

## SPECIAL ISSUE

### Risk assessment of plant protection products

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#### ABSTRACT

EFSA's Panel on Plant Protection Products and their Residues (PPR Panel) provides independent scientific advice in the field of risk assessment of plant protection products (PPPs, pesticides). Since its establishment in 2003 under Regulation (EC) No 178/2002, it has delivered a series of scientific outputs in support of evaluation of pesticide active substances, establishing scientific principles and guidance documents in the field of pesticide risk assessment and in support of decision making of European Union (EU) law makers. Next to a series of scientific opinions evaluating specific adverse effects of PPPs for human health (like for instance carcinogenicity) the Panel also delivered scientific opinions on general principles in the field of human health risk assessment (like reference value setting) and is, in particular over the last years, very much engaged in development of methodologies to meet new challenges in regulatory risk assessments such as assessment of toxicity of pesticide metabolites and potential cumulative effects of pesticides to human health. Fate, behaviour and transformation of pesticides after their application and consequent release to the environment are a major aspect of pesticide risk assessment. The PPR Panel has achieved major accomplishments by delivering guidance and scientific opinions on degradation in soil, exposure of soil organisms and assessment of environmental risks by use of pesticides in greenhouses or grown under cover. A series of scientific opinions have been delivered also in the field of environmental risk assessment of pesticides. Scientific output covered specific issues arising in the peer review of specific active substances, revision of data requirements, development of risk assessment methodologies and the development of guidance documents. A major milestone of the PPR Panel was the development of the methodological framework for deriving specific protection goals for environmental risk assessment of pesticides in view of the future dialogue between risk managers and risk assessors during the next steps of the revision of the ecotoxicology guidance documents.

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#### KEYWORDS

Human health risk assessment, residues, fate and behaviour, ecotoxicology, environmental risk assessment, pesticides, plant protection products

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## INTRODUCTION

The Panel on Plant Protection Products and their Residues (PPR Panel) provides independent scientific advice on the risk assessment of plant protection products (PPPs, pesticides) and their residues. It provides responses to requests from the European Commission or to initiatives within EFSA.

Regarding human health, this includes the evaluation of the risks resulting from the uses of pesticides for operators, workers in treated areas, residents, and consumers of treated food commodities. Regarding environmental health, this includes the evaluation of their behaviour in the different environmental compartments and of their effects on wildlife species. This helps to provide a sound foundation for European policies and legislation, and supports risk managers in the European Commission and the Member States in taking effective and timely decisions.

Since its establishment in 2003 under Regulation (EC) No 178/2002<sup>2</sup>, the emphasis of the Panel's work has changed from concentrating on individual active substances to the development of more widely applicable advice and generic guidance. Initially the Panel mostly addressed specific dossier-based questions arising from the peer review of active substances by EFSA and Member States (Hardy and Fontier, 2011; EFSA 2006a,b). More recently the main activities of the Panel have been to develop the advice and science underpinning more generic guidance on the risk assessment of plant protection products. This is done by collecting and analysing the scientific information regarding relevant risk assessment approaches, methodologies and models.

In the last ten years the PPR Panel has prepared and adopted 58 opinions, of which 17 have been on specific effects of particular active substances used in plant protection products and 41 opinions on generic issues related to the safety of the use of pesticides. In addition, two guidance documents have been very recently adopted. This article reviews the main achievements to date and challenges for the PPR Panel ahead.

## 1. TOXICOLOGY

In the field of toxicological effects and dietary residues of pesticides, the PPR Panel has dealt with a series of specific issues connected to active pesticidal substances that, based on their specificity, could not be dealt with during the peer review of pesticides and have therefore been referred to the PPR Panel. Over the time, the PPR Panel has delivered scientific opinions on, for instance, the tumourigenic potential of mepanipyrim (EFSA, 2003a), the genotoxicity/carcinogenicity of daminozide (EFSA, 2004a), the derivation of an Acute Reference Dose (ARfD) for imazalil (EFSA, 2007a), the safety of Maximum Residue Levels (MRLs) for aldicarb and dieldrin (EFSA, 2006c and EFSA, 2007b respectively), rate of dermal absorption of methamidophos (EFSA, 2004b) and developmental neurotoxicity of deltamethrin (EFSA, 2009a).

