

## STATEMENT

# Response to a report published by the Office for Risk Assessment & Research of the Netherlands Food and Product Safety Authority on three EFSA quantitative pest risk assessments

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The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>.

### Abstract

A report commenting on three quantitative pest risk assessments (qPRA) of the EFSA PLH Panel (Panel) was published in November 2025 by the Office for Risk Assessment & Research (BuRO) of the Netherlands Food and Product Safety Authority. In that report, the approaches applied by the Panel in three qPRA were narratively scrutinised against an unpublished protocol. According to the conclusions of the BuRO's report, all three qPRA approaches were methodologically valid and appropriate in substance. However, several assumptions made by the Panel in its assessments were debated and individual values of model parameters were questioned and/or replaced by BuRO calculations. This Panel statement responds to the specific comments, mathematically reviews the calculations in the BuRO's report and highlights how quantitative assessments under uncertainty may slightly differ in their output values when different risk assessors find different consensus interpretations of available background evidence. Some quantitative recalculations by BuRO required mathematical correction. Other recalculations depended on alternative ad hoc assumptions or parameter interpretations that the Panel does not consider sufficiently substantiated to replace those used in the assessments. Therefore, the conclusions of the three qPRA by the Panel remain unchanged. The Panel proposes recommendations to facilitate future commenting by external assessors on Panel outputs.

### KEYWORDS

*Citripestis sagittiferella*, *Elasmopalpus lignosellus*, quantitative pest risk assessment, *Thaumatotibia leucotreta*

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## CONTENTS

Abstract.....	1
1. Introduction .....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
1.1.1. Background .....	4
1.1.2. Terms of Reference.....	4
1.2. Interpretation of the Terms of Reference .....	4
1.3. General remarks .....	4
2. Data and Methodologies.....	5
2.1. Data.....	5
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. <i>Thaumatotibia leucotreta</i> .....	6
3.1.1. BuRO conclusion on the general assessment .....	6
3.1.2. BuRO conclusion on uncertainties.....	6
3.1.3. BuRO conclusion on general parameter estimation.....	7
3.1.4. BuRO conclusion on value of the infestation rate .....	7
3.1.5. BuRO conclusion on parametrisation of vase life.....	8
3.1.6. BuRO conclusion on parametrisation of trade volume .....	8
3.1.7. BuRO conclusion on the proportion of mated females.....	9
3.1.8. BuRO conclusion on the synchrony of life stages.....	10
3.1.9. BuRO conclusion on the infestation rate applied in the risk pathway model.....	11
3.1.10. BuRO conclusion on the comparison of risk estimates with reported outbreaks .....	11
3.1.11. BuRO conclusion on the adequacy of the title of the EFSA output.....	12
3.2. <i>Citripestis sagittiferella</i> .....	12
3.2.1. BuRO conclusion on the general assessment .....	12
3.2.2. BuRO conclusion on the infested volume at entry.....	13
3.2.3. BuRO conclusion on the number of infested transfer units.....	13
3.2.4. BuRO conclusion on the parameter dependencies .....	14
3.2.5. BuRO conclusion on the transfer outside of orchards .....	14
3.2.6. BuRO conclusion on the uncertainties .....	15
3.2.7. BuRO conclusion on the trend of trade volume.....	15
3.2.8. BuRO conclusion on the comparison of risk estimates and interception rates .....	15
3.2.9. BuRO conclusion on the details of transfer probability.....	16
3.2.10. BuRO conclusion on the probability of establishment.....	16
3.2.11. BuRO conclusion on the comparison of risk estimates with reported outbreaks .....	16
3.2.12. BuRO conclusion on the risk assessment terminology.....	17
3.3. <i>Elasmopalpus lignosellus</i> .....	17
3.3.1. BuRO conclusion on the general assessment .....	17
3.3.2. BuRO conclusion on the parameter 'survival of larvae' .....	18
3.3.3. BuRO conclusion on the parameter 'infestation rate of asparagus spears' .....	19
3.3.4. BuRO conclusion on the parameter 'mating rate' .....	21
3.3.5. BuRO conclusion on the parameter 'trade volume' .....	21
3.3.6. BuRO conclusion on the uncertainty assessment .....	23
3.3.7. BuRO conclusion on the final output.....	23
3.3.8. BuRO conclusion on the definition of 'transfer' .....	24
3.3.9. BuRO recalculation of the introduction model .....	25
3.4. Other statistical considerations .....	25

3.4.1. BuRO conclusion on the choice of fitted distributions.....	25
3.4.2. BuRO conclusion on the treatment of probabilities as proportions.....	26
4. Conclusions.....	26
5. Recommendation.....	27
Glossary .....	27
Acknowledgements .....	28
Requestor .....	28
Question number.....	28
Copyright for non-EFSA content.....	28
Panel members .....	28
Generic map disclaimer .....	28
References.....	28

## 1 | INTRODUCTION

### 1.1 | Background and Terms of Reference as provided by the requestor

#### 1.1.1 | Background

The EFSA Plant Health (PLH) Panel applies a quantitative pest risk assessment (qPRA) methodology (EFSA PLH Panel, 2018, 2024).

Previous mandates from EC SANTE to conduct pest risk assessments (Mandate number M-2021-00027) resulted in 12 qPRAs, applying the qPRA guidance, among which qPRAs on *Citripestis sagittiferella* (EFSA PLH Panel, 2023b) and *Elasmopalpus lignosellus* (EFSA PLH Panel, 2023c). In addition, a mandate to provide a scientific opinion (Mandate number M-2022-00007) on the probability of introduction of *Thaumatotibia leucotreta* with import of cut roses also applied the qPRA guidance (EFSA PLH Panel, 2023a).

In November 2025, a report by the Office for Risk Assessment & Research (BuRO) of the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit) (NVWA) titled "Evaluation of Three Assessments from the EFSA Panel on Plant Health Quantifying the Probability of Introduction of a Plant Pest into the European Union" (BuRO, 2025) provided feedback on some elements of the above-mentioned three EFSA's PLH Panel qPRAs.

#### 1.1.2 | Terms of Reference

This self-task mandate aims to deliver an EFSA PLH Panel statement in reply to the above-mentioned BuRO report. The EFSA PLH Panel statement will review the BuRO report and respond to the comments on methodological aspects of the three qPRAs.

The EFSA PLH Panel statement will be delivered at latest by 30 April 2026.

### 1.2 | Interpretation of the Terms of Reference

This statement of the EFSA PLH Panel (abbreviated hereafter as the Panel) responds to the BuRO (2025) report on the three above-mentioned Panel scientific opinions (EFSA PLH Panel, 2023a, 2023b, 2023c). For clarity purpose, and to avoid repetitions, the statement is organised as follows:

- A general remark on the approach of BuRO (2025) is provided in Section 1.3 below.
- A point-by-point reply to the conclusions of BuRO (2025) is then provided in the main text of the statement.
- When critical points are not covered in the conclusions of BuRO (2025), those are added to main text with the reply.

### 1.3 | General remarks

The Panel scientific opinion on the 'Assessment of the probability of introduction of *Thaumatotibia leucotreta* into the European Union with import of cut roses' was presented at the Standing Committee on Plants, Animals, Food and Feed (Plant Health Section) meeting of 17–18 October 2023 and at the 20th meeting of the EFSA Scientific Network for Risk Assessment in Plant Health on 5–7 December 2023. During these meetings and related email exchanges, in 2023, EFSA responded to comments from the Netherlands Food and Consumer Product Safety Authority (NVWA) representatives and offered a meeting to provide further clarifications and address questions. NVWA however declined the meeting, because of their insufficient capacity at that time to review the EFSA opinion in detail. Replies to comments by email exchanges were also provided to NVWA on the Panel scientific opinion on 'Risk assessment of *Citripestis sagittiferella* for the EU' (EFSA PLH Panel, 2023b).

The Panel notes that the open access, transparent and quantitative methodology applied in its risk assessments allows for review and update. Updating a qPRA in response to newer data is often beneficial and can foster our understanding in the plant health area. In the replies below, the Panel addresses instances where the BuRO report criticises the EFSA qPRAs on the basis of information that was not available at the time of the original assessments or that is not publicly accessible. The Panel considers it methodologically incorrect to criticise an assessment due to data that was not available at the time of writing or that is not publicly accessible. This can create unsubstantiated mistrust in qPRAs. The Panel is well aware that 'EFSA outputs directly influence the EU Plant health legislation' (as stated by BuRO (2025) report) and conducts its assessments with scientific rigour and based on available evidence.

Scientific review is an important component of the assessment process and is most effective when it is grounded in clear, well-substantiated reasoning and methodological consistency. Contributions that adhere to these principles facilitate constructive dialogue and support the robustness of the scientific exchange. In the context of a risk assessment mandate, an assessment must be delivered despite acknowledged data gaps and uncertainties, including unknown factors. Peer-review contributions can be particularly valuable when they consider the assessment framework in its entirety and, where appropriate, put forward concrete and feasible suggestions that could be integrated within the existing methodology.

Such an approach helps to ensure that comments contribute meaningfully to the ongoing development and refinement of the assessment.

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The document is based on the following literature which is published and openly accessible.

- EFSA PLH Panel (EFSA Panel on Plant Health), Bragard, C., Baptista, P., Chatzivassiliou, E., Di Serio, F., Gonthier, P., Jaques Miret, J. A., Fejer Justesen, A., MacLeod, A., Magnusson, C. S., Navas-Cortes, J. A., Parnell, S., Potting, R., Reignault, P. L., Stefani, E., Thulke, H.-H., Vicent Civera, A., Van der Werf, W., Yuen, J., ... Milonas, P. (2023a). Assessment of the probability of introduction of *Thaumatotibia leucotreta* into the European Union with import of cut roses. *EFSA Journal*, 21(10), 1–166. <https://doi.org/10.2903/j.efsa.2023.8107>
- EFSA PLH Panel (EFSA Panel on Plant Health), Bragard, C., Baptista, P., Chatzivassiliou, E., Di Serio, F., Gonthier, P., Jaques Miret, J. A., Justesen, A. F., MacLeod, A., Magnusson, C. S., Milonas, P., Navas-Cortes, J. A., Parnell, S., Potting, R., Reignault, P. L., Stefani, E., Thulke, H.-H., van der Werf, W., Yuen, J., ... Vicent Civera, A. (2023b). Scientific Opinion on the risk assessment of *Citripestis sagittiferella* for the EU. *EFSA Journal*, 21(2), 7838. <https://doi.org/10.2903/j.efsa.2023.7838>
- EFSA PLH Panel (EFSA Panel on Plant Health), Bragard, C., Baptista, P., Chatzivassiliou, E., Di Serio, F., Gonthier, P., Jaques Miret, J. A., Justesen, A. F., MacLeod, A., Magnusson, C. S., Milonas, P., Navas-Cortes, J. A., Parnell, S., Potting, R., Reignault, P. L., Stefani, E., Thulke, H.-H., Vicent Civera, A., Yuen, J., ... van der Werf, W. (2023c). Scientific Opinion on the pest risk assessment of *Elasmopalpus lignosellus* for the European Union. *EFSA Journal*, 21(5), 8004. <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8004>
- BuRO. (2025). Evaluation of three assessments from the EFSA Panel on Plant Health quantifying the probability of introduction of a pest into the European Union. Office for Risk Assessment & Research (BuRO) Netherlands Food and Consumer Product Safety Authority, 79 pp. <https://www.nvwa.nl/documenten/organisatie/buro/publicatie/evaluation-three-assessments-efsa-plant-health-probability-introduction-pest-eu>

Other data were the original download files from EUROSTAT as used during the preparation of the risk assessments. Updated data were only occasionally considered for consistency of the discussion.

### 2.2 | Methodologies

The Panel developed an ad hoc methodology for this statement to ensure that all elements of the argumentation presented in the BuRO (2025) report were adequately addressed. This approach was necessary owing to the unstructured format of the BuRO (2025) report which did not follow a standard format of published scientific information. Instead, the report presented notes, critiques and alternative calculations throughout the opinion document in a dispersed manner, making the response process particularly time-consuming.

The ad hoc methodology applied by the Panel is as follows:

Step 1. The Panel reviewed the BuRO report paragraph by paragraph to develop specific comments. This included determining whether it was necessary to re-examine the original data or model calculations, both of which are accessible under EFSA's transparency practice.

Step 2. The Panel then selected the methodological critique ('errors and inconsistencies') and calculations in BuRO's report proposed as potential refinement of the outputs of the risk assessments.

