The EFSA quantitative approach to pest risk assessment – methodological aspects and case studies*

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A new method for pest risk assessment and the identification and evaluation of risk-reducing options is currently under development by the European Food Safety Authority (EFSA) Plant Health Panel. The draft method has been tested on pests of concern to the European Union (EU). The method is adaptable and can focus either on all the steps and sub-steps of the assessment process or on specific parts if necessary. It is based on assessing changes in pest population abundance as the major driver of the impact on cultivated plants and on the environment. Like other pest risk assessment systems the method asks questions about the likelihood and magnitude of factors that contribute to risk. Responses can be based on data or expert judgment. Crucially, the approach is quantitative, and it captures uncertainty through the provision by risk assessors of quantile estimates of the probability distributions for the assessed variables and parameters. The assessment is based on comparisons between different scenarios, and the method integrates risk-reducing options where they apply to a scenario, for example current regulation against a scenario where risk-reducing options are not applied. A strategy has been developed to communicate the results of the risk assessment in a clear, comparable and transparent way, with the aim of providing the requestor of the risk assessment with a useful answer to the question(s) posed to the EFSA Plant Health Panel. The method has been applied to four case studies, two fungi, Ceratocystis platani and Cryphonectria parasitica, the nematode Ditylenchus destructor and the Grapevine flaevescence dorée phytoplasma. Selected results from these case studies illustrate the types of output that the method can deliver.

Introduction

Risk assessors in food safety should aim to express pest impact and uncertainty related to the assessment in quantitative terms, to the extent that this is scientifically achievable (EFSA, 2009, 2017; Codex 2015). A principal reason for this is that qualitative expressions are often ambiguous (e.g., Theil, 2002; MacLeod & Pietravalle, 2017) and can imply a value judgment outside the remit and scope of risk assessment. Furthermore, many risk management decisions are based on comparisons of scenarios and options for management, and such decisions could be better informed and made more transparent if risk assessments were underpinned by quantitative estimates to describe the magnitude and uncertainty of key risk elements (Morgan & Henrion, 1990). In addition, quantitative methods of risk assessment can be considered to have greater technical rigour because they can provide a dynamic and systemic representation of the processes related to the risk. In quantitative methods the assessed variables should refer to variables in the real world that can be counted/measured (e.g. the number of established populations in a certain time frame and area), providing a more transparent output that has a clear and unequivocal meaning.

The European Food Safety Authority (EFSA) recommends that efforts should be made to work towards more quantitative expression of both risk and uncertainty whenever possible. In cases where verbal terms are used, they

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should have quantitative definitions; associated uncertainties should always be made clear to reduce the risk of over-precise interpretation (EFSA, 2012). Guidance documents produced by EFSA panels need to be regularly reviewed (EFSA Scientific Committee, 2015). In reviewing the previous guidance for plant pest risk assessment (EFSA, 2010) the EFSA Plant Health Panel (PLH Panel) developed a draft pest risk assessment process that sought to address calls for increased quantitative assessment of risk. Previously, the PLH Panel conducted risk assessments using a modified version of an earlier EPPO risk assessment method (Appendix C of EFSA, 2010). This method rated the risk with terms such as ‘very unlikely’, ‘unlikely’, ‘moderately likely’, ‘likely’ and ‘very likely’. Although advice is available, together with examples of how these terms could be used more consistently (Schrader et al., 2010), they could still be interpreted differently by different risk assessors and risk managers (Schrader et al., 2012). However, the authors of this paper assume that the less ambiguous and more consistent and transparent a risk assessment system is, then the more efficiently the results can be used by risk managers. The interpretational challenges associated with any qualitative risk assessment method are key reasons to seek to develop a quantitative approach. Such thinking led the PLH Panel to develop and test a quantitative method for pest risk assessment that also permits the evaluation of risk-reducing options (RROs). The method has been trialled in a pilot phase by the PLH Panel when responding to requests for scientific opinions regarding risks posed by four pests listed in Annex II A II of plant health directive 2000/29/EC: the two fungi Ceratocystis platani and Cryphonectria parasitica, the nematode Ditylenchus destructor and the Grapevine flavescence dorée phytoplasma. This paper outlines the new approach with reference to these four case studies.