The PPR Panel also delivers scientific advice on overarching questions in the field of toxicology and exposure assessment of pesticides and has published for example in 2006 scientific opinions on the Guidance Document on Acceptable Operator Exposure Levels (AOELs) for pesticides (EFSA, 2006d) and also on the scientific principles in the assessment and guidance in the field of human toxicology of pesticides.

The PPR Panel has also an important role in supporting the European Commission in proposing new legislation or amending the existing legislative framework in the field of pesticides. Therefore, on request from the European Commission, in 2007 it has delivered a scientific opinion on the current data requirements for authorisation of pesticides, in which a series of recommendations for amending these data requirements were proposed (EFSA, 2007c).

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<sup>2</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.

A further major task of the PPR Panel is the development of guidance documents in the field of pesticide risk assessment.

Usually, in preparation of such guidance documents, scientific opinions are developed giving the scientific background for the elements presented in guidance documents.

In the field of toxicology, dietary and non-dietary exposure to pesticides a revised guidance on dermal absorption has been published in 2012 following publication of a scientific opinion giving the scientific background for the revised elements contained therein in 2011 (EFSA Panel on Plant Protection Products and their Residues (PPR), 2011 and EFSA Panel on Plant Protection Products and their Residues (PPR), 2012a respectively).

In 2010, the PPR Panel delivered also a scientific opinion on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents containing a draft guidance document on such exposure assessments (EFSA Panel on Plant Protection Products and their Residues (PPR), 2010a). EFSA is currently, with support of Panel members, finalising the draft guidance taking into account recommendations on risk management elements given by the European Commission.

In order to be able to assess toxicological relevance of pesticide metabolites occurring as residues in food, in 2012 the PPR Panel has published a scientific opinion introducing potentially useful approaches for such assessments that will be used to develop EFSA guidance on assessment of pesticide metabolites (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012b).

Currently adverse effects of pesticides are assessed and also regulated on a single substance basis. However, humans might in many instances be exposed simultaneously to more than one pesticide via the diet. The new PPP legislation (Regulation (EC) No 1107/2009<sup>3</sup>) requires that this notion should be reflected also in toxicological assessments. EFSA's PPR Panel has already at a very early stage embarked on the development of a methodology for assessment of "cumulative" effects. In 2006 EFSA organised a Scientific Colloquium on cumulative risk assessment of pesticides to human health (EFSA, 2007d). Already in 2008 a first scientific opinion on the general principles applicable and methodologies suitable for cumulative risk assessment of pesticides in the diet has been published (EFSA, 2008a) which was followed up in 2009 by an opinion in which these methodologies were tested in practice with selected pesticides (EFSA Panel on Plant Protection Products and their Residues (PPR), 2009). In order to complete its work on cumulative risk assessment and on basis of the first two opinions the PPR Panel is currently developing an opinion in which pesticides, which should be grouped together for cumulative risk assessment, are being identified. This opinion is scheduled for publication in 2013.

Since for carrying out cumulative risk assessment, dietary exposures must be assessed with probabilistic methods the PPR Panel has in parallel to the activities above also developed a guidance document for probabilistic exposure assessment which has been published also in 2012 (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012c).

The new PPP legislation encourages also development of methodologies for cumulative risk assessment for activities consequent on application of pesticides i.e. for pesticide operators, workers re-entering treated areas, bystanders and residents. EFSA's Pesticide Unit has already initiated preparatory activities in this regard that will be the starting point for the PPR Panel for developing a methodology for such assessments.

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<sup>3</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

## 2. ENVIRONMENTAL FATE AND BEHAVIOUR OF PESTICIDES AND THEIR TRANSFORMATION SUBSTANCES

Risk assessment of pesticides in the environment consists of an effect assessment and an exposure assessment. The exposure assessment addresses the environmental fate and behaviour of the pesticides and their transformation substances to the different environmental compartments. The environmental receptors to protect and to consider for the exposure assessment are: surface water, groundwater, soil and air.