Step 3. The Panel provided formal point-by-point responses to the conclusions of BuRO's report and, if purposeful, detailed argumentations in reply to other sections of the report, once per opinion document.

Step 4. The panel drafted recommendation statements to facilitate future commenting of external assessors on the EFSA output.

## 3 | ASSESSMENT

The assessment is organised in three sections, one per each EFSA scientific opinion i.e. Section 3.1 on *T. leucotreta* (EFSA PLH Panel, 2023a), Section 3.2 on *C. sagittiferella* (EFSA PLH Panel, 2023b) and Section 3.3. on *E. lignosellus* (EFSA PLH Panel, 2023c). Each conclusion stated in the BuRO's report is quoted from the original document and a concluding reply by the Panel and, where useful, a more detailed elaboration of the argumentation is provided. This is intended to enable non-involved readers to bridge between the two sources i.e. the EFSA scientific opinion and BuRO's report.

### 3.1 | *Thaumatotibia leucotreta*

The Panel scientific opinion about the false codling moth *T. leucotreta* published in 2023 (EFSA PLH Panel, 2023a) addressed the question whether the import of cut roses would constitute a pathway for pest introduction. To address this question, a partial risk assessment was performed to estimate the probability of importation into and distribution within the EU of this pest through the cut roses import trade, and its transfer until potential founder populations in EU NUTS2<sup>1</sup> regions suitable for pest establishment.

This section elaborates on the conclusions of the report published by BuRO (2025) on the evaluation of this Panel scientific opinion.

#### 3.1.1 | BuRO conclusion on the general assessment

Item A	Quoted text from BuRO document
<b>Structure of model</b>	<i>"The model to estimate the number of adults that emerges from imported cut roses was considered accurate..."</i>

##### Reply by the Panel

The Panel thanks BuRO for the critical evaluation of the qPRA approach and recognises the appreciation of its model design.

#### 3.1.2 | BuRO conclusion on uncertainties

Item B	Quoted text from BuRO document
<b>Uncertainties</b>	<i>"Uncertainties were addressed and clearly expressed in the parameter estimates and final output of the model. However, uncertainty concerning the proportion of mated females for every emerging adult was not accounted for."</i>

##### Reply by the Panel

The assumptions used in the estimation of the proportion of mated females for every emerging adult are explicitly mentioned along with the supporting data (see Detailed argumentation below) and affect the downstream uncertainty of the results. Therefore, the uncertainties associated with this factor are already transparent, including their quantitative effect on the final output.

##### Detailed response argumentation

The data input to the calculation of mated females per emerging adult were presented (EFSA PLH Panel, 2023a, p. 10–11) with the related uncertainty. This uncertainty is reflected in the model components addressing clustering of pest specimens in cut rose consignments, the likelihood of combining adult pest individuals in the final transfer unit (10 stems bunches), and the combinatory chance event that under these minimum two individuals a female can meet a male. The stochastic realisation brought the uncertainty downstream into the very final output and there it was accounted for when interpreting the outcome.

EFSA PLH Panel (2023a) highlighted the need to reduce uncertainties in future assessments by recommending data collection and research on the following dimensions:

1. the ecology and biology of *T. leucotreta* in its natural environment and in cut rose production in Eastern Africa;
2. the level of infestation and clustering of *T. leucotreta* in the cut roses consignments;
3. the level of effectiveness of the export and import border inspections in detecting the different life stages of *T. leucotreta* in cut roses;
4. the actual waste management processes at NUTS2 level in the EU, including the proportion of private composting; and
5. the timing between the initial waste disposal and the waste treatment.

Items 2, 4 and 5 are uncertainties explicitly linked with the output of the proportion of mated females for every emerging adult.

<sup>1</sup>NUTS=Nomenclature of territorial units for statistics. See <https://ec.europa.eu/eurostat/web/nuts>.

### 3.1.3 | BuRO conclusion on general parameter estimation

Item C	Quoted text from BuRO document
<b>Parameter specification</b>	<i>"The parameter estimates were generally considered to be sufficiently justified taking into account that the available information is generally limited."</i>

#### Reply by the Panel

The Panel thanks BuRO for the critical evaluation of the PRA approach and recognises the appreciation of the model parameterisation efforts.

### 3.1.4 | BuRO conclusion on value of the infestation rate

Item C.1	Quoted text from BuRO document
<b>Parameter specification -infestation rate</b>	<i>"However, the following errors or inconsistencies were found: The <b>estimated infestation rate</b> of cut roses (proportion of infested roses), based on the interception data, was considered too high leading to a considerable overestimation of the number of emerging adults. This overestimation was mainly due to the method used to calculate the <b>infestation rate of inspected consignments using interception data, which was deemed inaccurate</b>. The Panel calculated a higher infestation rate for consignments of which samples had been found non-infested than for consignments that had been found infested. Assuming the same infestation rate for all consignments BuRO calculated an infestation rate that was 98 times lower and considered this a better estimate of the actual infestation rate."</i>

#### Reply by the Panel

This item could cause the only influential change to EFSA PLH Panel (2023a), as a reduction in the infestation rate of the imported roses would reduce the quantitative level of pest burden of the proposed pathway. However, it will not change the conclusion of the opinion that the import of cut roses constitutes a pathway.

Unfortunately, BuRO's argument that errors and inconsistencies were identified in the estimation of the infestation rate of cut roses, and that the parameter should be 98 times lower – was difficult to substantiate mathematically from the report. None of the detailed recalculations supporting this reduction were incorporated into the conclusions, aligned with the assumptions in EFSA PLH Panel (2023a) or clearly identified as the preferred estimate.

EFSA estimated the infestation rate of inspected consignments depending on the result of the inspection, namely the number of specimens found in the sample (from 0 to 3 specimens). Additionally, the sample size was used to describe the precision of the estimation and the remaining uncertainty of the infestation rate. The average infestation rate increases for a sample size of 400 roses from 0.4% for no findings, to 0.6% (1 specimen), 0.8% (2 specimens) and 1.1% for 3 specimens (EFSA PLH Panel, 2023a, Table A.79 for the uncertainty distributions).

The alternative proposal of BuRO (2025, p. 18) considers neither the different infestation levels of the individual consignments, nor the uncertainties related to testing a limited number of roses from the consignment. Implicitly, it assumes that a positive sample is only contaminated with one specimen and no finding in the sample is equal to no specimen in the whole consignment. Both assumptions are wrong and reducing the estimated infestation rate finally by two orders of magnitude.

In fact, the clustering of specimens in the limited samples increases the possibility of the females to find a mating partner close by, which is neglected by BuRO. They even show that their low infestation rate would not reproduce the observed frequencies of multiple specimens at inspection (BuRO, 2025, Table 6). Instead of questioning their assumption of an equal infestation rate for all consignments, they claim that the sampling strategy is not random and restricted to only a 'limited number of boxes' (BuRO, 2025, p. 19). Following this line (that the infestation is low and concentrated in few boxes of a consignment) would imply that the control strategy has a high likelihood of undetected interceptions (false negative results), which is not considered by BuRO.

The Panel therefore finds insufficient justification in the BuRO report to revise this parameter and retains the estimate used in its scientific opinion.

#### Detailed response argumentation

The methodology of parameterising the infestation rate of cut roses in consignments arriving in the EU is detailed in Annex A (section A7). The estimation of the infestation rate followed a semi-formal expert knowledge elicitation (EKE) protocol, where the available data and evidence were considered by the experts including the interception data. Limitations of the evidence base were identified, listed as possible uncertainties and used to construct scenarios for the lower and upper limit of the infestation rate (credibility range). The experts were then asked to weigh the available evidence and judge on the median and inter-quartile range of the uncertainty distribution. The process is described in the EFSA guidance on EKE (EFSA, 2014) and uncertainty assessments (EFSA Scientific Committee, 2018a). The comprehensive interpretation of data and evidence during the EKE lowered the value derived from the interception data.

BuRO proposes an even lower value for the model parameter infestation rate of cut roses and presents alternative downstream calculations into a lowered final risk estimate i.e. the number of potential founder populations in terms of mated females able to escape waste treatment. However, no changes were made to the data input.

The Panel reconsidered all the calculation steps documented in its opinion to find the complained alleged 'errors or inconsistencies' identified by BuRO. However, no errors or inconsistencies were found. In fact, assuming for all consignments an equal infestation rate of 0.0000225, which BuRO considered a better estimate of parameter, makes the observed patterns of infestation at the border inspection implausible. However, the Panel considers valid alignment with observational patterns as necessary precondition for model calibrations and interpretation of model output.

Assuming an infestation rate of 0.0000225 (BuRO); and stochastically inspecting 20,967 times 400 roses (observed data), would result in the following expected distribution ( $n = 20,967, p = \text{Binomial}(k|400, 0.0000225)$ ) of interceptions which is not aligned to the reported data (Fisher exact test  $2 \times 3, p < 0.0001$ ). This means that it would be impossible to see 18 samples with 400 roses and three specimen interceptions (Table 1).

**TABLE 1** Hypothesis testing of the validity of the infestation rate BuRO proposed based on interception data.

Number of intercepted specimens	$k=3$	$k=2$	$k=1$
Expected counts when assuming the infestation rate proposed by BuRO (2025)	0	1	187
Observed numbers in inspection data	18	32	167

Therefore, the Panel does not find sufficient guidance in the BuRO report on how to lower the questioned model parameter while remaining consistent with the available observational evidence. The Panel therefore recommends retaining the opinion EKE estimate of infestation when calculating the burden associated with the cut rose pathway into the EU. The Panel does not assume a homogeneous infestation rate through all consignments entering the EU.

### 3.1.5 | BuRO conclusion on parametrisation of vase life

Item C.2	Quoted text from BuRO document
<b>Parameter specification – vase life</b>	<i>"A longer vase life was assumed for the imported cut roses than could be expected based on information provided in the qPRA. Using an overestimate of vase life leads to an overestimate of the number of emerging adults."</i>

#### Reply by the Panel

The BuRO report does not state which assumption regarding vase life in the estimation of the Panel is inadequate. Furthermore, BuRO does not provide additional evidence or data to improve the estimates of the Panel.

#### Detailed response argumentation

The vase life duration of cut roses is discussed in EFSA PLH Panel (2023a), for both presentation at retail and vase life at the consumer, in section 2.3.2 (p. 19) under bullet B 'Retail and private home under climatisation'. The minimum assumes 0 days at retail and 7 days at consumer, the maximum 4 days at retail and 10 days at consumer, most likely being the midpoint. Under best climatic conditions it was estimated that adult emergence happens after 30 days (=median, 90% uncertainty interval from 22 to 35 days). These split into average duration in cold conditions: 5 days; climatised: 10.5 days; and ambient: 14.2 days. Shorter time in climatised compartments may accelerate pest development but could also lead to earlier wilting and disposal of the roses. However, due to limited information on the time between disposal and waste treatment, the overall effect remains uncertain.

### 3.1.6 | BuRO conclusion on parametrisation of trade volume

Item C.3	Quoted text from BuRO document
<b>Parameter specification – Trade data outliers</b>	<i>"Trade data: a few outliers were identified, which may have been clerical errors but may have led to an overestimation of the number of emerging adults in Portugal and Spain."</i>

#### Reply by the Panel

In response to this conclusion the Panel reran the model calculations considering data currently available at EUROSTAT, i.e. the trade volume for 2 months concerning affected NUTS2 locations. The additional results are given in Table 2. The recalculation did not affect the magnitude of the output quantity contrary to what was suspected by the BuRO without calculations.

BuRO did not provide corrected data or any other data with regard to this item.

Detailed response argumentation

Two historical trade data points were considered as non-representative by the BuRO and proposed to be outliers when estimating annual cut roses trading volume. The Panel notes that these data reflect the Eurostat dataset available at the time and are not the result of clerical errors.

The Panel discussed these data and decided that down weighting individual data points from public statistics without factual evidence may introduce bias in the output. The assessment might have used data of EU Member States (MS) but there are technical issues regarding individual data points from EUROSTAT. As follow-up, EFSA has started a Service Level Agreement with the Joint Research Centre (JRC) of the European Commission to address also heterogeneity of EUROSTAT data for future assessments by robust methods.

In fact, one order of magnitude larger trade volumes were reported in EUROSTAT for Dec 2010 and Mar 2016 (Table 2). The data on the trade volume used in the Panel opinion were downloaded from EUROSTAT (EU trade since 1988 by HS2-4-6 and CN8 [DS-045409]) on the 24th of January 2023 including the ‘outliers’ identified by BuRO. The current download (done on 9th March 2026) shows corrected numbers (Table 2).