**Methods**

**Overview – design principles**

The quantitative approach was developed according to three design principles. (1) **Adaptability** was needed to account for the conditions and resources for the assessment, data availability or other aspects relating to the pest and the objective of the assessment. (2) The method is based on **pest population** since the invasion process is seen as a flow of events and processes that change the abundance of the pest population in all steps and sub-steps throughout the assessment. Such a mechanistic approach can take into account all relevant biological and ecological processes, and relies on data, existing models or expert judgment (Fig. 1). This approach directly integrates the RROs among the factors that change pest abundance. The RROs are assessed by considering specific scenarios in which they are applied at the appropriate step of the invasion process, e.g. during the entry or establishment steps. The effectiveness of RROs can be quantified by comparing scenarios, e.g. comparing the number of potential founder pest populations that enter the pest risk assessment area with and without a RRO in place. (3) In order to report such a finding the method has to be **quantitative**. Knowledge and uncertainty are combined using probability distribution of the assessed variables and parameters used in the assessment. To make the results of the assessment more transparent and facilitate consistency between assessments, the outcome of the assessment procedure is expressed in quantities that are measurable and have an explicit meaning in the real world. This contrasts with alternative methods that express pest entry in terms of probability of entry without revealing the magnitude of entry, i.e. without revealing propagule pressure. The new approach expresses pest entry in terms of the number of potential founder pest populations that enter the pest risk assessment area in the selected time unit (typically a year) and for a certain temporal horizon and spatial domain (typically the continental EU).

**Scenarios and scales**

To conduct the assessment, assessors envisage several scenarios according to the mandate for which the assessment is required. For example, a mandate may require a risk assessment for a pest that is being considered for

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Fig. 1 Conceptual representation of the quantitative method showing the major steps. Note that the assessment focuses on changes in pest abundance during the invasion process. [Colour figure can be viewed at wileyonlinelibrary.com].
deregulation. In this case assessors would compare one scenario that describes the current regulation against another scenario where the pest is deregulated and RROs are not applied. By assigning different scenarios to a pest, including pests not yet present, the probability distribution of the expected impacts can be estimated, thus informing risk management decision-making regarding appropriate RROs. Scenarios should state whether they include specific environmental conditions such as climate change, and if so, which climate change scenario.

Since the new approach is based on the assessment and comparison of different scenarios, all scenarios and scenario components should comply with the mandate to ensure that the risk that is being assessed is actually the risk about which risk managers want information. Hence it is useful for assessors to consult with risk managers to agree on the scenarios to be assessed. In cases where there is a sudden change to the risk managers’ concerns, it is possible to add additional scenarios. Once scenarios are agreed, the risk assessment is carried out for the selected scenarios, always considering a baseline scenario A₀ which reflects the current situation: namely, all open pathways, applied regulations, RROs. To account for the time horizon in the assessment, the current situation is projected to a certain time into the future. Changes in the pathways or RROs etc. (scenarios A₁–Aₙ) can then be evaluated against this baseline scenario. Clear units and values assigned to the assessed variables and parameters increase the transparency of the assessment – and the assessment, including the assumptions being made and the procedure being applied, can be checked.

With this mechanistic approach based on the spatial and temporal variations in pest abundance (defined in terms of density, incidence or prevalence), it is possible to estimate the spatial and temporal variability of the impact on cultivated plants and the environment (ecosystem services and biodiversity). The assessment of the impact is therefore conducted on specific and clearly defined spatial and temporal scales, which are the same as those at which the projection of the distribution of pest abundance is performed. For the spatial scale the extent is typically the continental EU, and the resolution is typically based on the geocode standard of NUTS (Nomenclature des unités territoriales statistiques; EuroStat, 2013). For the temporal scale, the time horizon over which the risk is assessed depends on the biology of the pest, its capacity to spread and other factors. Temporal resolution can be any relevant time interval, although annual or monthly time steps would seem most appropriate. The reasoning for the choice of spatial and temporal scales should be based on the mandate request and biological relevance.

