



REPORT FROM THE JOINT WORKING GROUP ON THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS & MAMMALS

Introduction

The scientific opinion of the Panel on Plant Protection Products and their Residues (PPR Panel) on the science behind the Guidance Document on Risk Assessment for Birds and Mammals (*The EFSA Journal (2008) 734:1-181*) and its 34 Appendices provided a comprehensive review of all publically available data on this topic and their expert opinion for how this information could be used. A Joint Working Group was asked to consider the scientific opinion and determine a way forward to develop the Guidance Document by deciding on different risk assessment options given in the Opinion. This report sets out the main decisions made by the Joint Working Group.

Aims and Objectives

The Joint Working Group, which was chaired by the Commission and comprised of risk managers from six Member States, supported by two PPR Panel members in their role as technical experts and scientific advisors and the Secretary of the PPR Panel facilitating the work of this group, was asked to achieve the following:

- Resolve risk management questions raised by the PPR Panel Opinion.
- Deliver a guidance document by October 2009, allowing Member States the opportunity to evaluate the proposals before being asked to note these at the respective Standing Committee on the Food Chain and Animal Health meeting.

The Joint Working Group also addressed some further challenges:

- To find ways to reduce the resources required by all involved in assessing the risks from plant protection products to birds and mammals.
- To focus resources on those plant protection products predicted by the models to be of most potential to cause damage to populations or mortality of individuals at unacceptable levels.
- To minimise the need for vertebrate testing.

Rationale for Decisions

Current experience is that approximately half of all bird and mammal risk assessments require higher tier considerations for risks to the reproductive phase. The extra data submitted generally relate to small samples of individuals monitored over short periods and are resource intensive to generate, interpret and evaluate. The outcome is most

usually that risk managers conclude the risk is acceptable. The PPR Panel Opinion included the information that around 10% of acute toxicity risk assessments would require a higher tier assessment. With this background, the Joint Working Group determined to make decisions that simplified the evaluation process and reduced the number of evaluations of reproductive toxicity that required higher tier considerations.

Undertaking this work, the Joint Working Group also recognised the following:

- The data submitted to address higher tier assessments represents a valuable collection of ecological data on farmland birds and mammals and that ways should be explored to make the best possible use of these data to avoid any duplication of effort and unnecessary stress to wildlife.
- As the PPR Panel Opinion outlines, the Toxicity Exposure Ratio (TER) acceptability criteria in current legislation (Annex VI) are not scientifically based.
- The PPR Panel did not have access to the confidential data submitted in support of authorisations to Competent Authorities which could have helped provide more generic advice in the future Guidance Document.
- The Guidance Document will focus on direct effects of plant protection products which are generally accepted to be relatively less significant on bird and mammal populations than indirect effects.
- Similarly, plant protection products are only one of the challenges that birds and mammals face in the environment.

Acute toxicity

The PPR Panel Opinion offered two approaches for assessing acute risk (TER and LD50/m²). The Joint Working Group decided to use the standard current approach (TER) to ensure consistency with the recently completed Annex I listing process and most product approvals. Analyses conducted during the development of the PPR Panel Opinion suggest around 1 in 10 active substances will require higher tier considerations. It is the opinion of the Joint Working Group that this is an appropriate level, targeting further attention on those substances that are predicted to pose the highest risk.

Reproductive toxicity

Having agreed to simplify the assessment for reproductive toxicity, the Joint Working Group carefully considered each aspect of the PPR Panel Opinion in this area. The following amendments to the approach proposed in the PPR Panel Opinion were agreed:

- The phased approach, currently at tier 1, is to be moved to higher tier assessment.
- First tier reproductive assessment to utilise the following:
 - Single toxicity endpoint
 - Mammals - lowest ecologically-relevant endpoint from two-generation rat study (or teratogenicity study if lower);
 - Birds – lowest of relevant reproduction study endpoints and LD50/10.
 - Single exposure estimate
 - Use long term exposure (21 day, time-weighted average) as default. The Joint Working Group recognised that the science regarding appropriate time periods for assessment of reproductive effects is uncertain and decided to continue the current practice of using 21 day

as a default, pending further advice from the PPR Panel (see Further Work below).

- Use short term exposure when there is reason to believe that this is appropriate for the substance in hand. The PPR Panel will be asked to suggest scientifically based rules on when to apply the short term exposure approach in reproductive assessments (see Further Work below).

Higher tier considerations

The Joint Working Group acknowledged the comprehensive and thorough approach of the PPR Panel together with the transparency of argument and presentation of expert opinion. The PPR Panel Opinion is an extremely valuable resource and it is proposed that much of this forms the basis of higher tier assessments, with the options, approaches and information used to the full.

Geomean

The Joint Working Group recognised the scientific logic and robustness of the geomean approach to addressing endpoints from multiple toxicity studies for different species. However, there were concerns for situations where species sensitivity distribution was particularly wide. The Joint Working Group decided on the following approaches:

- The geomean should be used for the acute assessment, except when the lowest species is more than a factor of 10 below the geomean.
- Where this is the case, then the most sensitive species will be used for the risk assessment but generally without an additional assessment factor (unless there are specific reasons to believe that this is not appropriate).
- The PPR Panel Opinion (footnote 29) stated that further investigation of assumptions affecting the applicability of the geomean to No Observed Effect Concentrations (NOEC) data would be desirable. The Joint Working Group decided that the reproductive assessment should continue to be based on the most sensitive species pending these investigations. The PPR Panel will therefore be asked to consider further the applicability of the geomean for NOEC for reproductive studies.