**TABLE 2** Trade volume of ‘Fresh cut roses and buds, of a kind suitable for bouquets or for ornamental purposes’, CN 06031100, from the Netherlands to Spain in pieces (EUROSTAT).

Month	December 2010	March 2016
Date downloaded	[roses]	
24/1/2023	47,149,450	22,271,871
9/3/2026	1,424,587	1,319,690

However, this data only affects the average trade volume of winter (12–02) and spring (03–05) in the NUTS2 regions of the Iberian Peninsula. There is a limited effect on the estimated number of mated females escaping for the winter season due to the climatic limitations in the NUTS2 where the trade was linked. Assuming the currently available values of EUROSTAT for winter 2010 (Trade from NL-BE to ES-PT: 9,630,169 roses) and for spring 2016 (Trade from NL-BE to ES-PT: 8,095,602 roses), the risk estimate is reduced between 10% and 25% for the affected suitable NUTS2 regions i.e. for the Iberian peninsula (ES & PT) and Andalusia (one of the NUTS2 region in the area with higher climate suitability (Table 3).

**TABLE 3** Outcome of the risk model when two data points of EUROSTAT trade data were updated to the new EUROSTAT data and comparison with the original model output published in the opinion.

Trade data	EUROSTAT, downloaded on 24/1/2023, as published in the opinion		EUROSTAT, downloaded on 9/3/2026 (with corrected ‘clerical errors’)		Relative reduction (%) when using the EUROSTAT data downloaded in 2026	
	ES & PT	Andalusia	ES & PT	Andalusia	ES & PT	Andalusia
Private waste treatment	Annual number of escaped females with mating partner (Median)				Relative reduction (%) when using the EUROSTAT data downloaded in 2026	
After 3 days	6.42	1.00	4.96	0.77	22.7%	23.0%
After 7 days	6.88	1.11	5.41	0.89	21.4%	19.8%
After 14 days	10.13	1.94	8.46	1.65	16.5%	14.9%
After 28 days	20.42	4.25	18.10	3.76	11.4%	11.5%

3.1.7 | BuRO conclusion on the proportion of mated females

Item D	Quoted text from BuRO document
<b>Adding individual lifetime mortality data</b>	<i>“The calculation method in the qPRA overestimates the number of mated females for every escaping adult because it does not take into account a decrease in pest density in a bunch of cut roses due to natural mortality, a factor that the Panel did take into account in the estimation of the number of emerging females. Using the same data and assumptions as in the qPRA but making a correction for this natural mortality and also taking into account that a bunch of 10 cut roses may include three specimens, BuRO estimated by simulation that there will be one mated female for every 690 adults instead of one for every 435 adults.”</i>

Reply by the Panel

The proposal of the BuRO exaggerates the individual mortality of the pest by applying the parameter twice. The Panel stands by the original model that applies lifetime mortality only once per introduced individual.

### Detailed response argumentation

The BuRO argumentation refers to errors or inconsistencies in EFSA PLH Panel (2023a) including the final calculation of mated females. With the proposed correction by the BuRO, the final risk estimate, i.e. the number of adults needed to escape for one mated female, was suggested to be reduced two-fold from 435 to 1004. The Panel takes the opportunity to compare the two equations i.e. from EFSA PLH Panel (2023a, p. 11) and BuRO (2025, p. 13):

$$\text{Equation EFSA: } 0.41 \times 2/3 \times 1/3 \times 0.025 \times 100 \quad \sim 0.23\% (\text{one mated female for every 435 adults})$$

$$\text{Equation BuRO: } 0.41 \times 2/3 \times 1/3 \times 0.0226 \times 100 \times 0.48 \quad \sim 0.10\% (\text{one mated female for every 1 004 adults})$$

where

- 0.41 refers to the proportion of samples of 400 cut roses taken at import, found infested and with more than one specimen (41%, 2+3 specimens; Table 5, p. 10 in EFSA PLH Panel (2023a), data from the Netherlands);
- $(2/3 \times 1/3 + 1/3 \times 2/3) \times 1/2 = 2/3 \times 1/3$  being the probability that a cut rose bunch with 2 insects will be MF or FM, pairing different sexes, with MF being equal to FM;
- 0.025 (Panel) / 0.0226 (BuRO) the likelihood that two specimens end up in the same bunch.
- 0.48 developmental mortality of an individual.

Referring to the individual developmental mortality of 48%, the BuRO introduces the mortality in the calculation of the proportion of surviving females that get mated. However, EFSA PLH Panel (2023a) accounts for the individual's mortality in the calculation of  $FCM_{\text{escape, NUTS2}}$  (before Table 9, p. 25), of these the proportion of females that get mated is calculated via the clustering outcome with the eq. EFSA above (EFSA PLH Panel 2023a, p. 11, see bullet point one after Table 9). Where individual mortality is accounted for in the multiplicative model does not matter, but it cannot be used twice. This leads to a correction of the BuRO estimation as follows:

$$\text{Equation EFSA: } 0.41 \times 2/3 \times 1/3 \times 0.025 \times 100 \quad \sim 0.23\% (\text{one mated female for every 435 adults})$$

$$\text{Equation BuRO – 2: } 0.41 \times 2/3 \times 1/3 \times 0.0226 \times 100 \quad \sim 0.21\% (\text{one mated female for every 476 adults})$$

The second difference refers to the calculated probability of aggregation i.e. that two specimens end in the same bunch of 10 roses. While BuRO proposed as better estimate a value of 0.0226 by selecting infested stems for the same bunch of 10 roses, the Panel calculated 0.025 by distributing insects to 40 bunches of 10 roses each. To assign a second insect into the bunch that already contains a specimen i.e. one out of 40 bunches of roses, is 1: 40 or 0.025. Both combinatoric approaches reflect the underlying assumptions, but the resulting difference is of marginal importance (see equations above).

Additionally, BuRO simulated a stochastic model with the result: 'one mated female for every 690 escaping adults' (BuRO, 2025, p. 14). To address the ambiguity, the Panel applied the R code annexed to BuRO's report (p. 55–57). Omitting the additional 48% developmental mortality (last code block on p. 55) yields one mated female per 331 adults (0.30% of escaping adults). This would suggest that EFSA's assessment underestimated the risk, contrary to BuRO's conclusion. In light of the inconsistent results, the Panel finds no clear basis to update its opinion.

### 3.1.8 | BuRO conclusion on the synchrony of life stages

Item D.1	Quoted text from BuRO document
<b>Synchrony of life cycle of introduced adults</b>	<i>"The number of mated females for every escaping adult may also be overestimated due the assumption that specimens present in the same bunch of flowers always have similar life stages and develop in parallel."</i>

#### Reply by the Panel

BuRO provides no additional evidence or calculations on the likelihood of mismatched developmental stages among individuals in the same bunch.

### Detailed response argumentation

The Panel used information on intercepted life stages of FCM on cut roses as reported by NVWA to the Panel in 2022 (EFSA PLH Panel, 2023a, Table A.66) to estimate the proportions of life stages at the border. As result of an EKE 50% (median) of the interceptions are eggs, and 32% (median) are early life stages of larvae (L1 + L2). Due to the short distribution chain, the consignments of roses will follow similar conditions (duration, temperature) for transportation, storage, distribution in bunches to the consumer, its decline and wasting, which synchronises the development of the early stages to adults. This synchronisation is strengthened as the mating window is not extremely short compared to the life cycle length. The Panel used, with no uncertainty, the assumption that males and females will mate if maturation overlaps at the same consumer destination/wasting facilities. It has to be noted that, following the explicit analysis of the presence of males and females

under the different scenarios, and considering the basic biology of Tortricidae, it would be extremely unlikely for mating not to occur.

### 3.1.9 | BuRO conclusion on the infestation rate applied in the risk pathway model

Item D.2	Quoted text from BuRO document
<b>Two different valuations of infestation rate</b>	<i>"For the calculation of the proportion of mated females, the Panel used different data or estimates for the infestation rate of cut roses than for the calculation of the number of emerging adults but did not give an explanation for this. The proportion of infested samples of 400 cut roses with two or more specimens was directly derived from interception data. However, the infestation rate to calculate the number of emerging adults was estimated by EKE informed by interception data. This infestation rate was lower (median value 0.0021) than the infestation rate calculated from the interception data (0.00319). A lower infestation rate would logically result in a lower number of specimens per sample of 400 cut roses and hence not only a lower number of emerging adults but also a lower proportion of mated females."</i>

#### Reply by the Panel

The Panel did consider only one estimate of the infestation rate for the pathway model calculations i.e. the parameter value resulting with uncertainty of the EKE. The proxy generated from the interception data was exclusively used as input for the EKE.

#### Detailed response argumentation

The Panel relied on the EKE-derived infestation rate as the single parameter in the model, as it integrates interception data while accounting for known biases in inspection processes, namely 0.0021 (as median). This ensures both internal consistency of the model and a more realistic representation of the underlying infestation rate.

The input evidence to the EKE included data and knowledge likewise the proxy estimate of infestation rate using interception data. The proxy estimation from interception data comprised acknowledged bias from the data generation procedure of border inspections. This includes the limited sample, the limited number of commodities inspected according to the protocol, the possible stopping of full infestation evaluation once the pest has been found multiple times in an inspection unit etc. Therefore, the Panel prefers the EKE estimate, where the experts considered the known sources of bias, as being closer to the real infestation rate compared to those derived from interception data, namely 0.00319. This interception-derived value was not used as an independent alternative estimate in the model calculations. Rather served as one line of evidence informing the EKE.

### 3.1.10 | BuRO conclusion on the comparison of risk estimates with reported outbreaks

Item E	Quoted text from BuRO document
<b>Comparison of the final output with the number of known outbreaks</b>	<i>"Lack of outbreaks of <i>T. leucotreta</i> reported in suitable regions suggests that either the estimated number of mated females per year is too high or the 'average' probability of oviposition and establishment, two parameters which have not been taken into account in the qPRA, after mating is very low (less than 0.01 or even less than 0.001)."</i>

#### Reply by the Panel

Establishment and oviposition were not considered beyond the principal suitability of European NUTS2 regions. The Panel assumed that both were not limiting once a mated female has escaped in a suitable area because the insect is highly polyphagous with more than 100 genera of host plants within more than 50 botanical families. Considering such polyphagy, in line with EPPO (2013), the Panel assumed that *T. leucotreta* will likely find suitable hosts for establishment outdoors in the climatically suitable areas.

BuRO did not provide other data or evidence to substantiate an acceptable number of founder populations given the lack of outbreaks.

#### Detailed response argumentation

The Panel does not follow that the absence of observed outbreaks implies a very low average probability of oviposition and establishment after mating. However, the following scenarios would balance the apparent contrast and underpin the Panel's estimation. An outbreak following establishment maybe small or of limited spread violating the homogeneity proposition of potential detection surveys, and hence their sensitivity in detecting the pest introduction. Further, the level of detection survey effort in suitable parts of the EU may not allow detection of infestation below 1% with usual confidence; and likely most critical, many host plant species are even not inspected in line with the detection surveys due to their marginal relevance for plant production. Therefore, the documented number of reported outbreaks of *T. leucotreta* does not necessarily match the number of mated females escaping and founding a population. However, independent of this discussion, the commodity of cut roses was shown a possible pathway to introduce the pest.

In addition, this point was already discussed in the scientific opinion (EFSA PLH Panel, 2023a, Conclusions section, p. 53). In the conclusion it was stated: ‘Overall, regular escape of pest insects on the territory of the EU is predicted through the cut roses but so far it has not led to outbreaks (other than few incursions) in the EU, possibly because of the relatively recent shift of pest pressure in Africa towards cut roses and of the fact that much of the cut roses consumption in the EU occurs in regions with less climate suitability. However, observations of flying adults have been reported in the EU’. The Panel also noted that ‘The main uncertainties about possible establishment in the EU territory are caused by the lack of demographic studies at different temperatures and population studies in the cultivated and natural environment in the areas of pest distribution’. To address such uncertainties, EFSA has funded, via an EFSA Art. 36 Grant, a research project to better understand the thermal ecology and biology of the different life stages of the false codling moth in East Africa. This project, started in March 2026, is coordinated by Ghent University in cooperation with ICIPE Kenya and includes experiments under controlled conditions, as well as ecological observations on *T. leucotreta* in natural environment and in farms in East Africa. The Panel notes also that this point is however not specific to the cut roses pathway, but it is generally applicable to all the entry pathways of this pest as assessed in the EPPO (2013) pest risk analysis.