**Method steps**

The quantitative risk assessment procedure is divided into a series of steps following the process of invasion from entry to establishment and spread, through to the impacts on host plants, ecosystem services and biodiversity in the risk assessment area. For an assessment considering a pathway consisting of a pest moving with a plant or plant product, the assessment begins by considering the abundance of the pest when it leaves the place of production. The within-step processes are mechanistically described by the use of step-specific models, possibly process-based models that take the conditions described in a specific scenario into consideration. The steps are integrated, considering the outcome of each step as the model initial conditions for the following step. At the end, this series of models is able to produce a projection of the distribution of population abundance from which the impact on cultivated plants and the environment is derived (Fig. 2).

The assessment of risks posed by the pest is conducted by creating a panel of experts on the pest, its host plants and other information needed (e.g. on pest management practices). The experts need to answer questions relating to risk elements (Fig. 3). In answering the questions, assessors review data and evidence or draw upon their knowledge to provide estimates of selected quantiles of the uncertainty distribution (1st, 25th, 50th, 75th and 99th quantiles). Elicitation of expert knowledge could also be used to generate group answers (EFSA, 2014a).

A harmonized communication strategy has been developed, with the aim of clearly and transparently communicating the results of the risk assessment. This strategy is based on comparisons between different uncertainty distributions related to different scenarios, the consideration of the source of uncertainties and their relative contribution. The uncertainties not explicitly considered in the

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**Fig. 2** A conceptual model showing how the impact is a consequence of the population abundance or prevalence, which is in turn influenced by environmental variables and pest management.
assessment model are listed and their possible effects on the assessment are discussed. Also the risk of different pests can be compared in the same way if needed.

Case studies: *Ceratocystis platani*

The fungus *Ceratocystis platani* infects *Platanus* trees, and is present in the EU in France, Greece and Italy. In this case study the effectiveness of RROs in the EU against the spread and impact of *C. platani* was assessed based on the mechanisms of spread by natural and human-assisted means, including waterways, root anastomosis, contaminated pruning tools, machinery, insects, contaminated insect frass and sawdust (EFSA, 2014b, 2016a). The following three scenarios were considered: the current situation (A0 scenario); the situation without RROs (A1); and the application of additional RROs (A2).

It was found that the risk of new introductions into the EU of *C. platani* by means of the main pathways of entry (i.e. plants for planting, wood and machinery, e.g. construction machinery and pruning/cutting tools) is relatively limited, but about 250 times higher for the A1 scenario than for the A2 scenario (median numbers of established populations). The risk of spread from already affected EU regions is higher, but varies depending on the scenario. Machinery is the most important mechanism of long-distance spread. If the additional RROs in the A2 scenario were focused on machinery, which is currently not regulated, the likelihood of further spread to as yet unaffected EU regions and impacts to *Platanus* trees would be effectively reduced.

Case studies: *Cryphonectria parasitica*

The bark-inhabiting fungus *Cryphonectria parasitica* causes blight of chestnut trees (*Castanea* spp.) and is widely distributed in non-protected zones in the EU. The aim of the risk assessment on this fungus was to assess the current EU phytosanitary requirements and to identify the RROs which would preserve the protected zone (PZ) status in some parts of the EU where the pathogen is not known to occur (EFSA, 2016b). To do this, three scenarios were chosen for the whole risk assessment area: the current situation in non-PZs (scenario A0), the situation in the EU without measures (A1) and the current situation in PZs with additional RROs.
Both intra-EU spread of C. parasitica strains that are not present in the non-PZs and introduction from non-EU countries of new, virulent strains that could jeopardize the currently effective hypo-virulence and thus cause severe impact, were considered to assess the risk of spread and impact of the fungus. It was found that the number of new introductions of C. parasitica into the EU would be reduced by approximately a factor of 5000 (median values) in scenario A2 compared with scenario A0. Under the different scenarios, the following median values of regions to be affected in the EU Member States were estimated:

- A0: 2 NUTS 1 regions in the next 10 years
- A1: 3.5 NUTS 1 regions in the next 10 years
- A2: 0.5 NUTS 1 regions in the next 10 years

The estimated relative impact on ecosystem services, due to the introduction and spread in the EU of new, virulent strains, is higher for scenario A1 than for the other two scenarios. The current EU requirements plus the RROs added in scenario A2 were assessed to be effective in reducing the risk of introduction and spread of C. parasitica, and preserving the PZ status in some parts of the EU.

