

## EFSA ACTIONS ON THE "GUIDELINES FOR EC COORDINATION OF PEST RISK ANALYSIS PROCESS"<sup>1</sup>

A meeting of the Council Working Party of Chief Officers of Plant Health Services (COPHS) took place in Brussels on 11-12 June 2009 under the auspices of the Czech Presidency. At the meeting the Working Party approved "Guidelines for EC coordination and handling of Pest Risk Analysis (PRA) documents and other scientific justification documents supporting the decision-making process for EC phytosanitary measures" (hereinafter COPHS Guidelines).

The COPHS Guidelines have been developed following discussions carried out during the Slovenian, French and Czech presidencies. The aim was to clarify the process of pest risk analysis in the EU and the roles of the various actors involved. EFSA was actively involved in this process, providing information and clarifications regarding its role and working principles as defined in the EFSA founding Regulation (EC) No 178/2002<sup>2</sup>.

The objective of the COPHS paper is to establish guidelines for the development, coordination and handling of pest risk analysis documents within the current European Union (hereinafter EU) legislative environment. The document also prescribes the rules applicable to other scientific and technical justifications produced by non-EU countries. Aiming to improve transparency and consistency the Guidelines are of particular importance in this period of review of the common plant health regime<sup>3</sup>.

EFSA welcomes the COPHS Guidelines and considers the COPHS document important in clarifying the roles of different institutions in the process of pest risk analysis in the EU. EFSA's response to issues that fall within the remit of the Authority is expressed below. The EFSA Actions on the COPHS Guidelines document is addressed to EU decision-makers and was prepared in consultation with EFSA's Panel on Plant Health, the European Commission and Member States.

Following the structure of the original COPHS document the respective sections of the COPHS Guidelines are indicated in bold and the corresponding EFSA actions listed after. When published, the Commission, COPHS, SCPH, EFSA Scientific Network for Risk Assessment in Plant Health and Plant Health Stakeholders will be notified.

### ***1. Standard procedure for handling PRAs and other justification documents***

#### ***1.1. Sources of PRAs and other justification documents***

#### EFSA Actions:

**Action 1.** The European Food Safety Authority (EFSA) is the keystone of European Union risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear

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<sup>1</sup> Outcome of Proceedings from Working Party of Chief Officers of Plant Health Services (COPHS), Annex I: Guidelines for EC coordination and handling of Pest Risk Analysis documents and other scientific justification documents supporting the decision-making process for EC phytosanitary measures. Council of the European Union, 10828/09, p.7-11.

<sup>2</sup> Regulation (EC) N°178/2002 of the European Parliament and 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.

<sup>3</sup> [http://ec.europa.eu/food/plant/strategy/index\\_en.htm](http://ec.europa.eu/food/plant/strategy/index_en.htm)

communication on existing and emerging risks associated with the food chain. EFSA is committed to provide high-quality, independent and transparent scientific advice for the European decision-makers.

**Action 2.** On request from the European Commission (hereinafter Commission) or on its own initiative<sup>2</sup> EFSA provides scientific opinions on plant health matters which fall under the Council Directive 2000/29/EC<sup>4</sup>. The Commission requests are always accompanied by terms of reference that describe the background of the request and the relevant EU interest. EFSA may also be requested to issue a scientific opinion by the European Parliament or a Member State.

**Action 3.** To address the Commission's demand for the provision of scientific opinions on plant health matters, a dedicated Panel on Plant Health was created (Commission Regulation (EC) 575/2006<sup>5</sup>). 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 range of organisms of concern includes: plant pathogenic microorganisms (viruses, bacteria, fungi, nematodes and other as yet unidentified pathogenic agents), phytophagous invertebrates, parasitic plants and weeds.

**Action 4.** When requested, EFSA can extend the scope of a national pest risk analysis to the whole EU territory. EFSA also conducts assessments of pest risk for the whole EU territory. EFSA's risk assessment can include the identification of pest risk management options and the evaluation of their effect on the level of pest risk. However, EFSA does not undertake socio-economic analyses.