### 3.1.11 | BuRO conclusion on the adequacy of the title of the EFSA output

Item F	Quoted text from BuRO document
<b>Other comments</b>	<i>“The model calculates the number of mated females in suitable regions but not the number of founder (established) populations. Therefore, the title of the qPRA ‘Assessment of the probability of introduction of Thaumatotibia leucotreta into the European Union with import of cut roses’ is not fully consistent with its contents because ‘establishment’ is part of ‘introduction’.”</i>

#### Reply by the Panel

The Panel does not follow the selective argument of BuRO. The opinion addressed the mandated question whether cut roses may form a pathway for *T. leucotreta* by modelling entry and transfer plus estimating eco-climatic suitability for pest establishment. The joined outcome led to the answer that cut roses are a pathway for introduction (i.e. entry and establishment).

#### Detailed response argumentation

The mandate addressed by EFSA followed the EPPO PRA already published. Hence, EFSA PLH Panel (2023a) did not have to be a full qPRA but just needed to reply to the question whether an individual pathway exists for the pest. BuRO considers ‘establishment’ as part of ‘introduction’ assessments; and therefore, argues that the title of the opinion is misleading. However, EFSA PLH Panel (2023a) addresses entry, transfer and establishment and the title of the qPRA correctly reflects these steps. The calculations estimate the number of potential founder populations together with geographically explicit ecological suitability of EU NUTS regions. Furthermore, the Panel notes that an estimation of founder populations was omitted due to the large set of host plants that did not limit the reproduction of the pest in suitable habitat. Therefore, the pathway was concluded valid if potential founder populations are possible.

## 3.2 | *Citripestis sagittiferella*

With the qPRA of *Citripestis sagittiferella* for the EU (EFSA PLH Panel, 2023b), the Panel delivered a qPRA according to the principles laid down in the EFSA guidance on qPRA (EFSA PLH Panel, 2018).

This section elaborates on the conclusions of the report published by BuRO (2025) on the evaluation of the qPRA on *C. sagittiferella* (EFSA PLH Panel, 2023b).

### 3.2.1 | BuRO conclusion on the general assessment

Item A	Quoted text from BuRO document
<b>Summary and conclusions</b>	<p><i>The Panel estimated the number of founder populations of <i>C. sagittiferella</i> introduced each year through the import of citrus fruit from Indonesia, Malaysia, Thailand, and Vietnam. The pest arrives as immature stages (eggs and larvae) in the fruit. It was estimated how many adults emerge from the fruit and establish a founder population. The estimate was made using a model with the following components:</i></p> <ul style="list-style-type: none"> <li>• <i>the import volume of fruits (in tons),</i></li> <li>• <i>the proportion of infested fruit after harvest,</i></li> <li>• <i>the proportion of infested fruit that is not removed by sorting in the country of origin,</i></li> <li>• <i>the proportion of fruits that is not removed by risk reduction options,</i></li> <li>• <i>a disaggregation factor reflecting the distribution of one ton of infested citrus fruit to several locations in the risk assessment area,</i></li> <li>• <i>the probability of transfer, and</i></li> <li>• <i>the probability of establishment.</i></li> </ul>

### Reply by the Panel

The Panel appreciates the structured and comprehensive summary of the modelling efforts in the opinion on *C. sagittiferella* published in EFSA PLH Panel (2023b).

### 3.2.2 | BuRO conclusion on the infested volume at entry

Item B	Quoted text from BuRO document
<b>Final number of founder populations</b> Infested volume at entry	<i>The product of the infestation rate after harvest and the proportion of infested fruit that is not removed by subsequent sorting in the country of origin is multiplied by the import volume in the EU but should instead be multiplied by the volume of citrus fruit before sorting to calculate the volume of infested fruit on arrival in the EU accurately.</i>

### Reply by the Panel

The Panel acknowledges that sorting may affect the total volume of fruit traded. However, in the model  $P_{\text{Sorting}}$  was not intended to represent the proportion of the total fruit volume removed by sorting. Rather, it represents the reduction in infestation prevalence in the traded fruit due to sorting and inspection in the country of origin. Sorting may have two effects: it may reduce the total volume of fruit entering trade and it may reduce the proportion of infested fruit among the fruit that remains in trade. The first effect is already reflected in  $N_{\text{trade}}$ ; the second effect is represented by  $(1P_{\text{sorting}})$ .

For this pest, only traded volume data were available from EUROSTAT. The Panel approached the problem by assuming that the level of infestation in any given volume on the pathway can be calculated by multiplying the volume by the prevalence corrected by the effect of sorting.

In EFSA PLH Panel (2023b),  $N_{\text{trade}}$  represents the traded volume and when this is multiplied with the correction factor  $[P_{\text{prevalence}} * (1P_{\text{sorting}})]$  it gives the infested fraction of the volume traded. The use of a volume with corrected infestation level operationalises the available data but does not affect the result of the pathway model. Under this approach, the model does not apply the removal of fruit twice; it is applying a reduction in prevalence to the traded volume.

### Detailed response argumentation

As a fully multiplicative model, the order of the parameters does not affect the calculation (it does not matter at which point any volume is multiplied by the prevalence):

$$N_{\text{Inf}} = [P_{\text{prevalence}} * (1P_{\text{sorting}})] * N_{\text{trade}} * (1RRO_{\text{effectiveness}}) * d * P_{\text{Transfer}}$$

where:

$P_{\text{prevalence}}$  is the estimated infestation level at origin, expressed as a unitless infestation proportion as defined in the opinion.  $P_{\text{sorting}}$  represents the overall effectiveness of pre-export sorting and inspection steps in reducing the infestation prevalence in the traded flow; therefore  $(1P_{\text{sorting}})$  represents the fraction of infestation prevalence remaining in the traded flow after sorting.  $RRO_{\text{effectiveness}}$  is the effectiveness of risk reduction options in reducing the infestation,  $d$  the disaggregation and  $P_{\text{transfer}}$  the probability of a transfer to host.

The issue therefore concerns a misinterpretation by BuRO and would be relevant only if  $P_{\text{sorting}}$  was interpreted as a removal fraction applied to a pre-sorting fruit numbers. This was not the intended parameter definition in the model. The issue therefore concerns the need to clarify the parameter definition in EFSA PLH Panel (2023b), rather than a correction to the model calculation.

### 3.2.3 | BuRO conclusion on the number of infested transfer units

Item C	Quoted text from BuRO document
<b>Final number of founder populations</b> number of infested transfer units	<i>The product of the number of pathway units (tons of fruit), infestation rate (proportion of fruits infested) and a disaggregation factor does not yield the number of infested transfer units, i.e. the number of disaggregated batches that contain at least one infested fruit. Instead, it yields the product of the total number of disaggregated batches and the proportion of infested fruit, which does not lead to an accurate estimate of the number of (potential) founder populations.</i>

### Reply by the Panel

The Panel cannot completely resolve the implication of this conclusion.

Elsewhere in the report, BuRO (2025) requires converting the trade volume expressed in tons into number of units before multiplying with the proportion of infestation (4.3.2.1.).

The Panel does not agree that such conversion is necessary in the present context and considers it appropriate to model infestation downstream using volumes. The volume weight was selected as unit instead of individual fruits because the large variability in the weight of citrus fruits depending on the species makes the volume recalculation less reliable.

#### Detailed response argumentation

In the entry model, the prevalence and sorting terms are used to model the fraction of infested material in the traded flow on a ton basis (e.g. kg of infested fruit per ton) and are not intended to represent the probability that a ton or batch contains at least one infested fruit. The disaggregation factor  $d$  represents how the infested fraction of the traded flow is distributed across distinct receiving locations relevant for transfer. Importantly, according to the model specification, each receiving location can generate at most one potential founder population regardless of how many infested fruits are present within the fraction delivered to that location. Accordingly,  $N_{inf}$  should be interpreted as the portion of a volume that leads to a potential founder population at distinct locations, not as a count of infested tons or batches.

### 3.2.4 | BuRO conclusion on the parameter dependencies

Item D	Quoted text from BuRO document
<b>Final number of founder populations</b> Parameter correlations	<i>It is likely that dependencies exist between some parameters. The Panel assumed a negative correlation between the proportion of infested fruit after harvest and the proportion of infested fruit that is not removed by sorting but the model does not account for this dependency. In addition, the probability of transfer and the disaggregation factor are negatively correlated. When these negative correlations are taken into account, the uncertainty range of the model output decreases.</i>

#### Reply by the Panel

In section 'Dependencies between parameters' of EFSA PLH Panel (2023b, p. 22), such dependencies are proposed and discussed together with the reasoning of the decision to include, or not, the formal structure of dependence between the parameters, including the need to parameterise the interaction, for example, between increasing infestation levels at production and the potentially resulting need for more intensive sorting of damaged fruits.

The Panel acknowledges BuRO's point that  $d$  and  $P_{Transfer}$  are mechanistically related and that the independence assumption can widen the uncertainty of the output. In EFSA PLH Panel (2023b), this dependency was considered in the elicitation of  $P_{Transfer}$  by explicitly considering different degrees of disaggregation when motivating the lower and upper quantiles. In the light of the limited available evidence, the Panel decided not to increase the complexity of the model formulation by imposing a formal dependence structure. Although imposing a negative correlation between these parameters would reduce the uncertainty range, this reduction would come at the cost of introducing an additional assumption that would itself need to be justified, namely the functional form and strength of the correlation. BuRO (2025) does not provide pest-specific data or a justified parameterisation that would support implementing an explicit dependence structure in the model.

#### Detailed response argumentation

The following assumption was made explicit in EFSA PLH Panel (2023b, p. 22) due to the severe shortage of biological and ecological data on *C. sagittiferella*: 'The Panel considers the parameters of the entry model to be independent of each other, with the possible exception of prevalence at the origin and sorting (the higher the prevalence at the origin, the more likely the sorting), but this dependency is expected not to affect the conclusions of the assessment, as the interaction was considered during the elicitation of  $P_{sorting}$ '.

As no additional data are provided in the BuRO's report, the Panel considers that more detailed analyses are not realistically feasible under the current evidence base.

### 3.2.5 | BuRO conclusion on the transfer outside of orchards

Item E	Quoted text from BuRO document
<b>Final number of founder populations</b> Founder population	<i>Transfer to citrus trees outside orchards (e.g. transfer from fruit at consumer's places to citrus trees in private gardens) was not taken into account.</i>

#### Reply by the Panel

The statement is incorrect. On the contrary, the parameter 'Probability that the pest in one disaggregated batch of citrus fruit is transferred to suitable hosts, thus leading to a founder population' ( $P_{Transfer}$ ), was estimated following a semi-formal EKE protocol using the available evidence. During this process, the Panel describes scenarios for reasonable high and low-transfer probability as outlined in EFSA PLH Panel (2023b, p. 19) and these scenarios encompass transfer occurring at different stages of the post-import chain, including consumer-level handling and disposal.

### 3.2.6 | BuRO conclusion on the uncertainties

Item F	Quoted text from BuRO document
<b>Uncertainties</b>	<i>Uncertainties were addressed and clearly expressed in the conclusions and abstract of the qPRA.</i>

#### Reply by the Panel

The Panel appreciates the reflection on the adequacy of the uncertainty evaluations.

### 3.2.7 | BuRO conclusion on the trend of trade volume

Item G	Quoted text from BuRO document
<b>Parameter estimates</b> Trade volume	<i>Trade volume: the Panel made the assumption that the import volume would increase linearly in the next ten years but no convincing evidence was provided for that. The evidence that was provided could also be used to argue that the import volume had stabilised after some years of increase.</i>

#### Reply by the Panel

In EFSA PLH Panel (2023b), a trend interpretation of the trade data was presented and justified (p. 14) based on the EUROSTAT data available at the time of the assessment. The Panel notes that BuRO refers to additional EUROSTAT data for 2022, 2023 and 2024 which were not available at the time of the assessment. If an alternative trend is proposed relative to that presented and justified in EFSA PLH Panel (2023b), this should be described based on the same evidence source, and, where appropriate, assessed by rerunning the model with the updated data and the alternative trend specification.

The Panel noted that the model output could be updated to reflect these new data, or any other information sources relating to changes in trade flows. However, the sensitivity analysis of the model presented in EFSA PLH Panel (2023b) revealed a marginal impact of the projected trade volume on the final risk estimate. Therefore, no major changes in the outcome are expected from such an update.

### 3.2.8 | BuRO conclusion on the comparison of risk estimates and interception rates

Item H	Quoted text from BuRO document
<b>Parameter estimates</b> Infestation rate	<i>Infestation rate: the Panel made no comparison between the number of infested fruits on arrival in the EU (i.e. the number of infested fruits after sorting) and interceptions. No interceptions have been notified in EU-databases but BuRO made a comparison between the estimated infestation rate and the number of interceptions (not notified) in the Netherlands. This interception rate was much lower than would be expected based on the estimated infestation rate, which was, therefore, considered too high.</i>

#### Reply by the Panel

The Panel notes that BuRO (2025) refers to information that was not accessible to EFSA at the time of the assessment: (*'interceptions (not notified) in the Netherlands'*). In addition, the Panel advises against directly comparing quantitative risk estimates with interception data because inspection procedures are subjected to intrinsic biases (also see section 3.1.10). Such comparisons are not epidemiologically valid unless reliable and harmonised detection data for non-regulated pests are available across the EU.

#### Detailed response argumentation

For clarity, relevant sources of biases in inspection outcomes include:

- The limited sample size, which is typically determined to detect an infestation level of 1% or above, with a confidence of 95%. Lower infestation levels maybe be detected, but with less confidence.
- The imperfect potentially low sensitivity of the inspection method.
- The missing confirmation of the findings.
- The lack of reporting of multiple findings (e.g. clustering of the infestation).
- No obligation to report detection of non-regulated pests (according to BuRO, 2025).

For these reasons, the Panel considers that the comparison made by BuRO (2025) between the modelled infestation rate and interception records cannot be used to conclude that the infestation rate estimated in the qPRA was too high. Such a conclusion would require reliable and harmonised detection data, together with explicit information on sampling intensity, inspection sensitivity, diagnostic confirmation and reporting completeness.

### 3.2.9 | BuRO conclusion on the details of transfer probability

Item I	Quoted text from BuRO document
<b>Parameter estimates</b> Probability of transfer	<i>Transfer: from the justification in the qPRA it is not clear whether all consecutive steps that need to take place for transfer to occur, including the distribution of units into suitable regions, the development of immature stages into adults, mating and oviposition, have sufficiently been taken into account. The probability of transfer may, therefore, have been overestimated.</i>

#### Reply by the Panel

To clarify, in EFSA PLH Panel (2023b)  $p_{\text{transfer}}$  was elicited to represent the probability that a fraction of imported infested fruit is delivered to a receiving location in an area with suitable climate for the pest and results in a potential founder population. This parameter includes the necessary steps of arrival in relevant areas, disposal under suitable conditions, completion of development, emergence, mating and oviposition. Also, the need for co-location of males and females in space and time was explicitly considered in the elicitation of  $p_{\text{transfer}}$ . While a more granular decomposition into sub-steps would have been feasible, the Panel decided to approach an integrated transfer parameter, to keep the model more parsimonious given the lack of biological evidence on *C. sagittiferella*.

### 3.2.10 | BuRO conclusion on the probability of establishment

Item J	Quoted text from BuRO document
<b>Parameter estimates</b> Probability of establishment	<i>Establishment: the justification of the estimate for the probability of establishment suggests that this estimate reflects the probability that the climate in the citrus-growing areas in the EU is suitable for establishment rather than the probability that a potential founder population becomes a founder population in an area suitable for establishment (which are different probabilities). Therefore, the probability of establishment may have been overestimated.</i>

#### Reply by the Panel

The Panel considers this conclusion incorrect. The EKE question for the probability of establishment was explicitly framed conditional on transfer having occurred. In EFSA PLH Panel (2023b), transfer was defined as arrival on suitable hosts within the risk assessment area under conditions compatible with development, including climatic suitability.

Under this condition, the EKE addressed the probability that a potential founder population becomes established. Factors affecting establishment, including host-pest interaction and influences on population dynamics, were considered in the elicitation (EFSA PLH Panel, 2023b, p. 26).

### 3.2.11 | BuRO conclusion on the comparison of risk estimates with reported outbreaks

Item K	Quoted text from BuRO document
<b>Comparison of the final output with the number of known outbreaks</b>	<i>BuRO considers the calculated median number of founder populations (4.8 per year) a considerable overestimate of the probability of introduction of <i>C. sagittiferella</i> into the EU taking into account the volume of citrus fruit that had been imported and the lack of known outbreaks (at the time the qPRA was adopted). Using the model as a prior and using the information of zero founder population during 2013–2019, BuRO calculated a posterior probability. This calculation resulted in one founder population expected per 30 years with a 90%-uncertainty range between one founder population per 35,000 years and 0.61 founder populations per year for the period 2023–2032 using an average trade volume of 13,000 tons per year as estimated in the qPRA. Using a trade volume of 7500 tons per year, which BuRO considers more likely, the number of expected founder populations would be approximately one per 45 years.</i>

#### Reply by the Panel

The absence of reported outbreaks cannot be taken as a formal invalidation of the model, since surveillance effort is uneven, detection is imperfect and reporting practices vary across countries and over time. The value of such quantitative comparisons is even more doubtful for non-regulated pests. See also the related commenting and analogous reply for *T. leucotreta* (Section 3.1.10).

The Panel disagrees with the use of Bayesian updates to refine the assessment (Appendix E, p. 66 of the BuRO, 2025 report) for the following reasons:

- EFSA PLH Panel (2023b) evaluated the available evidence, including the absence of outbreaks and was not done to determine a prior distribution that can subsequently be updated with evidence already considered during the assessment.
- The information used by BuRO for the update was already part of the evidence base considered in the assessment and should not be used twice.

- The number of recognised outbreaks is likely an underestimation of the correct number of founder populations introduced by the pathway. As repeatedly remarked, the reported outbreaks are conditional on detection, surveillance and reporting processes, particularly for non-quarantine pests, and are therefore likely to be highly biased as a measure of the true number of founder populations.

### 3.2.12 | BuRO conclusion on the risk assessment terminology

Item L	Quoted text from BuRO document
<b>Other comments</b>	<i>The terminology is not completely in line with EFSA's guidance: the term 'founder populations' is used instead of 'potential founder populations' before establishment has actually occurred.</i>

#### Reply by the Panel

The Panel takes note of BuRO's remark on terminology but considers that the quantitative output is not affected. Consistent with the PLH qPRA guidance and the protocol for pest risk assessment, future qPRAs will distinguish more explicitly between '*potential founder populations*', where establishment has not yet occurred, and '*founder populations*', where establishment is considered to have occurred.

#### Detailed response argumentation

In EFSA PLH Panel (2023b),  $N_{\text{inf}}$  denotes the output of the entry component prior to applying the establishment probability, while  $N_{\text{est}}$  denotes the number of established populations after applying  $P_{\text{Estab}}$ . In the qPRA guidance (EFSA PLH Panel, 2018) and in published standard protocols (Crotta et al., 2024; EFSA PLH Panel, 2024), the former is referred to as '*potential founder populations*'. The Panel acknowledges that the term '*founder populations*' was used for  $N_{\text{inf}}$  in parts of the text of EFSA PLH Panel (2023b). This inconsistency in terminology should not have been overseen but is a matter of presentation. The terminology issue does not affect the model structure, its parameterisation or the numerical results reported.

## 3.3 | *Elasmopalpus lignosellus*

With the qPRA of *E. lignosellus* for the EU (EFSA PLH Panel, 2023c), the Panel delivered a qPRA according to the principles laid down in the EFSA guidance on qPRA (EFSA PLH Panel, 2018). Additionally, EU regions that could become suitable for establishment of *E. lignosellus* in the future were identified taking climate change scenarios into account.

This section elaborates on the conclusions of the report published by BuRO (2025) on the evaluation of the qPRA on *E. lignosellus* (EFSA PLH Panel, 2023c).

### 3.3.1 | BuRO conclusion on the general assessment

Item A	Quoted text from BuRO document
<b>Structure of model</b>	<i>"The model is considered accurate. The model probably includes a parameter for the proportion of females, which is correct but is not explicitly indicated in the qPRA."</i>

#### Reply by the Panel

The Panel is constantly striving to adapt its scientific assessments to the needs and requirements of the readers and stakeholders. Therefore, the main body of an opinion focuses on the results, the underpinning reasoning and the conclusions. Detailed information concerning the evaluation of evidence, datasets and calculations is mainly of interest for the technical reviewer and therefore it is included in the corresponding appendices and annexes. To also enable interested readers to rerun the model calculations, the full documentation of the model was attached as Annex A under the Supporting Information section on the online version of EFSA PLH Panel (2023c). The information is structured in EXCEL spreadsheets (File: efs28004-sup-0001-annex\_a.xlsx), which include references (with textual descriptions), datasets used and calculation formulas. Also included, but deactivated in the Excel spreadsheets, are all codes, which are needed to re-run the Monte-Carlo simulation with @RISK software. Readers with access to a valid @RISK licence can easily activate the code and rerun and scrutinise all calculations. BuRO may have overlooked the corresponding reference in the data and methodology chapter (EFSA PLH Panel, 2023c, end of section 2.1, p. 11).

#### Detailed response argumentation

BuRO stated that 'No formula is presented in the qPRA' (BuRO, 2025, p. 37) and 'A parameter for the proportion of females ( $p_{\text{female}}$ ) is not included in the description' [ibidem]. The formula of the pathway model for introduction (entry and establishment) is given in Annex A, spreadsheet 'Model\_Current' as:

$$q = a / b \times d \times f \times h \times j \times l \times m \times o$$

with all intermediate steps, including the proportion of females (m) (Table 4).

**TABLE 4** The parameters of the entry model of *Elasmopalpus lignosellus* with their definition and interpretation by BuRO (2025).

Model parameter as defined in EFSA PLH Panel (2023c, Annex A)			As interpreted in BuRO (2025, Table 9)	
Abbr.	Parameter description	Unit	Abbr.	Description
a	Import of fresh asparagus from Peru into the EU-27	[kg]	V	Imported quantity of asparagus from Peru into the EU
b	Average weight of one asparagus spear	[kg]	$W_{\text{unit}}$	Weight of a single asparagus spear
d	Infestation rate of asparagus from Peru	[1/10000]	$p_{\text{inf}}$	Proportion of asparagus spears that is infested
f	Proportion spears in suitable area	[%]	$p_{\text{clim}}$	Proportion of infested spears entering an area where the climate is suitable for establishment of <i>E. lignosellus</i> (defined as NUTS 2 regions where $EI \geq 30$ )
h	Proportion of discarded infested spears	[%]	$p_{\text{waste}}$	Proportion of asparagus spears disposed of as waste
j	Proportion of adults emerging from the waste	[-]	$p_{\text{adult}}$	Probability that a larva develops to adulthood and escapes from a discarded asparagus
l	Proportion of females finding mating partner	[-]	$p_{\text{mate}}$	Probability that a female will mate
m	Proportion of females	[-]	$p_{\text{female}}$	Proportion of females
o	Probability of established founder populations	[-]	$p_{\text{est}}$	Probability that a mated female will oviposit and establish a founder population
q	Number of founder populations in risk areas	[founder populations]	$N_{\text{established}}$	Number of founder populations of <i>E. lignosellus</i>

For each parameter a separate sheet lists the actual parameter value, the references, datasets and – if applicable – necessary conversions or transformations; and a description of the estimated/modelled uncertainty as probability distribution.

While the Annex A gives all detailed information to evaluate the calculations, the main text focusses on the intermediate steps of the pathway model (EFSA PLH Panel, 2023c, Figure 2):

1.	Trade volume [kg]:	a
2.	Number of transfer units (asparagus spears):	$c = a/b$
3.	Number of infested spears entering EU:	$e = c \times d$
4.	Number of infested spears in NUTS2 regions where $EI \geq 30$ (NUTS2 <sub>30</sub> ):	$g = e \times f$
5.	Number of infested spears discarded across NUTS2 <sub>30</sub> regions:	$i = g \times h$
6.	Number of adults emerging across all NUTS2 <sub>30</sub> regions:	$k = i \times j$
7.	Number of mated females across NUTS2 <sub>30</sub> regions:	$n = k \times l \times m$
8.	Number of founder populations across all NUTS2 <sub>30</sub> regions:	$q = n \times o$

The necessary proportions to calculate the number of founder populations for each NUTS2<sub>30</sub> region are given on sheet 'SuitableNUTS'. The distribution to the individual NUTS2<sub>30</sub> regions is shown in Figure 12 (EFSA PLH Panel, 2023c, p. 28).

### 3.3.2 | BuRO conclusion on the parameter 'survival of larvae'

Item B	Quoted text from BuRO document
<b>Parameter estimations</b>	"The Panel provided justifications for the different parameter estimates except for the 'probability of larvae surviving to develop to adulthood'".

