

## SPECIAL ISSUE

### Risk assessment in support of plant health

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#### ABSTRACT

With the establishment of the Plant Health Panel in 2006, EFSA became the body responsible for risk assessment in the plant health area for the European Union (EU). Since then more than 70 outputs have been produced dealing with the full range of organisms harmful to plant health across all crop types and plants in the environment. There has been an increasing trend towards producing scientific opinions which are full pest risk assessments for the whole EU territory. In its work, and as a contribution to the wider development of risk assessment methodology, the Panel has developed a series of guidance documents. These deal with the peer review of existing pest risk assessments, a framework for conducting risk assessments which harmonise standards set by the International Plant Protection Convention and the legislative requirements of the EU, and extension of this framework to include environmental risk assessment and the evaluation of risk reducing options. Quantitative approaches have become increasingly important during this time. The Panel has developed such methods in climatic mapping (in association with the Joint Research Councils), application of spatial spread models, re-evaluation of quantitative pathway analyses, and in statistical modelling of experimental data. A Plant Health Network has been established to facilitate interaction with EU Member States, especially in relation to data collection and co-ordination of risk assessment activities. At the current time a revision of the EU Plant Health Regime is being formulated. The legislative consequences of the revision will be of considerable significance for the work of the Plant Health Panel.

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#### KEY WORDS

EU Plant Health Regime, ecosystem services, harmonised risk assessment framework, pathway analysis, plant health, risk-reducing options

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## INTRODUCTION

The EFSA Scientific Panel on Plant Health (hereinafter, the PLH Panel) was established in 2006, four years after the establishment of EFSA, with the Commission Regulation (EC) No 575/2006<sup>3</sup>, recognising the protection of plant health as an essential factor in the security of the food chain. EFSA then became the EU responsible body for risk assessment in the plant health area (Schans et al., 2008). The Panel provides scientific opinions on risks posed by non-endemic living organisms harmful to plants and/or plant products that are associated with movement of plants and/or plant products and that may enter, establish, spread and cause harmful effects on plant production and plants in the environment.

The European Community Council Directive 2000/29/EC<sup>4</sup> codifies the right to take protective measures to prevent the introduction and further spread into the Member States of the European Union of organisms harmful to plants or plant products, ranging from viroids and virus-like particles to molluscs and flowering plants. Internationally endorsed guidelines for “Pest risk analysis” have been developed by the International Plant Protection Convention (IPPC) (FAO, 2011a), with a more detailed regional standard developed in Europe by the European and Mediterranean Plant Protection Organisation (EPPO, 2011).

### 1. SCIENTIFIC ACHIEVEMENTS

Production of pest risk assessments and evaluation of pest risk analyses and guidance documents represent the core outputs of the PLH Panel. PLH risk assessments can include the identification of pest risk management options and evaluation of their effect on the level of pest risk. During its first two mandates (June 2006 - June 2012), the PLH Panel produced more than 70 outputs, of which six were risk assessments of plant pests in the EU territory. The breakdowns of these outputs according to various categories are shown in Figures 1 and 2. The PLH Panel also developed new methods in risk assessment and shared the results of its work through public consultation, scientific publications and participation in international conferences. In particular, a series of guidance documents has been published in support of its risk assessments.