Case studies: Ditylenchus destructor

For the potato rot nematode, Ditylenchus destructor, present in most EU countries but mostly with restricted distribution, the risks of entry, establishment, spread and impact on potato (Solanum tuberosum) and tulip (Tulipa spp.) were assessed for the EU, considering the two main pathways for entry and for spread, namely plants for planting, including seed potatoes, and flower bulbs (EFSA, 2016c). It was found that changes in pest-specific regulations have little influence on further entry of the pest as other non-specific regulations already lead to a good level of protection against new introductions of the nematode into the pest risk assessment area. The entire risk assessment area is suitable for establishment of D. destructor, but there is insufficient information to make a statement on the likelihood that those nematodes that arrive would transfer to hosts and survive to initiate populations that would be capable of establishment.

Case studies: Grapevine flavescence dorée

Three scenarios were analysed to quantitatively assess the risk posed by the Grapevine flavescence dorée phytoplasma to EU territory (EFSA, 2016d). Scenario A0 is the baseline scenario with current measures in place; scenario A1 is designed to improve the phytosanitary status of grapevine propagation material; and scenario A2 is based on a reinforced eradication and containment programme. The potential for Grapevine flavescence dorée phytoplasma to enter the EU is limited, since the phytoplasma is almost non-existent outside the EU. Grapevine flavescence dorée phytoplasma and its major vector, Scaphoideus titanus, have already established in many member states of the EU, partly with restricted distribution, and have the potential to establish in a large fraction of the currently unaffected EU territory. With the current measures in place (A0), spread of Grapevine flavescence dorée phytoplasma is predicted to continue with a progression of between a few and approximately 20 newly infested NUTS 2 regions expected during the next 10 years, illustrating the limitations of the current control measures against spread. Spread is similar between scenarios A1 and A2, but more restricted than under scenario A0.

Under scenario A0, Grapevine flavescence dorée phytoplasma has a 0.5–1% impact on the overall yield of EU grapes and wine production, reflecting the effectiveness of the current control measures against impact. Under both A1 and A2 scenarios, the impact of Grapevine flavescence dorée phytoplasma would be reduced by approximately one-third (A1) to two-thirds (A2) compared with A0; however, the associated uncertainties are high. The generalized use of hot water treatment for planting material produced in infected zones makes the most important contribution to impact reduction for Grapevine flavescence dorée phytoplasma in scenario A1 and has a high feasibility for implementation. Both increased eradication and containment measures contribute to impact reduction under scenario A2 but the overall feasibility of these measures in this scenario is lower than in scenario A1.

Discussion

A new method has been developed for plant pest risk assessors to conduct pest risk assessment in a fully quantitative way. The method is aligned with ISPM 11 (FAO, 2004). It helps make the process more transparent and allows comparisons to be made between different scenarios within a risk assessment as well as between risk assessments for different pests.

However, conducting a quantitative risk assessment is not without its challenges. Major challenges were discussed at an EFSA Scientific Colloquium in 2007 (EFSA, 2007). The working groups trialling the quantitative method experienced severe difficulties in obtaining the required data and the approach was typically characterized as ‘data hungry’. Lack of data to enable precise responses to the types of questions typically asked in pest risk assessment schemes was an issue in 2007 (EFSA, 2007), and remains a significant challenge today. However, lack of data is always a problem for risk assessors, regardless of whether a quantitative or qualitative method is being used. Judgments made in qualitative schemes and the mechanisms used to combine risk factors to derive an overall assessment of risk can be less transparent in qualitative methods. In the longer term, in this age of information, the adoption of more quantitative methods could drive greater and more accurate data collection and increase the efficiency of quantitative risk assessments.

Another key experience reported by groups testing the method was the workload involved in the quantitative assessment of uncertainty. Risk managers commissioning
risk assessments and those responsible for delivering assessments need to balance the resources required to conduct a quantitative assessment with the benefits that such assessment provides.

To facilitate take-up of the revised method and to ensure the new method is appropriate for the purpose it seeks to support, i.e. to inform plant health pest risk management decision-making, communication between EFSA and risk managers needs to be intensified. A survey seeking feedback from users of the risk assessment method would highlight areas where any further necessary refinements to the quantitative method are required. Further testing of the method with more case studies should enhance mutual understanding of the method. Currently, a second set of case studies is being conducted, taking into account experience and feedback from the first batch of studies and from a training event carried out in November 2016. To communicate results in a harmonized way, the new method will be presented using a template with a communication strategy embedded with recommendations on how to visualize and interpret the results. It will also provide guidance for conducting the method and presenting uncertainty in a standardized way to simplify results and increase transparency.

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Approche quantitative de l’EFSA pour l’évaluation du risque phytosanitaire - Aspects méthodologiques et études de cas

Le Panel Santé des plantes de l’EFSA développe actuellement une nouvelle méthode pour l’évaluation du risque phytosanitaire, ainsi que l’identification et l’étude des options de réduction du risque. La méthode, non finalisée, a été testée sur des organismes nuisibles d’importance pour l’Union européenne. Elle est adaptable et peut ainsi s’appliquer, soit à la totalité des étapes et sous-étapes du processus d’évaluation, soit à certaines parties seulement si nécessaire. Elle repose sur l’évaluation des changements d’abondance de population d’un organisme nuisible comme étant le moteur premier des impacts sur les plantes cultivées et sur l’environnement. Comme pour d’autres systèmes d’évaluation du risque, la méthode consiste en une succession de questions quant à la vraisemblance et l’importance des facteurs contribuant au risque. Les réponses s’appuient soit sur des données, soit sur un jugement à dire d’expert. L’approche est essentiellement quantitative, et rend compte des incertitudes par des estimations, en quantiles, de la probabilité de distribution des variables et paramètres évalués. L’évaluation se base sur la comparaison de différents scénarios et la méthode intègre des options de réduction du risque qui s’appliquent, ou non, à ces scénarios (par exemple: la réglementation actuelle par rapport à un scénario où aucune option de réduction du risque n’est appliquée). Une stratégie a été développée afin de permettre de communiquer les résultats de l’évaluation du risque, de façon claire, homogène et transparente, et avec pour objectif de fournir au commanditaire de l’évaluation du risque une réponse utile à la (ou aux) question(s) posée(s) au Panel Santé des Plantes de l’EFSA. La méthode a été mise en application au cours de 4 études de cas, sur les deux champignons Ceratocystis platani et Cryphonectria parasitica, sur le nématode Ditylenchus destructor, ainsi que sur le phytoplasme de la Flavescence dorée de la vigne. Des extraits de ces études de cas illustrent le type de rendus que la méthode peut délivrer.

Количественный подход EFSA к оценке фитосанитарного риска. Методологические аспекты и конкретные исследования

Группой экспертов по карантину растений Европейского агентства по безопасности продуктов питания (EFSA) разрабатывается новая методика оценки фитосанитарного риска, а также отбор и оценки вариантов снижения риска (BCP). Проект этой методики тестировался на вредных организмах, имеющих значение для ЕС. Эта методика может адаптироваться и концентрироваться либо на всех полноценных и промежуточных этапах процесса оценки, либо, в случае необходимости, на определенных его частях. Она основывается на оценке изменений в численности популяции вредного организма, принятых за главный драйвер воздействия на культурные растения и на окружающую среду. Также как и другие системы оценки фитосанитарного риска, эта методика ставит вопросы о вероятности действия факторов, способствующих риску, и о их масштабе. Ответы на эти вопросы могут основываться либо на конкретных данных, либо на экспертном мнении. Важно, что такой подход является количественным, он фиксирует неопределенность оценок экспертов, представляя квантильные оценки распределений вероятностей оцененных переменных величин и параметров. Оценка основывается на сравнениях между различными сценариями, и методика интегрирует варианты снижения риска применительно к конкретному сценарию, например, к действующим регламентациям, по сравнению с таким сценарием, в котором ВСР отменяются. Стратегия была разработана таким образом, чтобы выдавать результаты оценки риска четкими, сопоставимыми и прозрачными, с тем чтобы представлять заказчикам, требующим оценки риска,
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