#### Reply by the Panel

For each model parameter of the entry model a justification, reference or evidence base is given in Annex A (File: efs28004-sup-0001-annex\_a.xlsx) of the scientific opinion. For the parameter 'Proportion of adults emerging from the waste (j)' (referred in BuRO, 2025 as 'Probability that a larva develops to adulthood and escapes from a discarded asparagus ( $P_{\text{adult}}$ )'), an EKE was conducted to weigh all available evidence resulting in an uncertainty distribution with median value of 1.2% (90% certainty range between 0.12% and 4.2%). The used evidence includes the life stage of *E. lignosellus* ('Eggs and pupae

do not enter in asparagus') (EFSA PLH Panel, 2023c, p. 65), the developmental times of larvae (Sandhu et al., 2010) and the Panel waste model for the organic fraction of the solid waste (EFSA PLH Panel, 2023c, section A.9.) (Table 5).

### Detailed response argumentation

**TABLE 5** Justification of model parameter as given in EFSA PLH Panel (2023c, Annex A).

Model parameter as defined in EFSA PLH Panel (2023c, Annex A)		
Abbr.	Parameter description	Justification/uncertainty
A	Import of fresh asparagus from Peru into the EU-27	Annual data for 2017 to 2022 are extracted from EUROSTAT, table: EU trade since 1988 by HS2-4-6 and CN8 [DS-045409] for exporter "Peru", product "Fresh or chilled asparagus", flow "Import", and reporter "European Union" - 27 countries (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK). Last update: 20/02.2022, download 23/02.2023. The uncertainty is estimated by a normal distribution with sample mean and standard deviation
B	Average weight of one asparagus spear	Average of European unit weights (EU mean) of "asparagus" reported in the EFSA Primo model to estimate the acute pesticide intake (RAC). (EFSA, 2018) Model: <a href="http://www.efsa.europa.eu/sites/default/files/applications/EFSA_PRIMO_rev3.1.xlsm">www.efsa.europa.eu/sites/default/files/applications/EFSA_PRIMO_rev3.1.xlsm</a> The value is taken as European default value without uncertainty.
D	Infestation rate of Asparagus from Peru	A semi-formal EKE was conducted with the question: <i>How many out of 10,000 spears of fresh asparagus will be on average infested with E. lignosellus, when entering the EU from Peru?</i> The uncertainty is expressed as uncertainty distribution (LogNormal)
F	Proportion spears in suitable area	The EU area suitable for establishment of <i>E. lignosellus</i> was evaluated using CLIMEX models with the threshold: EI <sup>3</sup> 30. (EFSA PLH Panel, 2023c, Figures 10 and 11). The proportion of spears corresponds to the proportion of European population living on 1st Jan 2021 in the NUTS2 region [EUROSTAT on 1 January by age group, sex and NUTS3 region, downloaded 16/11/2022]
H	Proportion of discarded infested spears	Study by Gould et al. (2006) on the American situation was used.
J	Proportion of adults emerging from the waste	A semi-formal EKE was conducted with the question: <i>What is probability that a larva in the waste will result in an adult emerging from the waste?</i> The uncertainty is expressed as uncertainty distribution (BetaGeneral)
L	Proportion of females finding mating partner	A semi-formal EKE was conducted with the question: <i>Assuming an entry of about 100 escaped adults in the NUTS2 region of Andalusia or about a thousand over the whole area suitable for establishment in Europe in the time frame of about eight months (June–January), what is the probability that an escaped adult female will find a mate either before flying off to find a host or at the host?</i> The uncertainty is expressed as uncertainty distribution (BetaGeneral)
M	Proportion of females	The sex ratio was taken from Mack et al. (1987) No uncertainty was considered.
O	Probability of established founder populations	A semi-formal EKE was conducted with the question: <i>What is the probability that the hundred or so eggs laid by one female during her lifetime will initiate a lasting founder population?</i> The uncertainty is expressed as uncertainty distribution (BetaGeneral)

### 3.3.3 | BuRO conclusion on the parameter 'infestation rate of asparagus spears'

Item C	Quoted text from BuRO document
<b>Parameter estimations</b>	<i>"The infestation rate of asparagus (proportion of infested spears) from Peru may have been underestimated by more than a factor of 10. The estimate by the Panel was partly based on notified interceptions by EU Member States. Interceptions had mainly been notified by the UK, which notified the last interception on 1 March 2020. Therefore, the sharp decline in the number interceptions after 1 March 2020 may have (partly) been due to the withdrawal of the UK from the EU instead of the presumed decrease in infestation rate."</i>

### Reply by the Panel

The 'Infestation rate of asparagus from Peru (d)' was estimated following a semi-formal EKE protocol. In this structured process all available evidence was reviewed, including reported interceptions, but not limited to these. Limitations of the evidence base were identified, listed as possible uncertainties and used to construct scenarios for the lower and upper limit of the infestation rate (credible range). The experts were then asked to weigh the available evidence and judge on the median and inter-quartile range of the uncertainty distribution. The process is described in detail in the EFSA Guidance on EKE (EFSA, 2014) and Uncertainty Assessments (EFSA Scientific Committee, 2018a).

The Panel strongly recommends not to limit the estimation of the infestation rate to the interpretation of the interceptions solely (see Section 3.3.7 for more details).

Weighing all available evidence resulted in the estimated value for the average infestation rate of 0.11 out of 10,000 spears, with 90% certainty range from 0.016 to 0.72 out of 10,000 spears and a credibility range from 0.0071 to 1.6 out of 10,000 spears. The uncertainty distribution is a LogNormal distribution with parameters (0.20823, 0.35138).

The aspect mentioned by BuRO (2025) is only one part of the evidence used by the Panel, but it would also be covered by the assessed uncertainty.

The Panel uses this methodology to describe the uncertainty in the estimation of a parameter in a quantitative way. The result could be interpreted that it is likely that the true (but unknown) infestation rate is up to 6-times lower or higher, but it is extremely unlikely that the true infestation rate is less than 15-times lower or more than 15-times higher.

The aspect mentioned by BuRO (2025) is only one part of the evidence used by the Panel, but it would also be covered by the assessed uncertainty.

It should be mentioned that, for most of the parameters, uncertainties are explicitly quantified and used by a Monte-Carlo simulation of the entry model to quantify the total uncertainty of the result, the 'Number of founder populations across all NUTS<sub>2-30</sub> regions'.

### Detailed response argumentation

The EKE protocol notes the following aspects considered for the judgement of the infestation rate:

#### Factors influencing the lower limits

- Pesticide treatments are used and are assumed to be effective
- Low survival during cold transport/storage
- Interceptions of dead larvae (indicate treatment works)
- Lower abundance of pest in Peru during summer (cooler period) when imports begin to increase
- Asparagus is high quality, important for 'brand Peru'
- Production from one site is integrated with supply chain
- Clean material is used for replanting
- Pest pressure is lower during summer (cooler period)
- Later larvae will show clear damages, e.g. dry plants
- Young larvae are outside and can be washed off
- Soil stages will be reduced by irrigation
- Insect is native in Peru where natural enemies could lower pest abundance
- Occurrence of pest on harvested spears is recognised as an export problem to access EU markets
- Real quality issue for the consumer
- Inspection required before phytosanitary certificate is issued; 0% infestation tolerance for exports to EU (NAHS, 2022)

#### Factors influencing the upper limits

- Overlapping generations, continuous development year round
- Fast infestation of new plots
- Early larvae do not show damage
- Harvest occurs just after the larvae enter the stem of asparagus
- Unclear use of pesticides, e.g. product, period
- Biological control not effective
- Infestation can be difficult to detect
- High pest pressure in the country of origin/production areas
- High impact reported in other crops
- Interceptions at EU border may not be reported (no need to notify as *E. lignosellus* is not a quarantine pest)
- When exports are combined from many sites of production

#### Median:

- The pest is prevalent under field conditions. Fields are eligible for harvesting for export provided not more than 7% of spears in the field are infested.
- Harvesting is done by hand, and harvesters would avoid bad looking spears or bad looking patches.
- Within the packing house stringent procedures are followed to ensure pest freedom.
- Pest freedom is of paramount interest to exporters
- However, with the pest being prevalent under field conditions, and with human resources and time being limiting, zero infestation may not be reached in practice.

### Inter-quartile range:

- At upper ranges, reduces by factor of 2.5 (100 to 40; 15 to 6) but as numbers lower it becomes more difficult to lower further hence reduce by factor of 2 (4 to 2, 2 to 1). (EFSA PLH Panel, 2023c, p. 51)

### 3.3.4 | BuRO conclusion on the parameter 'mating rate'

Item D	Quoted text from BuRO document
<b>Parameter estimations</b>	<i>"BuRO considers the justification of the probability of mating to be incomplete. The model estimated a very low number of escaped adults per region per year, roughly less than 0.2. With such low numbers, the probability that a female will find a mate may even be lower than the value estimated in the qPRA (<math>p = 0.00081</math>). The presence of more than one specimen in a consignment (clustering of specimens) may, however, increase the probability of mating. This possibility is not addressed in the qPRA. The probability of mating may also be higher due to a higher infestation rate than estimated in the qPRA."</i>

#### Reply by the Panel

Also, the 'Proportion of females finding a mating partner (l)' was estimated following a semi-formal EKE protocol using all available evidence of the assessment.

The estimated value for the proportion is 0.081% (8.1 out of 10,000 females), with 90% certainty range from 0.018% to 0.17% and a credibility range from 0.0071% to 0.2%. The uncertainty distribution is described as a GeneralBeta distribution with parameters ( $a = 1.8097$ ,  $b = 3.2291$ ,  $\min = 0$ ,  $\max = 0.0024$ ).

The result could be interpreted that it is likely that the true (but unknown) mating rate is up to 4.5-times lower or 2-times higher, but it is extreme unlikely that the true infestation rate is less than 11.5-times lower or more than 2.5-times higher.

The Panel strongly recommends to communicate the uncertainties in a quantitative manner, instead of giving vague descriptions as *'the probability that a female will find a mate may even be lower than the value estimated'* (BuRO, 2025, p. 43) or *'The probability of mating may also be higher due to a higher infestation rate than estimated in the qPRA'*. [ibidem].

The evidence used and discussed includes the intermediate result of 'Number of infested spears discarded across NUTS2<sub>30</sub> regions (i)', the 'proportion of adults emerging from the waste (j)', their break down to single regions, the clustering of populations within the regions, the timely distribution of imports during the year, lifetime of adults of *E. lignosellus* and the possible flight/spread capacity.

The fact that *'the Netherlands has found more than one specimen (up to four) of E. lignosellus in samples from consignments originating in Peru'* (BuRO, 2025, p. 42) was not available to EFSA at the time of the assessment. Please see Section 3.3.7 for further discussion.

#### Detailed response argumentation

Due to the complexity to integrate spatial and temporal variations of asparagus import the EKE focussed on NUTS2<sub>30</sub> regions with a high pest pressure. These are: Provence-Alpes-Cote d'Azur (FRL0), Attiki (EL30), Campagna (ITF3), Puglia (ITF4), Sicilia (ITG3), Lazio (ITI4), Catalunya (ES51), Comunitat Valenciana (ES52) and Andalucia (ES61). (EFSA PLH Panel, 2023c, Table D.2). Common characteristic of these regions is an agglomeration of the population (more than 0.8% of the total EU population per region) and as consequence a concentrated waste management.

Given that approximately 10% of imported asparagus spears, regardless of infestation status, are directed to professional organic waste treatment (Gould et al., 2006; EFSA PLH Panel, 2023c, p. 64), the possibility of spatial coincidence should be considered.

To reflect this approach the EKE question on 'Proportion of females finding a mating partner (l)' was adapted to: 'Assuming an entry of about 100 escaped adults in the NUTS2 region of Andalucia or about a thousand over the whole area suitable for establishment in Europe in the time frame of about eight months (June–January), what is the probability that an escaped adult female will find a mate either before flying off to find a host or at the host?' (EFSA PLH Panel, 2023c, Annex A).

Additional evidence on the population dynamics of *E. lignosellus* was taken from Mack et al. (1987). Discussions are summarised in the sections D.4 and D.6 of the EFSA qPRA (EFSA PLH Panel, 2023c).