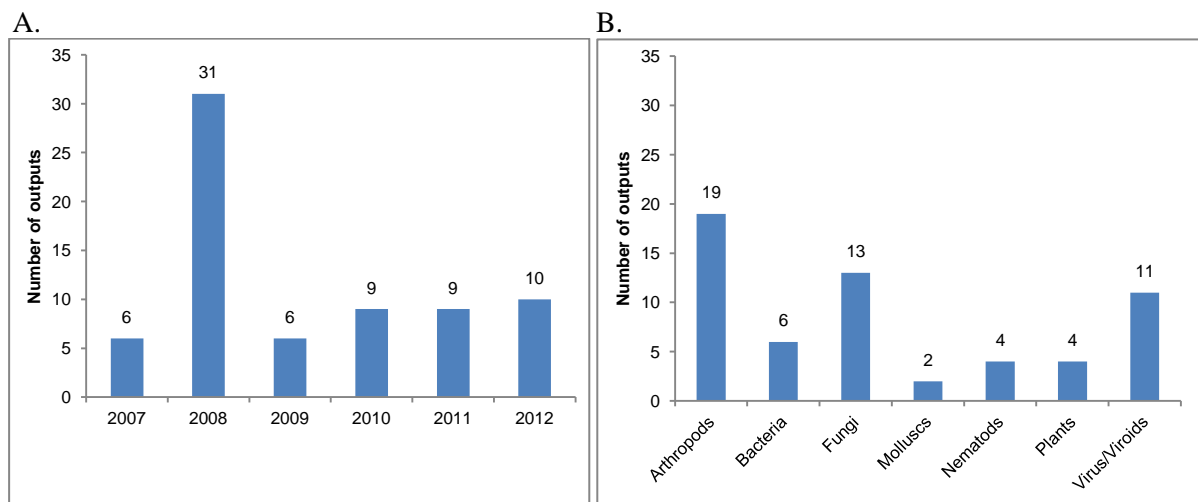
#### 1.1. Evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC

During its first mandate (2006-2009) the Panel evaluated risk assessment documents produced by Member States of the EU and other organisations and prepared according to the International Standards for Phytosanitary Measures (ISPMs), especially ISPM No 11 (FAO, 2011b), as provided by the International Plant Protection Convention. These documents varied greatly in the level of detail, the range of addressed aspects, the approach to assessing risk components and the clarity of the conclusions reached. In order to produce consistent evaluations, the Panel developed a guidance document (EFSA Panel on Plant Health (PLH), 2009) which addresses the equivalence and differences between the terminology of ISPM No 11 and of the EFSA founding regulation<sup>5</sup>, resulting in an adaptation of ISPM No 11 that fits within the remit of EFSA. In particular, all reference to monetary terms in ISPM has been changed to their biological and physical meanings, as the economic impact of plant pests falls outside the Panel’s remit. In addition, the guidance document provides a flow chart describing the evaluation process followed by the Panel.

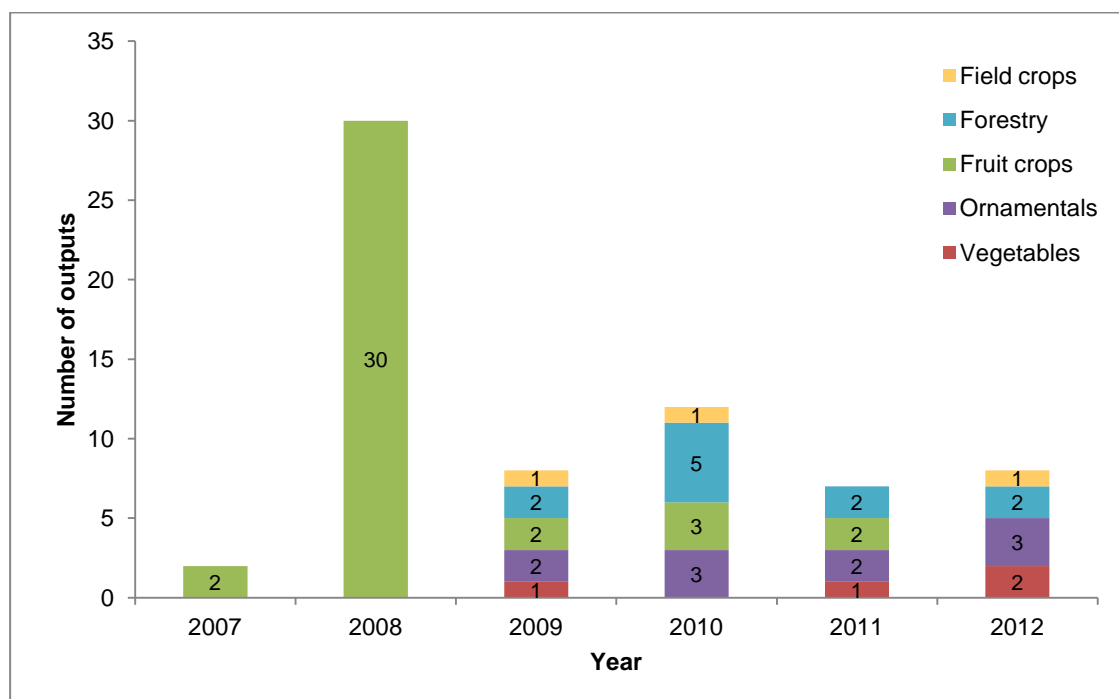
<sup>3</sup> Commission Regulation (EC) No 575/2006 of 7 April 2006 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority. OJ L 100, 8.4.2006, p. 3–3.

<sup>4</sup> Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. OJ L 169, 10.7.2000, p.1–112.

<sup>5</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.



**Figure 1:** Outputs published during the first two PLH Panel mandates (from June 2006 to June 2012): total number of outputs (A), and number of output published for each grouping of harmful organism (B). The very high amount of outputs appearing in 2008 in (A) is the result of a single mandate requiring multiple outputs: the peer-review of 30 pest risk assessments for the French Overseas Departments territory (Caffier et al., 2008).



**Figure 2:** Outputs published during the first two PLH Panel mandates (from June 2006 to June 2012) according to affected crops. Some harmful organisms can impact more than one crop type. The very high amount of outputs appearing in 2008 in (A) is the result of a single mandate requiring multiple outputs: the peer-review of 30 PRA for the French Overseas Departments territory (Caffier et al., 2008).

## **1.2. Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA**

At the end of the first mandate, the PLH Panel was requested in several cases to expand national risk assessments from the level of a Member State to the level of the EU territory, which requires the performance of a new, full pest risk assessment. The Panel's harmonised framework for pest risk assessment (EFSA Panel on Plant Health, 2010a) not only provides guidance on the elements of risk assessment, but also on the overall characterisation of risk, the identification and assessment of risk management options, harmonised methodologies that may be used, definition of data requirements and procedures for documentation and submission of dossiers. Furthermore, in order to ensure transparency in risk assessment, uncertainties are identified, characterised and documented. The main difference between the EFSA framework and the IPPC standards on pest risk analysis are that EFSA does not: (i) describe the process as "Pest Risk Analysis"; (ii) assess impacts in monetary terms; (iii) determine the cost effectiveness of phytosanitary measures; or (iv) evaluate the acceptability of risk.

## **1.3. Guidance on the environmental risk assessment of plant pests**

Following from the harmonised framework guidance, the PLH Panel identified the need to use the ecosystem services concept to frame the environmental impact linked to plant health. The PLH Panel further articulated standardised methodology for environmental risk assessment (ERA) of pest introductions by developing specific guidelines (EFSA Panel on Plant Health (PLH), 2011a). The ERA is separated into structural and functional aspects of biodiversity. The impact on structural biodiversity is restricted to species, genetic and landscape components as a proper approximation of diversity according to internationally accepted terminology. The functional assessment of biodiversity is based on identifying key ecosystem services in three classes: provisioning, regulating and supporting, and cultural services<sup>6</sup>. The schema is build up with a list of questions for assessors to evaluate the environmental risk in the current area of distribution of the pest and in the risk assessment area. The evaluation of the impact is based on a probabilistic approach, with explicit consideration of the associated uncertainty. The ERA guidance document is a contribution to horizontal harmonisation activities within EFSA in environmental risk assessment.