The PPR Panel has accomplished some major achievements through development of new and science-based methodology for exposure assessment. Regarding methodology for degradation in soil and exposure to soil organisms, a guidance and an opinion have been produced. The guidance in degradation in soil provides a procedure on how data from laboratory and terrestrial field dissipation studies can be applied to derive the degradation time where 50 % of the applied dose of a substance has degraded (EFSA Panel on Plant Protection Products and their Residues (PPR), 2010b). This value, referred to as DegT50, is very important for the exposure assessment as it determines the length of time the pesticide, or its transformation products, are present in the environment. The new methodology is a step forward as it reduces the variability of the DegT50 values compared to the approach currently used today.

The opinion on exposure to soil organisms provides a scientific approach on how to predict environmental concentrations in soil (PECs) (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012d). A tiered exposure assessment scheme containing a simple and conservative lower tier and more realistic and refined higher tiers is proposed. The new exposure assessment methodology will be supported by software tools to allow exposure assessments for substances in a consistent and reliable manner.

A consultation with Member States identified a gap in the environmental assessment of pesticides for use in covered crops (greenhouses and crops grown under cover). Based on the response, the PPR Panel produced two separate opinions on emissions from protected crops. The first opinion contains an inventory for classification of protected crop systems based on data collection of structures and systems in Europe (EFSA Panel on Plant Protection Products and their Residues (PPR), 2010c). The second opinion provides an outline for clustering and ranking of the structures and systems and contains guidance on situations where a risk assessment on the environmental receptors outside the structure should be carried out (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012e).

Exposure assessments of pesticides in the environment are often derived from calculations using standardised software tools like PEARL, PELMO, PRZM and MACRO. The models contain default values e.g. the Q10 factor used to describe the temperature effect on transformation rates of pesticides in soil. The Panel produced two opinions to revise the existing Q10 factor based on a data collection and review of the available literature (EFSA, 2006e; EFSA, 2008b). Today, the revised Q10 default factor is used as an EU standard parameter for exposure assessment.

The PPR Panel reviewed the drafts of the Forum for the Co-ordination of Pesticide Fate Models and their Use (FOCUS) reports and prepared opinions on the respective reports; these included exposure to air, landscape and mitigation factors in ecological risk assessment and degradation kinetics from environmental fate studies (EFSA, 2006f, 2007e,f). The FOCUS Working Groups took the recommendations from the PPR opinions into consideration before finalising the FOCUS reports. The review by the Panel was an important contribution for the scientific quality of the FOCUS reports.

### 3. ENVIRONMENTAL RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS

In the area of environmental risk assessment, the PPR Panel developed several scientific opinions in four main areas:

#### 3.1. Opinions addressing specific issues arising in the peer-review of specific active substances.

The PPR Panel answered upon request of EFSA or the European Commission several specific questions related to issues raised in the peer-review of active substances. The questions and active substances addressed were e.g. mesoscom studies related to cyprodinil (EFSA, 2006g), acute risk assessment for birds for pirimicarb (EFSA, 2005a), long-term risk assessment for fish for dimoxystrobin (EFSA, 2005b), acute, short and long-term exposure of birds and mammals to methamidophos (EFSA, 2004c), risk assessment for non-target arthropods and birds of azinphos-methyl (EFSA, 2003b). The findings on these specific examples were later reviewed by the PPR Panel and aspects highlighted that could be generally applied to the environmental risk assessment of other pesticides (EFSA, 2006h).

#### 3.2. Opinions to support the revision of the data requirements for Directive 91/414/EEC<sup>4</sup>

In 2007, upon request of the European Commission, the PPR Panel published a scientific opinion related to the revision of the data requirements under Directive 91/414/EEC (EFSA, 2007g). Upon request of EFSA, the PPR Panel reviewed this opinion in 2009 and issued an updating opinion to cover relevant new scientific state of the art knowledge (EFSA, 2009b). The opinions provide recommendations on e.g. reduction of vertebrate studies, derivation of more detailed information from existing studies, a risk assessment procedure for amphibians, aquatic risk assessment for other invertebrates than crustaceans, further harmonisation of risk assessment for terrestrial organisms including structural endpoints, use of “x % effect concentrations” (EC<sub>x</sub>) versus “no observed effect concentrations” (NOEC) and harmonisation of risk assessment quotients.