### 3.3.5 | BuRO conclusion on the parameter 'trade volume'

Item E	Quoted text from BuRO document
<b>Parameter estimations</b>	<i>"The trade volume of asparagus spears from Peru appears to have been (unintentionally) overestimated. This may have led to an overestimate of the number of founder populations by roughly 30%."</i>

## Reply by the Panel

The Panel confirms the view of BuRO that ‘Details on the trade chain of the commodity on which the pest may arrive in the PRA area are needed to estimate the probability of transfer’ (BuRO, 2025, p. 47). Therefore, at the beginning of each qPRA the Panel collects data on the global trade of relevant commodities, stratified by exporting/importing countries, transportation means, temporal patterns during the year and time trends over the years. This includes regularly trade statistics from EUROSTAT, FAO-STAT, Interception data from TRACES, UNECE Quality Standards, market analysis from the Dutch Centre for the Promotion of Imports from developing countries (CBI), etc. If needed, hearing experts from EU MS and industry are invited to give additional information or clarifications.

This overview allows the selection of relevant pathways for the qPRA. The introduction of section C.1 (EFSA PLH Panel, 2023c) provides the reasoning for the selected pathway ‘fresh asparagus from Peru’ by comparing the import from Peru with other countries, the trend in volume since 2018 and the import pattern during the year.

Table C.1 and Figure C.1 (EFSA PLH Panel, 2023c) illustrate the reasoning. The data were extracted on 15th November 2022 from EUROSTAT table ‘Extra-EU trade since 2000 by mode of transport’ and show the import via air transport. We apologise that in the table header the addition ‘by air’ is missing and will update the opinion accordingly.

During this process each data source is also scrutinised on their possible usage for the quantitative analysis. Once the pathway is selected, the most relevant sources for the entry model are analysed and used. As documented in Annex A efs28004-sup-0001-annex\_a (EFSA PLH Panel, 2023c) the trade volume of fresh asparagus from Peru was estimated using annual data for 2017 to 2022 extracted from EUROSTAT, table: EU trade since 1988 by HS2-4-6 and CN8 for exporter ‘Peru’, product ‘Fresh or chilled asparagus’, flow ‘Import’ and reporter ‘European Union’ – 27 countries (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK). Last update: 20/02.2022, download 23/02.2023.

This choice is reasoned, because the data on the transportation mean in EUROSTAT are less complete, and partly difficult to interpret, as they refer to the last transportation mean before taxation/control.

The observed difference between the model estimates and the values of Table C.1 (EFSA PLH Panel, 2023c) is caused by confusion on the two steps in the assessment. The estimate of the ‘Import of fresh asparagus from Peru into the EU-27 (a)’ in the entry model is correct.

## Detailed response argumentation

**TABLE 6** Annual trade of ‘fresh and chilled asparagus’ from Peru to EU27 [in kg]. The limitations of the detailed data of EUROSTAT are shown, the data were extracted on 10th April 2026.

Transportation mean	Year								
	2017	2018	2019	2020	2021	2022	2023	2024	
	<b>Extracted from EUROSTAT table ‘Extra-EU trade since 2002 by mode of transport, by HS2-4-6’ on 10/4/2026</b>								
Air	14,653,600	17,950,122	18,550,780	12,737,442	15,911,618	15,805,263	11,350,345	12,445,495	
Sea	3,059,897	3,240,455	3,254,264	3,190,094	3,614,780	2,850,213	1,575,114	588,950	
Inland Waterway	1507	0	0	0	0	0	0	0	
Rail	0	0	0	0	0	0	0	0	
Road	1,792,067	2,167,069	2,837,334	2,436,798	3,064,945	2,908,098	2,149,839	2,383,260	
Unknown	0	0	26	0	22,585	962,274	359,911	309,081	
Sum	<b>19,507,071</b>	<b>23,357,646</b>	<b>24,642,404</b>	<b>18,364,334</b>	<b>22,613,928</b>	<b>22,525,848</b>	<b>15,435,209</b>	<b>15,726,786</b>	
	<b>Extracted from EUROSTAT table ‘Extra-EU trade since 2002 by mode of transport, by HS2-4-6’ on 15/11/2022</b>								
Air (Table C.1)		17,950,100	18,550,800	13,373,600	15,911,600	15,807,800			
	<b>Extracted from EUROSTAT table ‘EU trade since 1988 by HS2-4-6 and CN8’ on 10/4/2026</b>								
<b>Total</b>	<b>19,507,071</b>	<b>23,357,646</b>	<b>24,642,404</b>	<b>18,364,334</b>	<b>22,613,928</b>	<b>22,525,848</b>	<b>15,435,209</b>	<b>15,726,786</b>	
	<b>Extracted from EUROSTAT table ‘EU trade since 1988 by HS2-4-6 and CN8’ on 23/2/2023</b>								
Total (Annex A)	19,507,071	23,357,646	24,642,404	18,364,334	22,613,928	22,528,267			

EUROSTAT explains the transportation mean as: ‘Mode of transport – This identifies the active means of transport (e.g. road, rail, sea) by which the goods leave/enter the statistical territory of a Member State for intra-EU trade and of the EU for extra-EU trade. Note that the collection of the mode of transport for intra-EU trade flows became optional in 2001. Therefore, the information is not available for all the EU MS since January 2001 as reference month’. [Reference metadata of ‘International trade in goods – detailed data’ published on [http://ec.europa.eu/eurostat/cache/metadata/en/ext\\_go\\_detail\\_sims.htm](http://ec.europa.eu/eurostat/cache/metadata/en/ext_go_detail_sims.htm), accessed on 10/4/2026.]

These data are incomplete in some years (coded as ‘unknown transportation mean’) and not reliable, as the active means of transportation from Peru to the EU are unlikely by ‘Road’ or ‘Inland waterways’ (Table 6). The Panel interprets the transportation mean as the ‘last mean before taxation/control’.

Nevertheless, to avoid underestimation of the import the total import (sum over all means) of fresh or chilled asparagus from Peru to the EU was used as quantification of the parameter 'Import of fresh asparagus from Peru into the EU-27 (a)' in the entry model. The import is not distinguished between air and sea transport.

### 3.3.6 | BuRO conclusion on the uncertainty assessment

Item F	Quoted text from BuRO document
<b>Uncertainties</b>	<i>"Uncertainties are addressed and clearly expressed in the conclusions and abstract of the qPRA."</i>

#### Reply by the Panel

The Panel appreciates the recognition of the uncertainty assessment because all uncertainties of the input parameters and the overall model uncertainties are done quantitatively as described in the EFSA guidance on uncertainty assessment (EFSA Scientific Committee, 2018a).

### 3.3.7 | BuRO conclusion on the final output

Item G	Quoted text from BuRO document
<b>Comparison of the final output with the number of known outbreaks</b>	<i>"The final output (median value of one founder population per 10,000 years) was not in contradiction to field observations in the EU (no outbreaks detected)."</i>

#### Reply by the Panel

While theoretically the validation of model results with empirical observations is to be recommended, in practice existing observations seldom allow this comparison, due to their limited data quality.

BuRO (2025, p. 40) implies that interceptions at the border control should give the possibility to validate the estimate of the 'Infestation rate of asparagus from Peru (d)'. The Panel searches regularly for interceptions in Europhyt (1995 to until May 2020) and TRACES (June 2020-ongoing). Unfortunately, as mentioned in BuRO (2025) '(...) Member States (...) may not have notified their interceptions because the pest had no quarantine status'. (BuRO, 2025, p. 41). In fact, none of the Dutch findings: 'From 2010 to 2023, 45 interceptions/findings have been registered with most (25) in the years 2021 and 2022. In four samples more than one specimen (up to 4) have been registered. The Netherlands intercepted/found *E. lignosellus* during import inspections (for quality), during export inspections and during surveys on imported products that do not require a phytosanitary import inspection'. could be retrieved via Europhyt/TRACES at the time of publication of EFSA PLH Panel (2023c). Therefore, interception rates at the border are biased to lower values by underreporting.

The Panel appreciates the willingness of the Authority from the Netherlands to share internal interception data for non-regulated pests and for pests that have only recently been regulated based on EFSA opinions (BuRO, 2025, section 6.4 Recommendations).

Nevertheless, additional information on the control density, consignment and sample sizes, and detailed results (e.g. multiple findings) are needed to perform a complete analysis, especially to include information from negative controls. In absence of this detailed information from the UK (with reported interceptions) the Panel conducted an analysis of 9 reasonable scenarios. These results were used as input into the EKE of the parameter 'Infestation rate of asparagus from Peru (d)'. Further limitations of the interception data are:

Further limitations of the interception data are:

- the limited sample size, which is typically calculated to detect an infestation level of above 1% with a likelihood of more than 95%. Thus, lower infestation levels maybe be detected, but with lower likelihood.
- the lacking sensitivity of the inspection method and/or missing further confirmation of the finding.
- The lacking reporting of multiple findings (e.g. clustering of the infestation).

Outbreak reports should give another possibility to validate the results. Nevertheless, also outbreak reports show considerable limitations:

- *Elasmopalpus lignosellus* as highly polyphagous pest may establish on less examined crops or natural plants, e.g. grasses or weeds, without or delayed recognition of an outbreak.
- Time until detection may take also years in cropping systems, due to longer lag phases and/or limited damage.
- Measures applied in regular farming practice of other cropping systems, e.g. chemical pest management, may suppress the establishment of the pest or limits the yield/quality loss to a level, 'such that EU farmers consider the organism a member of the general pest fauna' (EFSA PLH Panel, 2023c). For details see section 3.4 on Impact in EFSA PLH Panel (2023c).

Thus, major underreporting of outbreaks of *E. lignosellus* is expected.

Under these circumstances the use of interception and/or outbreak data to validate the entry model of *E. lignosellus* is not reasonable.

### 3.3.8 | BuRO conclusion on the definition of 'transfer'

Item H	Quoted text from BuRO document
<b>Other comments</b>	<i>"There are contradictory statements about the steps involved in 'transfer' and those involved in 'establishment', but this does not affect the output of the model."</i>

#### Reply by the Panel

The qPRA of *E. lignosellus* was performed using the methodology described in the corresponding EFSA guidance (EFSA PLH Panel, 2018). This document describes the basic terminology and methodological concepts of the risk assessment. It should be seen as integral part of the scientific opinion.

The quantitative pathway model covers the full pest introduction comprising entry and establishment. Therefore, intermediate steps, such as 'Likelihood of movement of a pest to a place where the pest can establish / contact with a host (Transfer)' and 'Number of potential founder populations (Outcome of entry/start of establishment)' are not necessarily sub-steps of the pathway model on introduction.

In fact, the parameter 'Probability of established founder populations (o)' comprises the transition from a mated female to an established founder population, including finding a suitable host for laying eggs, building a potential founder population and establishment – in summary: the probability that a mated female will establish a founder population (EFSA PLH Panel, 2023c, Figure 2). This parameter covers aspects of transfer, entry and establishment. Nevertheless, no separate entry pathway model is claimed by the Panel.

The Panel does not see an additional value to split the pathway model on introduction in a part for entry (including transfer), and a separate part for establishment. The theoretical definitions of entry, (introduction, transfer) and establishment is unchanged.

#### Detailed response argumentation

The following definitions are given in the guidance on quantitative PRA (EFSA PLH Panel, 2018):

- *Transfer = Pest transfer has been defined as the movement of a pest from an imported commodity to a place where the pest can establish; see also ISPM 11, Section 2.2.1.5 (FAO, 2017)*
- *Transfer unit = A unit composed by one or more pathway units or subunits, which moves as a cluster within the risk assessment area and carries a pest population that goes to the final destination where establishment occurs (e.g. a field) and which can come into contact with the host and potentially be a founder population. Example: 100 tubers of seed potatoes to be planted in the same field*
- *Pathway unit = A unit of material or other means potentially affected by the pest that can be used to measure the flux along the pathway (number of pathway units per time unit). Examples are: a specific/certain number of crates of nectarines, metric ton of seed potatoes, cubic metre for wood/timber. The flux can be expressed in terms of a certain number of pathway units, e.g. per year. A pathway unit may or may not be affected (EFSA PLH Panel, 2018, Glossary)*

On page 11 of the qPRA of *E. lignosellus* it is stated that: 'The risk assessment used spears of asparagus as the most suitable unit because data are available on sampling procedures used for inspection, both at the origin and at entry in the EU. The sampling protocols use the asparagus spears as a unit of sampling'. (EFSA PLH Panel, 2023c, p. 11). Thus, no clustering is used in the pathway model, which would distinguish a 'Pathway unit' from a 'Transfer unit'.

In fact, neither a standardised package for the consumer (e.g. bundles of 250 g, 330 g, 400 g, 420 g, 450 g, 500 g and more are common), nor the thickness classes of asparagus (e.g. small, standard, large, extra, jumbo) would allow a suitable number of spears per pathway unit = consumer package. More common are standardised boxes of 5kg, which could be used as transfer units until retail. The necessary conversion into number of spears would need additional information on the market share of different thickness classes. In conclusion the Panel decided to use a single asparagus spear as unit – transfer and pathway unit – in the introduction model.

Even when the name 'transfer unit' includes 'transfer', it is not meant that a single transfer unit allows transfer of the pest to a place where the pest can establish as indicated in BuRO (2025, p. 37).

### 3.3.9 | BuRO recalculation of the introduction model

Item I	Quoted text from BuRO document
<b>Appendix F</b>	<p><i>“BuRO attempted to replicate the results shown in Table 4 on p. 29 of the qPRA of <i>Elasmopalpus lignosellus</i>. The replicated estimates were obtained by Monte Carlo simulation using R 4.2.3.</i></p> <p><i>Independent samples were drawn from the fitted distributions for each of the model parameters. For each draw the resulting values were multiplied according to the model structure to calculate the respective quantity of interest, using the fixed values of <math>p_{clim}</math> and <math>p_{waste}</math> as given in Table F1 where appropriate.”</i></p>

#### Reply by the Panel

The Panel appreciates the effort done by BuRO to implement the introduction model in R software and re-run the simulation. Major differences between the two implementations appeared only because BuRO overlooked the existence of the parameter ‘Proportion of females (m)’ in the EFSA model. (BuRO, 2025, Tables F7 and F8). The remaining differences were below +/- 2.5% for the 90% certainty interval, which is usually reported in EFSA opinions. These are likely caused by variations between simulation runs and limited number of replications.

The provision of the full model implementation in @RISK, as given in the EXCEL file of Annex A (File: efs28004-sup-0001-annex\_a.xlsx) should enable more readers to re-run and evaluate the simulations without an additional implementation in another software environment, which also allows the evaluation of the simulation stability.

The implementation in @RISK as add-on to EXCEL has some advantages also for all users of EXCEL only:

- Clearly formatted structure for documentation of each input parameter, incl. basic statistics and graphical representations.
- Parallel provision of underlying datasets, including necessary conversions, transformations etc.
- Possibility of complete documentation, including screenshots of references etc.
- Model definition using common EXCEL formula with the possibility to recode in other Monte-Carlo packages, like R.

In case the reader has a valid @RISK licence, additional advantages are:

- Possibility to re-activate the @RISK code and re-run the simulation, examine its stability and calculate parameter sensitivities.
- Full documentation of simulation parameter using @RISK functionalities.

For the second implementation by BuRO (2025, p. 74, Tables F10 to F12) see the reply in Section 3.4.2.

The Panel also notes that, following the completion of the three above-mentioned qPRA, an R Package for qPRA entry assessment was developed by a research project co-funded by EFSA and published (Rosace et al., 2025; <https://cran.r-project.org/package=qPRAentry>; <https://github.com/mcendoya/qPRAentryReferences>). Further work to streamline the qPRA assessment is currently being conducted in the Trade Intelligence Platform of the JRC, within a Service Level Agreement between EFSA and JRC.

## 3.4 | Other statistical considerations

### 3.4.1 | BuRO conclusion on the choice of fitted distributions

Item A	Quoted text from BuRO document
	<p><i>“At some places in the three qPRAs evaluated in this document, the fitted distributions show some undesirable behaviour, which manifests itself in two ways:</i></p> <ol style="list-style-type: none"> <li><i>1. insufficiently bounded distributions,</i></li> <li><i>2. overly strict bounds on distributions.”</i></li> </ol>

#### Reply by the Panel

The EFSA methodology on EKE is detailed in the corresponding EFSA guidance (EFSA, 2014). Its application in uncertainty assessment is further outlined in EFSA guidance on uncertainty (EFSA Scientific Committee, 2018a) and methodological background (EFSA Scientific Committee, 2018b).

The final goal of the application of EKE is to provide a quantitative description of the remaining uncertainties of the outcome of a risk assessment, in this case a qPRA.

In a structured process a group of experts is enabled to express the uncertainties in form of subjective probability distributions, avoiding heuristic biases as much as possible, allowing the review of the evidence and reasoning, and allowing – at least in principle – the repeatability of the full process.

The EKE protocol used in the three qPRAs, which were reviewed by BuRO (2025), is a semi-formal EKE within the EFSA Working Group of experts, using the quartile method to elicit individual judgements and behavioural aggregation to develop the group judgement.

In the final step the agreed values of the group, namely the credibility range, the median and the inter-quartile range are used to fit a continuous distribution (by minimising the squared distance between the 1st, 25th, 50th, 75th and 99th percentiles with the cumulative distribution function). The result is confirmed by the group of experts as adequate representation of the remaining uncertainties.

Due to psychological limitations to judge very small (close to 0% or 100%) probabilities, extrapolations outside the credibility range are vague. The bounded GeneralBeta distribution with given 1st and 99th percentile is a possible method to avoid far extrapolations outside the credible range, which are not substantiated by the expert judgements.

The resulting bounds should not be interpreted as theoretical limitations, but as a range, where the experts express their view, that values outside the range are extremely unlikely. BuRO states that ‘such a sharp boundary does not seem reasonable’ (BuRO, 2025, p. 78) without pointing out, which extrapolation method should be used to go beyond the elicited credible range.

Of course, existing theoretical bounds have to be respected. In case of unlimited or one-side-bounded distributions the fitted distribution should be truncated to its theoretical bounds, if it would otherwise leave the region with theoretical support. Truncation is required to ensure that the fitted uncertainty distribution respects theoretical bounds and does not assign probability to impossible values or unsupported extreme tails. Nevertheless, the knowledge on the theoretical bounds maybe also uncertain, as for the theoretical upper limit of the disaggregation factor.

### 3.4.2 | BuRO conclusion on the treatment of probabilities as proportions

Item B	Quoted text from BuRO document
	<p><i>“All of the models in the qPRAs evaluated here include parameters that are described as probabilities [Footnote: Note that these are different from the probabilities used for the probability distributions for the parameters.]. In all of these models, these probabilities are multiplied with other model parameters to obtain the final estimated number of event (and uncertainties). In general, this approach is valid for proportions but not for probabilities. In this context the use of a proportion implies that a particular event will always happen for a given fraction of a population. For example, if the infestation of fruits is modelled using a proportion X (with associated uncertainty) then each batch of size N to which this proportion is applied will be assumed to contain exactly X * N infested fruits. On the other hand, the infestation of fruits could also be modelled using a probability Y (again with associated uncertainty). If this probability Y is applied at the level of the batch, then the batch is either infested (with probability Y) or not infested (with probability 1-Y). If the probability Y is applied at the level of the individual fruit, then for each fruit there is a probability ability Y that the fruit is infested. All of these implementations have the same expectation as long as X = Y, i.e. over a large number of batches the total number of infested fruit will be approximately the same in each implementation.”</i></p>

#### Reply by the Panel

As described in the section before the goal of defining uncertainty distributions is to estimate the impact of remaining scientific uncertainties on the final outcome and conclusions of the EFSA scientific opinion in a quantitative way (EFSA Scientific Committee, 2018a), e.g. the number of founder populations. The Panel uses Monte-Carlo simulations as a simple tool to propagate the uncertainties through the model equation as numerical integration of subjective probabilities.

Independent from this method is the interpretation of the equation of the introduction model as mapping the pathway from the country with the pest to the outbreak in the EU. The model is a simple multiplicative volume model, which starts with the predicted annual import volume of a commodity, converted to the number of possible infested pathway units, and stepwise multiplied by factors describing (independent) transformations on the pathway. Each factor describes a reduction of risky volume as the expected average of the process. This model is NOT stochastic. The naming of the different factors as ‘rate’, ‘proportion’ or ‘probability’ is only used colloquially, and follows a common wording by the topic experts.

The simulation should not rebuild a stochastic process, which happens at different stages of the pathways, e.g. if a consignment is rejected after testing. Therefore, the interpretation of BuRO (2025), that the parameter name ‘probability’ indicates a stochastic Bernoulli experiment is not correct.

#### Detailed response argumentation

Of course, BuRO can calculate a stochastic process model to map the pathway. Especially when several measures are applied within a system approach, this is also advised to capture dependences between the application of measures and integrate the decision rules of the system approach into the model.

For the simple multiplicative volume model, the additional effort is not necessary, as for larger volumes (infinite replications) the stochastic model converts to the expected values, as BuRO (2025) also concluded on page 79.

## 4 | CONCLUSIONS

The Panel responded in this Statement to a report published in November 2025 by the Office for Risk Assessment & Research (BuRO) of the Netherlands Food and Product Safety Authority. In that report, the approaches applied by the EFSA PLH Panel (Panel) in three qPRA were narratively scrutinised against an unpublished protocol. According to the conclusions

of the BuRO's report, all three Panel approaches were methodologically valid and appropriate in substance. However, several assumptions made by the Panel in its assessments were debated and individual values of model parameters were questioned and/or replaced by BuRO calculations.

This Panel statement responds to the specific comments, mathematically reviews the calculations in the BuRO's report and highlights how quantitative assessments under uncertainty may slightly differ in their output values when different risk assessors find different consensus interpretations of available background evidence. Some quantitative recalculations by BuRO required mathematical correction. Other recalculations depended on alternative ad hoc assumptions or parameter interpretations that the Panel does not consider sufficiently substantiated to replace those used in the assessments. Therefore, the conclusions of the three qPRA by the EFSA PLH Panel remain unchanged.

All comments provided by BuRO were carefully considered, the consequences for the outcome of the evaluated Panel opinions were drawn, and no modifications were found to be necessary to those outcomes. Few editorial changes were identified, and action was taken to modify the Panel opinions accordingly.

The Panel noted that this exercise was time-consuming for both parties, and that it could have benefited from more collaboration. An open dialogue and dedicated meetings could have avoided or at least reduced misunderstandings and made better use of the common discussion platform provided by the EFSA Scientific Network with Member States on Plant Health Risk Assessment.

The Panel notes that some misunderstandings in the BuRO evaluation of the Panel opinions may stem from the separation of content between the main text (intended for accessibility) and the Appendix/Annex (containing technical details). In some cases, it appears that only the main text was considered, without full reference to the supporting material. The Panel will address this in future Opinions by improving the clarity and communication of how content is structured between the main text and the Appendix/Annex.

The issue of using a consistent terminology was taken on board and will be carefully considered in the new protocol for pest risk assessment and future pest risk assessments.

The recurring comment on matching the risk estimates with numbers of outbreaks / interceptions has been addressed in this statement. Attempting to validate or invalidate risk estimates using only outbreak or interception data is considered inappropriate, as both are based on convenience samples that are subject to a range of known biases and confounding factors.

Regarding the BuRO (2025) report recommendation that EFSA PLH Panel's outputs should be peer-reviewed by experts on PRA and statistics and modelling before publication, the Panel notes that EFSA already applies a robust and independent scientific review process designed to avoid methodological errors and the use of inappropriate approaches. Draft scientific opinions are developed by dedicated Working Groups and are subsequently reviewed and commented on by the relevant Scientific Panel before adoption. Panels are composed of independent experts selected through public open calls, covering a wide range of disciplines, including pest risk assessment, statistics and modelling, ensuring that the necessary expertise is fully represented throughout the assessment process. Where uncertainty or complex judgements need to be addressed, EKE is applied in line with EFSA (2014) guidance, following a transparent and structured methodology and involving experts with the relevant scientific and statistical expertise. This multi-layered review mechanism ensures rigorous scrutiny of both methods and conclusions prior to publication and underpins the scientific quality and reliability of EFSA outputs supporting EU plant health legislation.

## 5 | RECOMMENDATION

To facilitate future commenting of external assessors on the EFSA output it is recommended:

- To make more use of regular opportunities to clarify questions with EFSA by discussing at EFSA Scientific Network on Plant health risk assessment or at dedicated meetings and by actively engaging in EFSA public or ad hoc consultations;
- To use a more structured approach for written commenting that can be elaborated in a point-by-point manner including numbered comment items with related data, calculations and reinterpretations placed together, so that the effort required for the replies can be focused on constructive improvements to pest risk assessment in the EU.

### GLOSSARY

BuRO	Office for Risk Assessment & Research (the Netherlands)
EKE	expert knowledge elicitation
EU MS	European Union Member States
JRC	Joint Research Centre
NUTS	Nomenclature of territorial units for statistics
NVWA	Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit)
PLH	Plant Health
qPRA	quantitative Pest Risk Assessment

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## REQUESTOR

European Food Safety Authority

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