Annex to the minutes of the 75th Plenary meeting of the Scientific Panel on Plant Protection Products and their Residues

Recommendations of the PPR Panel on possible future activities supporting the risk assessment of plant protection products

Non dietary cumulative exposure and risk assessment

From 2007 to 2013 the Panel has elaborated methodologies for the assessment of cumulative risks of pesticides resulting from dietary exposure in the context of Regulation (EC) No 396/2005 on MRLs of pesticides in food and feed.

The regulation (EC) No 1107/2009 provides that cumulative risks resulting from non-dietary exposure need also to be considered. In the recent years EFSA has funded 2 data collections on non-dietary cumulative exposure to pesticides:

- Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment:

  (http://www.efsa.europa.eu/en/supporting/pub/346e.htm)

- Collection of pesticide application data in view of performing Environmental Risk Assessments for pesticides (To be published).

The Panel recommends preparing a Scientific Opinion on the science behind the elaboration of a methodology to evaluate the risks resulting from the non-dietary combined exposure to pesticides. This Opinion could include:

- An analysis of the relevance of different modes of combined toxicity (dose addition, response addition, interaction) in the context of non-dietary exposure;
- An assessment of the applicability of the methodology for hazard identification and characterisation of specific effects governing the Cumulative Assessment Groups elaborated in the context of dietary exposure;
- The elaboration of recommendations for the assessment of non-dietary combined exposure and risk;

At longer term, combined exposures from the dietary and non-dietary routes should be aggregated thanks to an appropriate methodology.

Ecotoxicology

Birds and Mammals

In 2009 EFSA published Guidance on the risk assessment for birds and mammals. The Panel is aware of the need identified by the Pesticide Steering Network to update this Guidance and of the respective agreed Terms of Reference.

Non-dietary routes of exposure are however not covered in the current Guidance. In order to address these routes of exposure in future updates of the Guidance, information on dermal and inhalation exposure of birds and mammals was collected through outsourcing an extensive literature review on the topic. The Panel recommends that the external report published in 2014 (http://www.efsa.europa.eu/en/supporting/pub/637e.htm) is used as preparatory work for a Scientific Opinion of the Panel addressing:

- The relevance of inhalation and dermal exposure to pesticides for birds and mammals;
- The development of exposure models and recommendations for risk assessment.

Before updating the Guidance it is recommended to clarify with risk managers the specific protection goals for birds and mammals, in particular with regard to long-term (population level) effects. Furthermore it should be investigated whether juvenile life stages are sufficiently protected by the current risk assessment.

Aquatic Organisms

In 2013 the Panel developed and published Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters.

Referring to this Guidance, the Panel recommends in particular the preparation of Scientific Opinions on:

- The calibration of all tiers Assessment Factors (AFs) for chronic risk assessment on aquatic and sediment organisms;
- The calibration of all tiers AFs for acute risk assessment of active substances with novel modes of action on aquatic organisms;
- The validation of Tier 2 approaches (Geometric Mean and Species Sensitivity Distribution (SSD)) to be applied to chronic toxicity data on aquatic organisms;
- The development of a RA methodology for aquatic and sediment microorganisms;

- The validation of QSAR as non-testing methods to provide valid endpoints for hazard characterisation.

In July 2014, the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) took note of this Guidance with the following notes in the meeting summary report:

"The following statement needs to be reported for clarification: "It is important to note that, whilst the use in an aquatic life risk assessment of a time weighted average (TWA) 'exposure' or 'effect' concentration may in certain circumstances be appropriate, such an approach is only considered scientifically valid when supported by sufficient evidence to support the reciprocity of effects at relevant concentrations and exposure durations." The following statement was submitted by Germany: "The German delegation has noted the guidance document based on the agreement that there will be a revision of the guidance document until end of 2016 latest. For the determination of priorities for revision by EFSA, the concerns already expressed by some MS in the joint comment (05/20014 and 07/2004 SCFCAH) and hitherto existing experiences in the use of the guidance should be considered in particular (e.g. criteria for use of TWA PEC values for aquatic macrophytes; use of geomean and/or SSD approach when one species seems to be clearly more sensitive than other species, such as *Lemna* with sulfonylureas; when toxicity endpoint from the standard laboratory studies should be expressed on the basis of nominal concentration, initial measured concentrations, final measured concentration, peak concentration, mean measured concentration. German responsible authorities will support the settings for the priorities in the responsible EFSA committee and assist the working group in the revision process."

The Panel recommends therefore that EFSA determines the conditions of the revision of the Guidance based on the PAFF committee statement and the initial experience already available with its use.

Bees

The Panel has adopted in May 2015 a Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level on 27 May 2015.

It is highlighted in this Statement that the BEEHAVE model does not include a pesticide module which is essential for using the model in the context of pesticides risk assessment.

Therefore the Panel recommended that such a module is developed. To this end the Panel recommends to be involved in the further development of the BEEHAVE model or of any other model in view of their use in the regulatory risk assessment of pesticides.

Terrestrial organisms (bees, NTA, earthworms, collembolan, etc.)

In its Guidance on tiered risk assessment for edge-of-field surface water, 2 intermediate tiers have been proposed by the Panel based on the available data: the geometric mean and the Species Sensitivity Distribution (SSD).

The panel in its Scientific Opinion on the science behind the risk assessment for non-target arthropods has acknowledged the usefulness of the SSD conceptual model. However, the Panel could not advise to use of this approach because of the lack of data to further validate it. Therefore, the Panel recommends to further work on a Scientific Opinion on:

- The use and appropriateness of the Geometric Mean, SSD, Weight of Evidence (WoE) or other methods to be used as intermediate tier for non-target organisms other than aquatic organisms, including the calibration of the AFs to be used in this intermediate effect assessment tier.
- The calibration/validation of Tier 1 AF for in soil organisms

Landscape based environmental scenarios for all non-target organisms

The Panel in its Scientific Opinion on the science behind the risk assessment for non-target arthropods has recommended a risk assessment at the landscape level which considers diverse range of structures and the agricultural practice.

As an initial action to move to a landscape based risk assessment, The Panel 2012-2015 recommends preparing Scientific Opinions on the development of EU landscape-based environmental/ecological scenarios.

These Opinions could make use of the information generated by the External Scientific Report (To be published) on a collection of pesticide application data in view of performing Environmental Risk Assessments for pesticides.

As a first step it is proposed to define the procedures on how to derive the environmental scenarios. It is recommended that quantified specific protection goals are elaborated before developing such environmental scenarios. The landscape based environmental scenarios to be developed should be usable in Guidance documents and compatible with modelling activities.

Environmental Fate and Behaviour

Spray drift values

The Panel in the Scientific Opinions on non-target terrestrial plants and non-target arthropods considered and recommended reviewing new research on spray drift values and to update the spray drift models after this review has been carried out. US-EPA defines pesticide spray drift as the physical movement of a pesticide through air at the time of application or soon thereafter, to any site other than that intended for application. The Panel finds the following activities relevant:

- Literature/data collection on current information on spray drift values;
- Scientific Opinion on proposals for updated spray drift values and development of methodology to estimate spray drift.

Updating spray drift values would be relevant not only for non-target plants and non-target arthropods exposed to pesticides outside treated fields but could also be relevant for the aquatic exposure of organisms living in water bodies adjacent to fields in the farm land.

Half-life for decline of the dislodgeable foliar residue (DFR) and other canopy processes

The Panel recommended in the Scientific Opinion for predicting environmental concentrations of plant protection products in soil to collect and analyse all relevant literature data on the decline of the DFR in order to further underpin the default value of the DFR half-life. Further the DFR value should be considered in relation to other relevant canopy processes e.g. crop interception, wash-off and volatilisation. The Panel finds the following activities relevant:

- Literature/data collection on current information on DFR values;
- Scientific Opinion on the state of the art of DFR values in relation to development of methodology for measuring and estimating canopy processes relevant for exposure assessment.

Updating DFR values and developing methodology for estimating canopy processes would be relevant for the ground water, aquatic and terrestrial exposure assessment as well as for human exposure assessment of workers and residents.

Development of groundwater scenarios taking new soil maps and preferential flow into account

The Panel recommended in the Scientific Opinions on the FOCUS groundwater report to re-assess the groundwater scenarios following the scenario selection procedure proposed in the Scientific Opinion on scenario selection and scenario parameterisation for exposure assessment in soil. Development of new scenarios should take new soil, crop and weather data into account.

The Scientific Opinions on the FOCUS groundwater report also recommended taking preferential flow into account when updating the procedure. Recently knowledge and databases became available to take account of preferential flow in the leaching assessment. Preferential flow refers to the uneven and often rapid movement of water through porous media in e.g. soil characterised by enhanced flux to ground water through structures such as wormholes, root holes and cracks. The Panel finds the following activities relevant:

- Data collection through e.g. JRC for updating soil, crop and weather data in EU;
- Preparing a Scientific Opinion for a proposal on how the ground water scenarios could be developed taking new soil maps and preferential flow into account.

Methodology development in this area would improve the assessment of concentrations of active substances and metabolites in ground water and enable taking preferential flow into account. Developing methodology for how to account for heterogeneous distribution of irrigation water should also be considered. Proposals for protection goals, scenario development, calibration of ties and uncertainties could be included under this activity.

Development of the surface water scenarios taking information on water bodies in EU into account

The Panel recommended in the Scientific Opinions on the appropriateness of using the current FOCUS surface water scenarios (2005) and on the final report of the FOCUS Working Group on landscape and mitigation factors in ecological risk assessment (2007) to make some improvements to the current procedure.

Further the Pesticide Steering Network made a proposal for reconsideration of the surface water scenarios taking into account recent advances in Geographic Information System and EU wide soil mapping information and of the relevance of the current standard FOCUS water bodies. The Panel finds the following activities relevant:

- Data collection through e.g. JRC for collecting spatial and temporal data on water bodies in EU;
- Preparing a Scientific Opinion for a proposal on how surface water scenarios could be revised taking spatial and temporal data of water bodies into account.

Development of surface water scenarios is relevant for the aquatic exposure assessment to organisms living in water bodies adjacent to fields in the farm land. The Panel could also investigate the feasibility for deriving environmental scenarios (integrating exposure and ecological scenarios) for different water bodies in different regions of the EU.

Med-Rice Guidance

In its Opinion adopted on the 30th January 2003, the Scientific Committee on Plants recommended a check on the scientific validity of the stepwise procedure proposed in the MEDRICE Report, and identified some concerns about the modelling framework.

In its Scientific Opinion adopted in 2007 related to the revision of the data requirements on fate and behaviour in the environment, the Panel reminded the Commission of the need to update the MEDRICE Report.

The Panel notes that in the meantime the Pesticide Steering Network has prepared and agreed on Terms of Reference for the revision of the Med-Rice Guidance.

The Panel acknowledges the importance of this project and recommends the update of the MEDRICE report to support the exposure assessment to organisms living in or around rice paddies.

Developmental Neurotoxicity Testing Strategy

In its Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid, the Panel made a series of recommendations, including recommendation on the DNT testing framework.

The Panel supports the development of an integrated neurotoxicity testing strategy supplementary to the *in vivo* assay OECD TG 426 in order to screen the

DNT potential of pesticides. *In vitro* and non-mammalian alternative systems-based models, along with *in silico* approaches, could provide scientifically robust methods suitable for the initial screening or prioritisation of pesticides for their potential to cause DNT and could also possibly provide a robust point of departure for risk assessment based on read across to known developmental neurotoxic pesticides.

The External Scientific Report (EFSA 2015) on a 'literature review on in vitro and alternative Developmental Neurotoxicity (DNT) testing methods' provides an overview of the scientific state-of-play in this area and the Panel recommends:

- The organisation of a stakeholder conference/workshop with interested partners i.e. JRC and OECD in order to foster cooperation in the field of DNT and to collect the views of stakeholders for the further development of a Scientific Opinion;
- The preparation of a Scientific Opinion on the development of an integrated testing strategy for the exploration of hazards linked to DNT.

Risk assessment for microorganisms used as plant protection products

In 2013 and 2015, EFSA published 2 External Scientific Reports on literature search and data collection on the risk assessment of microorganisms used as plant protection products for the impact on environment

(http://www.efsa.europa.eu/en/supporting/pub/518e.htm) and on human health (http://www.efsa.europa.eu/en/supporting/pub/801e.htm), respectively.

The Panel recommends to further develop the key findings of these report among experts from academia, industry, risk assessment bodies and risk managers through the organisation of a stakeholder workshop addressing the specific challenges of the risk assessment of microorganisms used as plant products and aiming at identifying areas for which scientific Guidance could be developed and areas where the actual data requirements do not provide conclusive information for risk assessment.

Optimising control experiments in regulatory risk assessment of pesticides

The Panel recommends the preparation of a Scientific Opinion investigating the use of control experiments and their role in regulatory testing. This Scientific Opinion is intended to investigate, discuss and give recommendations on experimental design and laboratory testing, minimal requirements for control experiments and use of historical control experiments focusing on studies relevant to pesticides authorization. In addition, the review of present practice is expected to reveal opportunities to optimise the risk assessment to achieve greater scientific excellence.