#### 3.3. Opinions on generic methodologies

The PPR Panel issued two opinions addressing overarching issues in environmental effect assessment.

In 2005, the PPR Panel identified a range of methods for taking data for additional species tested into account in the risk assessment. By considering data for additional species the uncertainty will be lowered and thus the assessment factor can be adjusted in order to maintain the same level of protection (EFSA, 2005c).

A major milestone of the PPR Panel was the development of the methodological framework for deriving specific protection goals for environmental risk assessment of pesticides in view of the future dialogue between risk managers and risk assessors during the next steps of the revision of the ecotoxicology guidance documents (EFSA Panel on Plant Protection Products and their Residues (PPR), 2010d, Nienstedt et al, 2012). In the European Union legislation only general protection goals are stated. However, for developing robust and efficient environmental risk assessment procedures it is crucial to know what to protect, where to protect it and over what time period. The Panel developed a framework for defining specific protection goals (SPGs) based on the ecosystem services concept. SPG options were proposed for groups of organisms, so called key drivers, which provide important ecosystem services such as e.g. food provisioning, regulating services (water purification, nutrient cycling, pest control) and genetic resources. The following groups of organisms were defined as key drivers: microbes, algae, non-target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non-target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates. To ensure ecosystem services, taxa representative for the key drivers need to be protected at the population level or higher. However, for aesthetic reasons (cultural ecosystem services) and in some

<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

cases to protect populations of rare species, it may be necessary to protect vertebrates at the individual level. Options for protection goals are developed for the different groups of organisms. Risk managers from Member States present in the Standing Committee on the Food Chain and Animal Health (SCFCAH) are consulted to decide finally on the ecological entities (individuals, populations, processes), magnitude of effects and spatial and temporal scale of effects. The risk assessment Guidance Documents (GDs) developed by the Panel need to ensure that these protection goals can be assessed. The concept is currently applied in the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002).

### **3.4. Opinions and guidance related to risk assessment for specific organism groups**

For the effect and environmental risk assessment (RA) of active substances, GDs in the area of aquatic and terrestrial ecotoxicology and for the RA for birds and mammals are used. The PPR Panel develops opinions on the state of the science for the RA of the different relevant organism groups. These Panel opinions serve as a basis to develop practical EFSA Guidance on the RA.

The Panel issued a scientific opinion on the science behind the RA for birds and mammals in 2008 (EFSA, 2008c). The related EFSA guidance was published by EFSA one year later (EFSA, 2009c).

Currently, the PPR Panel is tasked to revise the GDs on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). Within this framework, several opinions and GDs will be issued in the coming years covering RA of aquatic organisms, in soil organisms, non-target terrestrial plants, non-target terrestrial arthropods, amphibians and reptiles.

Upon a separate request from the European Commission but within the framework of the revision of the GD on Terrestrial Ecotoxicology, the PPR Panel recently published an opinion on the state of the science behind the RA of honey bees, bumblebees and solitary bees (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012f) which will be followed up by a related EFSA Guidance by the end of 2012.

## **CONCLUSIONS**

During the last ten years the PPR Panel has provided key advice and direction to review and progress the complex science behind the risk assessment of plant protection products. The development of guidance should also take account of the views of risk managers and other stakeholders. The Panel and the Pesticides Unit have organised public consultations and discussion meetings and technical workshops in Brussels and Parma publishing the outcomes as appropriate. In order to support the Panel's activities and to gather key information, EFSA has developed an extensive outsourcing programme through public contracts or thanks to the European networking of organisations operating in the fields of its mission. This has resulted in the publication of an increasing number of external reports relevant to the Panel's work by EFSA.

The main demanding challenges ahead include the development of new risk assessment methodologies to address exposure to multistressors (mixtures, repeated exposure to different pesticides) for both the consumer and the environment. The Panel's continuing work on cumulative risk assessment and the inclusion of repeated exposures to pesticide mixtures in future guidance on environmental risk assessment will keep the expertise of the Panel at the forefront of these important issues.

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