## **1.4. Guidance on methodology for evaluation of the effectiveness of options for reducing the risk of introduction and spread of organisms harmful to plant health**

The Panel is frequently asked to identify options that reduce the risk of introduction and spread of harmful organisms in the EU territory and has produced guidance on methodology for the evaluation of the effectiveness of risk-reducing options (EFSA Panel on Plant Health (PLH), 2012). Two operational tools were developed in this guidance: a checklist for evaluating a proposed risk reduction option (RRO) and a database of references corresponding to published guidance documents or experimental assessments of RROs. The checklist can be used by the Panel or the dossier-submitting parties to verify whether all required information is provided in support of a RRO, to quickly describe information supplied to EFSA and to identify major gaps in the data. The database of references is intended to assist the Panel in: (i) identifying potential RROs for a given pest and plant material; and (ii) quickly retrieving relevant experimental data and guidance documents for assessing a proposed RRO. In addition, the guidance provides recommendations on experimental design, the use of statistical methods including approaches for studying uncertainty, the use of quantitative pathway analysis and spread models, and on recommendations for general surveillance and specific surveys.

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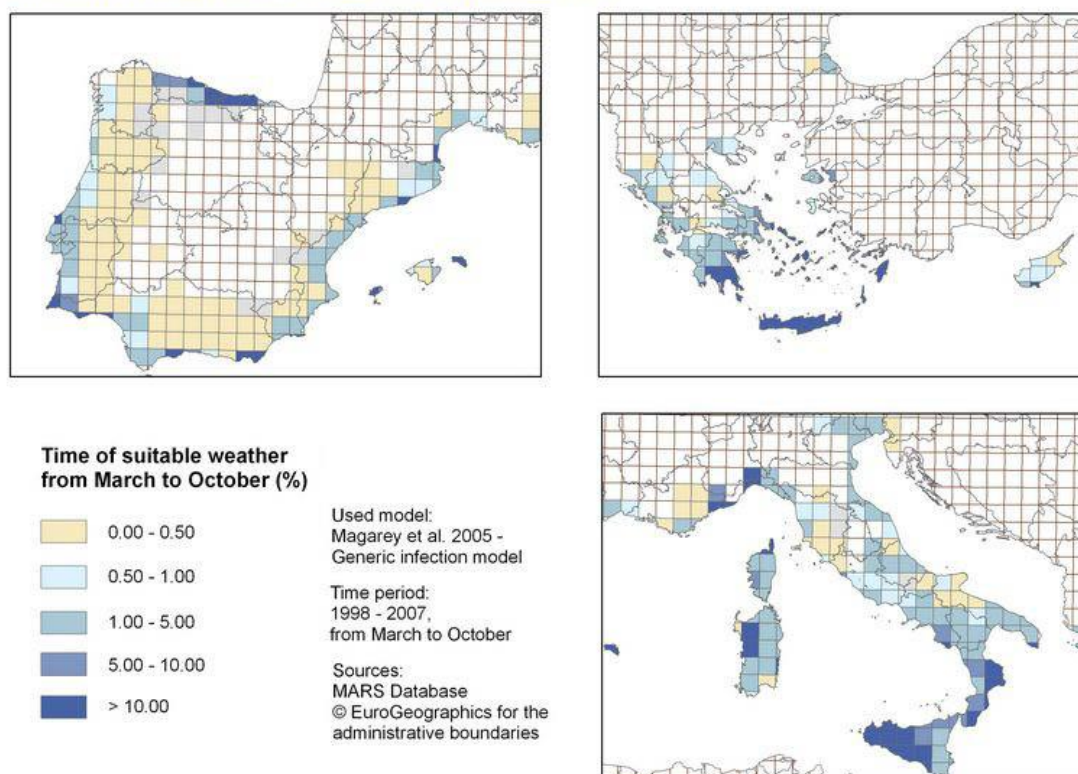
<sup>6</sup> "Provisioning services such as food and water; regulating services such as regulation of floods, drought, land degradation, and disease; supporting services such as soil formation and nutrient cycling; and cultural services such as recreational, spiritual, religious and other nonmaterial benefits"; quoted from MA (Millennium Ecosystem Assessment), 2005. Ecosystems and Human Well-Being: Synthesis, Island Press. Washington DC.