**Action 5.** In order to provide high quality, transparent and consistent scientific opinions on plant health, EFSA has developed "Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA"<sup>6</sup>. The guidance applies to risk assessments to be carried out by EFSA's Panel on Plant Health.

**Action 6.** To ensure that up-to-date information and tools are available for scientific opinions, inventories of data sources and models applicable in plant health risk assessment have been delivered through grants awarded by EFSA based on Article 36 of the EFSA founding regulation.

**Action 7.** Taking into consideration the most recent scientific developments and recognising future challenges, EFSA's priority is to further develop methodologies for risk assessment in plant health. To draw on cutting-edge research EFSA has established close collaboration with projects funded under the EU R&D Framework Programmes<sup>7,8</sup>.

**Action 8.** To further strengthen scientific cooperation on plant health risk related issues in the EU, to build mutual understanding of the risk assessment process between EFSA and EU Member States and to provide increased transparency in the pest risk analysis process EFSA has developed a scientific network to share best practice in pest risk assessment, exchange data and information, and harmonise methodologies<sup>9</sup>. The Scientific Network for Risk Assessment in Plant Health replaced the EFSA Special Advisory Forum on Plant Health<sup>10</sup>.

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<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> 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 of the permanent Scientific Panels of the European Food Safety Authority. OJ L100, 8.4.2006, p.3.

<sup>6</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1495.htm>

<sup>7</sup> PRATIQUE: Enhancement of pest risk analysis techniques, project funded under EU FP7, URL: <https://secure.fera.defra.gov.uk/pratique/index.cfm>. SHARCO: Sharka containment in view of EU expansion, project funded under EU FP7, URL: <http://www.sharco.eu/sharco/>. EUPHRESCO: European Research Area - Network project for research policy development and implementation in the field of statutory and emerging plant pests, diseases and invasive species, funded under EU FP6 ERA-NET Scheme, URL: <http://www.euphresco.org/>.

<sup>8</sup> [http://cordis.europa.eu/home\\_en.html](http://cordis.europa.eu/home_en.html)

<sup>9</sup> <http://www.efsa.europa.eu/en/keydocs/docs/networksoperation.pdf>

<sup>10</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902957134.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902957134.htm)

**Action 9.** To enhance synergies in pest risk assessment, EFSA created an Information Exchange Platform, where Member States can share their pest risk analyses and other information relevant to the pest risk assessment process.

**Action 10.** To ensure that duplication of efforts in undertaking preparation of pest risk analyses is avoided, EFSA is involved in consultation with the European and Mediterranean Plant Protection Organisation (EPPO)<sup>11</sup> and information exchange continues to take place between EFSA and EPPO.

**Action 11.** Whenever necessary, EFSA is willing to present the opinions produced in the meetings of the Standing Committee on Plant Health after their publication on the EFSA website.

### ***1.3. Review***

#### EFSA Actions

**Action 12.** The pest risk analyses that are subject to EFSA scientific opinions may originate from various sources: from an EU Member State or group of Member States, as a result of EU funded research projects, from EPPO or from third countries. To ensure transparent and consistent review of any document submitted for EFSA evaluation, EFSA in close collaboration with MS regularly reviews and updates the guidance document on evaluation of pest risk assessments and risk management options<sup>12</sup>.

### ***2. Fast-track procedure to produce a preliminary PRA document***

#### EFSA Actions

**Action 13.** EFSA will work in close collaboration with the Commission to forecast the need for scientific advice in emergency situations for plant health and their possible impact on the work of EFSA.

**Action 14.** EFSA continuously explores the availability of data in order to support the assessment work both in the usual situations as well as preparatory work for fast-track advice<sup>13</sup>. Inventories of data sources applicable in plant health (mentioned in Action 6.) will be shared and collaborative initiatives with the Member State instigated to improve data availability. EFSA will work towards developing procedures for the preparation and delivery of “fast-track” advice.

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<sup>11</sup> European and Mediterranean Plant Protection Organisation <http://www.eppo.org/>

<sup>12</sup> Evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC, Guidance of the Panel on Plant Health, *The EFSA Journal* (2009) 2654, 1-18. [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902601351.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902601351.htm)

<sup>13</sup> MB 17 12 09 - Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and their Working Groups. <http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf>