

EFSA ACTIONS ON THE "GUIDELINES FOR EC COORDINATION OF PEST RISK ANALYSIS PROCESS"¹

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 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 178/2002².

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 regime³.

EFSA welcomes the COPHS document and considers it important in clarifying the roles of different institutions in the process of pest risk analysis in the EU. EFSA's response on issues that fall within the remit of the Authority is expressed below, following the structure of the COPHS document. The respective sections of the COPHS Guidelines are indicated in bold and the corresponding EFSA actions listed after.

This paper was prepared in the consultation with the EFSA's Panel on Plant Health, European Commission and Member States (MSs).

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 the 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

¹ 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.

² 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.

³ http://ec.europa.eu/food/plant/strategy/index_en.htm

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

36 **Action 2.** On request from the European Commission (hereinafter Commission) or on its own
37 initiative² (so called self-task) EFSA provides scientific opinions on plant health matters which fall
38 under the Council Directive 2000/29/EC⁴. EFSA may also be requested to issue a scientific opinion by
39 the European Parliament or a Member State (MS). The Commission requests are always accompanied
40 by terms of reference that describe the background of the request and the relevant EU interest.

41 **Action 3.** To address the demand of the Commission for provision of scientific opinions on
42 plant health matters a dedicated Panel on Plant Health was created following the Commission
43 Regulation (EC) 575/2006⁵. The Panel provides scientific opinions on risks posed by non-endemic
44 living organisms harmful to plants and/or plant products that are associated with movement of plants
45 and/or plant products and that may enter, establish, spread and cause harmful effects on plant
46 production and plants in the environment. The range of organisms of concern includes: plant
47 pathogenic microorganisms (viruses, bacteria, fungi, nematodes and other as yet unidentified
48 pathogenic agents), phytophagous invertebrates, parasitic plants and weeds.

49 **Action 4.** Evaluation of pest risk analyses and other justification documents presents the core
50 activity of EFSA in the plant health area. When requested, EFSA extends the scope of a national pest
51 risk analysis to the whole EU territory. EFSA also conducts assessments of pest risk for the whole EU
52 territory. EFSA's risk assessment can include the identification of pest risk management options and
53 the evaluation of their effect on the level of pest risk. However, EFSA does not undertake socio-
54 economic analyses.

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

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

62 **Action 7.** Taking into consideration the most recent scientific developments and recognising
63 future challenges, EFSA's priority is to further develop methodologies for risk assessment in plant
64 health. To draw on cutting-edge research EFSA has established close collaboration with projects
65 funded by the EU under RTD Framework Programmes⁷.

66 **Action 8.** To facilitate scientific collaboration with MSs a Special Group on Plant Health was
67 set up under the EFSA Advisory Forum (Sp AF PLH)⁸. Composed of representatives of competent
68 authorities engaged in plant health at national level, the Sp AF PLH provided a privileged
69 environment for discussion and information exchange on issues relevant to pest risk assessment
70 activities in the EU. To strengthen scientific cooperation on plant health risk related issues in the EU,
71 to build mutual understanding of the risk assessment process between EFSA and EU MSs and to
72 provide increased transparency in the pest risk analysis process EFSA developed a scientific network

⁴ 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.

⁵ 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.

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

⁷ PRATIQUE: Enhancement of pest risk analysis techniques, project funded under EU FP7, URL: <https://secure.fera.defra.gov.uk/pratique/index.cfm>. EUPHRESKO: 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/>. SHARCO: Sharka containment in view of EU expansion, project funded under EU FP7, URL: <http://www.sharco.eu/sharco/>

⁸ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902957134.htm

73 with MSs to share best practice, exchange data and information, and harmonise methodologies. In
74 2010, this network replaces the afore-mentioned Sp AF on PLH.

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

78 **Action 10.** To ensure that duplication of efforts in undertaking preparation of pest risk analyses is
79 avoided, EFSA is involved in consultation with the European and Mediterranean Plant Protection
80 Organisation (EPPO)⁹ and information exchange continues to take place between EFSA and EPPO.

81 **1.3. Review**

82 EFSA Actions

83 **Action 11.** As EFSA is the EU reference body for risk assessment in the plant health area, the
84 evaluation of pest risk analyses and other justification documents constitutes the core activity of
85 EFSA's Panel on Plant Health. The pest risk analyses that are subject of EFSA scientific opinions may
86 originate from various sources: from an EU MS or group of MSs, as a result of EU funded research
87 projects, from EPPO or from third countries. To ensure transparent and consistent review of any
88 document submitted for EFSA evaluation, EFSA in close collaboration with MS regularly reviews and
89 updates the guidance document on evaluation of pest risk assessments and risk management options¹⁰.
90 Whenever necessary, EFSA is willing to present the opinions produced in the meetings of the
91 Standing Committee on Plant Health after their publication on the EFSA website.

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

94 EFSA Actions

95 **Action 12.** EFSA will work in close collaboration with the Commission to forecast the need for
96 scientific advice in emergency situations for plant health and their possible impact on the work of
97 EFSA.

98 **Action 13.** EFSA continuously explores the availability of data in order to support the assessment
99 work both in the usual situations as well as preparatory work for fast-track advice¹¹. Inventories of
100 data sources applicable in plant health (mentioned in Action 6.) will be shared and collaborative
101 initiatives with the MS instigated to improve data availability. EFSA will work towards developing
102 procedures for the preparation and delivery of "fast-track" advice.

⁹ European and Mediterranean Plant Protection Organisation <http://www.eppo.org/>

¹⁰ 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

¹¹ 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>