## 2. QUANTITATIVE PATHWAY ANALYSIS AND STATISTICAL MODELLING

Models using climatic variables (e.g. temperature, wetness duration) and parameters describing the climatic requirements of the pests (e.g. minimal and maximal temperature for establishment) are useful to assess the probability of establishment and spread of plant pests. Their outputs can be displayed in maps showing different levels of risk of pest establishment and spread as, for example, in the opinion on the fungus *Guignardia citricarpa* (Figure 3 from EFSA, 2008a). Within a project funded by EFSA, a model framework has been developed by the Joint Research Centre of the European Commission to assess climate suitability for the establishment of plant pests and diseases in EU (Donatelli et al., 2012). Quantitative pathway models constitute another type of mathematical model used by the PLH Panel. The start of the pathway is an infested area with known prevalence and number of host plants. The model should cover the pathway of the pest from the starting point of the pest to the end of the pathway over a given period of time. The end of the pathway is a target area (e.g. an area cultivated with a given host plant in the EU). As an example, the PLH Panel has evaluated a quantitative pathway analysis of the likelihood of *Tilletia indica* being introduced into the EU with imports of United States wheat (USDA APHIS, 2008; EFSA Panel on Plant Health (PLH), 2010b). When experimental data are available, statistical regression models (generalised linear models) are used by the PLH Panel to assess the effectiveness of risk reduction option (e.g. heat treatment of plant materials). Such models were used by the PLH Panel to verify the mortality of pinewood nematode from high temperature treatment of shavings and assess the effectiveness of the heat treatment of wood against *Agilus planipennis* (EFSA Panel on Plant Health (PLH), 2011b).

### CITRUS black spot potential infections

Percentage of hours of suitable weather for successful infections events to start for D50 = 14 by ascospores



**Figure 3:** Percentages of hours with potential successful infection by *Guignardia citricarpa* ascospores per month for October over the period 1998-2007, with D50 = 14 (Note: in grids with grey colour the percentage is equal to 0). Figure published in the EFSA PLH opinion on *G. citricarpa* (EFSA, 2008a).

### 3. INTERACTION WITH PLH STAKEHOLDERS AND SCIENTIFIC COMMUNITY

To promote an open scientific debate on key issues related to plant health risk assessment, EFSA has organised two scientific colloquia. The first was held in 2007 to discuss the use of qualitative versus quantitative approaches in pest risk, as well as the challenges due to global change scenarios and to methods used to evaluate the evidence and to address uncertainties (EFSA, 2008b). The second, held in June 2011, brought together risk assessors, risk managers, scientists and stakeholders from 31 countries and the international plant protection organisations to debate on the identification of emerging risks in plant health at different scales. Key issues identified were the need for an enhanced cooperation, updating of databases and tools, and the benefit of analysing past invasions to prioritise strategies for detection and prevention of emerging risks (EFSA, 2011).

To coordinate activities on pest risk assessment, exchange of information and data, and facilitate harmonisation of good practices and methodologies, EFSA has established a Scientific Network for Risk Assessment in Plant Health<sup>7</sup>.

Several grants were awarded by EFSA to Member State organisations to develop methodologies and to conduct preparatory work for pest risk assessment on structured inventories of data sources and models for pest risk assessment (Rossi et al., 2009a,b); comparison of pest risk assessment case-studies (MacLeod et al., 2010) and on knowledge gaps and uncertainties (Steffek et al., 2011, 2012).

The Panel's Scientific Opinions are presented to the Standing Committee on Plant Health, which takes decisions and follow up on the application of phytosanitary measures.

#### CONCLUSIONS: CHALLENGES AND FUTURE PERSPECTIVES

Plant health legislation is concerned with all harmful organisms having a negative effect on plant health, ranging from viroids and virus-like particles to molluscs and flowering plants. In practice, the main organisms of concern are plant viruses, pathogenic bacteria, fungi, oomycetes, nematodes and arthropods. The Plant Health Panel has 21 experts to cover the broad range of organism-based disciplines – a challenge considering that broader aspects of plant health have to be considered, including crop production systems (from arable crops to protected cultivation), and impacts on native ecosystems (woodland, riparian and aquatic environments). It is invariably necessary to call upon external experts to supplement the Panel's expertise in the Working Groups.

In carrying out its mandates, the Panel needs access to climatic records, cropping statistics and vegetation inventories, and EU-wide pest distribution data. The latter is particularly important and presents many challenges in obtaining data collected at an appropriate scale and using common methods across member states. Often these data have to be supplemented by relevant databases such as those provided by CABI (CAB International) and EPPO (European and Mediterranean Plant Protection Organisation). The establishment of an EFSA Plant Health Network has provided the opportunity to discuss at biannual meetings the information needs for current mandates.

Worldwide, national plant health legislations refer to the IPPC. Important future considerations for the IPPC are to ensure a balance between international trade, agriculture and the protection of the environment. As such, the legal framework must have a level of flexibility to accommodate new concepts and procedures over time. As a consequence the Plant Health Panel must operate in a flexible and pragmatic way to develop its Scientific Opinions. The signatories to the IPPC are the individual Member States. The European Union is also a signatory and the Common Plant Health Regime (CPHR) is the main legal instrument of the EU to protect the territory of the Member States against plant pests. In 2008, the European Council requested an evaluation of the CPHR and for the European Commission to develop, based on this evaluation, a new plant health strategy. A conference in preparation for this, a meeting "Towards a new EU plant health strategy" was held in September 2010, involving stakeholders and national plant protection services in Member States, to discuss a

<sup>7</sup> <http://www.efsa.europa.eu/en/plh/plhnetworks.htm>

comprehensive evaluation of the regime<sup>8</sup>, the outcome of which will provide the cornerstone of a new plant health strategy to be included in draft revised legislation in 2012. At this time the content of the revised legislation has not been made public, but the key elements of the evaluation, if adopted only in part in the new plant health regime, will be of key relevance to the work of the Plant Health Panel in its continuing risk assessment mandates.

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## REFERENCES

- Caffier DJ, Choiseul E, Dormannsné Simon E, Jones D, Makowski C, Manceau L, Manici L, Oude Lansink A, Porta Puglia A, Smith J, Stancanelli G, Steffek R, Stefani E, Strömberg A and Vloutoglou I, 2008. Evaluation of risk assessments on fungal and bacterial pathogens of banana for the French overseas departments. *Journal of Plant Pathology*, 90 (2, Supplement), S2.41.
- Donatelli M, Bregaglio S, Fumagalli D and Baruth B, 2012. Model framework for the assessment of EU climatic suitability for the establishment of organisms harmful to plants and plant products – CLIMPEST project (SLA/EFSA-JRC/2008/PLH/01). Supporting Publications 2012:EN-247. [63 pp.]. Available from: <http://www.efsa.europa.eu/en/supporting/doc/247e.pdf>
- EPPO (European Plant Protection Organisation), 2011. Guidelines on Pest Risk Analysis PM 5/3 (5) 11-17053. Decision-support scheme for quarantine pests. European and Mediterranean Plant Protection Organization, pp. 44. Available from: <http://archives.eppo.int/EPPOStandards/prah.htm>
- EFSA (European Food Safety Authority), 2008a. Scientific Opinion of the Panel on Plant Health on a request from the European Commission on *Guignardia citricarpa* Kiely. *The EFSA Journal* (2008) 925, 1-108.
- EFSA (European Food Safety Authority), 2008b. EFSA's 10th Scientific Colloquium - Pest risk assessment - Science in support of phytosanitary decision making in the European Community. EFSA, December 2007, Parma, Italy. Available from: <http://www.efsa.europa.eu/en/supporting/pub/120e.htm>
- EFSA (European Food Safety Authority), 2011. EFSA's 16th Scientific Colloquium on emerging risks in plant health: from plant pest interactions to global change. EFSA, June 2011, Parma, Italy. Available from: <http://www.efsa.europa.eu/en/supporting/pub/199e.htm>
- EFSA Panel on Plant Health (PLH), 2009. Guidance of the Panel on Plant Health following a request from EFSA on the evaluation of pest risk assessments and risk management options prepared to

