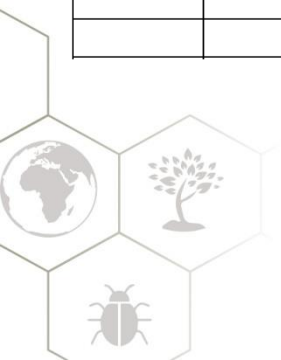


Appendix D – Steps to select pests that may require phytosanitary mitigation measures



List of EU regulated pests, present in the applicant third country and known to use the plant species or genus of the commodity as 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
						<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"/>



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

Table D2 – 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)	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 uncertainty on association with the commodity	Does the pest have impact in applicant third country	Evidence and uncertainty on the level of impact ⁵	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"/>



Table D3

Table D3 – Summary table of pest species, present in the applicant third country, associated with the commodity and that may have a potential risk for EU for which technical data will be requested in Appendix E.

For the pest species associated to the commodity and that may have a potential risk for EU (selected from tables D1 and D2).provide the following information:

- **Pest species** (Latin name)
- **Regulated pest in EU:** indicate if the pest is a quarantine pest in the EU according to the current plant health legislation⁸.

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"/>

For each of the pests in Table D3 provide the data indicated in point 4.4 of this document.



Evidence to support the assessment of the efficacy of phytosanitary mitigation measures

Appendix E – Evidence to support the assessment of the efficacy of phytosanitary mitigation measures

Applicant should provide, using Tables E1 and E2, the technical data supporting the evaluation of the efficacy of the phytosanitary mitigation measures for each of the pests listed in Table D3. Please provide, using Table E3 as template (this template may need to be adapted for different commodities), a calendar where pest presence and mitigation measure/s are presented. It is essential that the estimation of efficacy provided by the applicant is supported by scientific and technical evidence (i.e., probit 9, average survival time, etc.).

Then use Table E4 for summarising the overall efficacy for each of the pests listed in Table D3, emphasizing the likelihood of pest-freedom of the commodity and its associated uncertainties. Include a clear justification and provide supporting evidence where appropriate.

Table E1 - Details of pesticide treatment

Pesticide/s used (active substance/s)	Scientific name of the target pest species	Targeted life stage of the pests	Timing of the treatment ⁹	Dose in kg/ha used for each treatment ¹⁰	Use the information reported in the officially approved label	Restrictions if any	Estimation of efficacy ¹¹	Evidence for the efficacy ¹²
					<ul style="list-style-type: none"> • Application type • Application time • Time period for which a treatment remains effective • Life stages affected 			
					•			



Table E2 - Details of other mitigation measures (other than pesticides)

Measures used ¹³	Scientific name of the target pest species	Targeted life stage of the pests	Timing of the treatment ¹⁴	Details on the measure used	Reference to a protocol standards	Restrictions if any	Estimation of efficacy ¹⁵	Evidence for the efficacy ¹⁶
				e.g. temperature	e.g. ISPM 15 (FAO, 2018a)			
					•			
					•			



Table E3 - Example of a calendar including relevant crop phenology data, pest presence in the crop and timing of treatment

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Crop phenology			Bloom					Mature fruit				
Presence of target stage	A d u l t s											
Treatments							Mass trapping					
	Sterile Insect Technique											
							Pesticide X					
	Cultural/Biological control: cover crops											
	Sanitation									Sanitation		



Table E4 - Assessment of the overall efficacy of phytosanitary mitigation measures (combination of pesticide and non-pesticide measures).

Pest species	Estimation of the overall efficacy of phytosanitary mitigation measures ¹⁷	Associated uncertainties	Justification (reasoning and evidence) for the overall efficacy ¹⁸



ANNEXES

Annex A – Member States’ comments on the draft EFSA Technical Report

Annex B – List of elements of the technical dossier for which confidentiality treatment is requested by the applicant



Muchas gracias por vuestra atención