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<sup>8</sup> [http://ec.europa.eu/food/plant/strategy/evaluation\\_CPHR\\_en.htm](http://ec.europa.eu/food/plant/strategy/evaluation_CPHR_en.htm)

- justify requests for phytosanitary measures under Council Directive 2000/29/EC, EFSA Journal (2009) 1194, 1-18.
- EFSA Panel on Plant Health (PLH), 2010a. Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA. EFSA Journal 2010;8(2):1495. [66 pp.].
- EFSA Panel on Plant Health (PLH), 2010b. Scientific opinion on a quantitative pathway analysis of the likelihood of *Tilletia indica* M. introduction into EU with importation of US wheat. EFSA Journal 2010;8(6):1621. [88 pp.].
- EFSA Panel on Plant Health (PLH), 2011a. Guidance on the environmental risk assessment of plant pests. EFSA Journal 2011;9(12):2460. [121 pp.].
- EFSA Panel on Plant Health (PLH), 2011b. Scientific Opinion on a technical file submitted by the US Authorities to support a request to list a new option among the EU import requirements for wood of *Agrilus planipennis* host plants. EFSA Journal 2011;9(7):2185. [51 pp.].
- EFSA Panel on Plant Health (PLH), 2012. Scientific Opinion on Guidance of the Scientific Panel on Plant Health on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms harmful to plant health in the EU territory. EFSA Journal 2012;10(6):2755. [92 pp.].
- FAO (Food and Agriculture Organization of the United Nations), 2011a. IPPC (International Plant Protection Convention) 1997, 18pp.
- FAO (Food and Agriculture Organization of the United Nations), 2011b. ISPM (International Standards for Phytosanitary Measures) No 11, Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms – 2004, 30pp.
- MacLeod A, Anderson H, Gaag DJVD, Holt J, Karadjova O, Kehlenbeck H, Labonne G, Pruvost O, Reynaud P, Schrader G, Smith J, Steffek R, Viaene N and Vloutoglou I, 2010. Prima phacie: a new European Food Safety Authority funded research project taking a comparative approach to pest risk assessment and methods to evaluate pest risk management. OEPP/EPPO Bulletin 40, 435-439.
- Rossi V, Giosuè S and Bernazzani R, 2009a. Pest risk assessment in the European Community: inventory of data sources. External scientific report. Published 15 December 2009. Available from: <http://www.efsa.europa.eu/en/supporting/pub/29e.htm>
- Rossi V, Salinari F, Bernazzani R, Giosuè S and Mazzoni E, 2009b. Models for pest's epidemiology: review, documentation and evaluation for Pest Risk Analysis (Mopest). External scientific report. Published 16 December 2009. Available from: <http://www.efsa.europa.eu/en/supporting/pub/28e.htm>
- Schans J, Ceglarska EB, Cheek S and Stancanelli G, 2008. The EFSA Panel on plant health: accomplishments and challenges for the EU pest risk assessment. Journal of Plant Pathology (2008), 90 (2, Supplement), S2.40.
- Steffek R, Follak S, Strauss G, Verhoeven K, Potting R, Karadjova O, Ventislavov V, Krumor V and MacLeod A, 2011. On the distribution of *Ca. Phytoplasma pyri* in the European Union based on a systematic literature review approach. Bulletin of Insectology 64 (Supplement): S271-S272, 2011.
- Steffek R, Follak S, Sauvion N, Labonne G and MacLeod A, 2012. Distribution of '*Candidatus* *Phytoplasma prunorum*' and its vector *Cacopsylla pruni* in European fruit growing areas: a review. OEPP/EPPO Bulletin (in press).
- USDA APHIS (United States Department of Agriculture, Animal and Plant Health Inspection Service), 2008. Quantitative pathway analysis: likelihood of karnal bunt, (*Tilletia indica* M.), introduction as a result of the importation of United States wheat for Grain into the European Union and Desert durum wheat for grain into Italy. United States Department of Agriculture-Animal and Plant Health Inspection Service, 105 pp.