Further Risk Management Considerations

The approach taken in the PPR Panel Opinion is to protect the individual such that the population is protected. In the Uniform Principles as well as in Guidance Documents for other areas of environmental risk assessment, protection of populations is stated as the generic protection goal. In actual use, it is clear that only a proportion of any population is exposed to an active substance at any one time. However, there are other factors to take into consideration including the following:

- Multiple exposures from return visits to the treated field or other adjacent fields.
- The mobility of bird and mammal species to enable them to find other food sources.
- The area likely to be treated in relation to population distribution.
- The potential for an affected population to decline or recover.
- Species that are already declining will have less resilience to additional effects.

The Joint Working Group recognised that, due to the complexity of these factors, any scientific assessment of population effects is subject to high uncertainty, which needs to be taken into account when making risk management decisions on authorisation. Therefore, the Joint Working Group recommends that in future evaluations, any scientific consideration of population effects should be included as a distinct part of the risk assessment and, where the risk assessment indicates potential for impacts on individuals, the Member State Competent Authority should produce a separate section where any risk management considerations affecting the final decision, either for no authorisation or for authorisation, are explained in full. One of the benefits of this approach will be to assist other Competent Authorities when making their decisions on applications for mutual recognition or, in future, zonal authorisations.

Plant protection products are applied for the benefits they provide. Where risk managers consider that these benefits outweigh any predicted adverse effects from the risk assessment, they may take the decision that authorisation is justifiable. For example, use of a plant protection product on a minor crop may be deemed essential and pose a lower threat to a population than use on a major crop, although the potential for aggregation of effects over multiple minor crops may also be relevant.

Other Issues

The Joint Working Group reviewed all sections and Appendices of the Opinion and agreed a limited number of other, minor changes to be made when finalising the Guidance Document.

Further Work

The Joint Working Group agreed to the formation of an 'editorial team' of the EFSA Secretary and two PPR Panel members to use the decisions made by the risk managers and revisit the PPR Panel Opinion to produce the revised Guidance Document. The intention is for this to be finalised by 30 October 2009 and presented to the subsequent meeting of the Standing Committee on the Food Chain and Animal Health for noting. If agreement is forthcoming, the Guidance Document will be published in late 2009/early 2010 with implementation six months later.

The Joint Working Group has requested further advice from the PPR Panel on the following:

- The need for clear scientifically based rules on when to apply the short term exposure approach in reproductive assessments (covering both birds and mammals) (high priority).
- The need for the vole scenario in the Guidance Document given the resilience of vole populations (high priority).
- Opinion to further investigate protectiveness of geometric approach with regard to errors in NOECs (medium priority).
- Extrapolated LD50 values from limit dose tests for mammals (low priority).
- Granules in puddles. The PPR Panel recommended that further research be performed to determine whether the conditions that have caused poisoning

incidents of this type are likely to be repeated under EU conditions and, if so, what the likely frequency of these occurrences would be (low priority).

The Joint Working Group recognised that much relevant data, generated to support applications and owned by the industry were not available to the PPR Panel. Access to this information could help the development of generic values for use in risk assessments and reduce the future work required by all involved. Efforts should continue to find ways of obtaining access to this information and using it for refining the generic exposure scenarios.

EFSA are developing a tool to assist in first tier assessments. The Joint Working Group have requested that the tool provides one page that summarises all input and output values. This can then be 'cut and pasted' into submissions and evaluations. A first prototype of this tool was presented to the Joint Working Group who gave positive feedback on it. The Joint Working Group have also suggested producing further tools to support users in performing higher-tier calculations (e.g. for mixed diets of focal species).

Direct and Indirect Effects

Research following use of plant protection products in the field has often demonstrated that the indirect effects have a significant impact on bird populations. Less is known about impacts on mammals but there is every reason to believe the same is true. The PPR Panel and the Joint Working Group have not considered indirect effects. Should there be the desire to determine the extent of such effects, further research will be required. To reduce any such effect, it may be beneficial to introduce other measures, such as the agri-environment schemes adopted by some Member States.

Protected Species

Many Member States have identified particular bird and mammal species where their populations are particularly threatened (e.g. red list species, biodiversity action plan species). This can be due to a range of issues and may include the direct or indirect effects of the use of plant protection products. A consideration of these issues was not within the remit of either the PPR Panel or the Joint Working Group. If plant protection products are identified as posing risks to such species, other measures are required to address these.

Validation and Review

While the PPR Panel are to be complimented for making every effort to validate the models in the Opinion against field data, this was only achieved for acute toxicity to birds. While the models are based on expert judgement, it has to be recognised that there is still a great deal of uncertainty and many unknowns. Thus, the Joint Working Group would like to stress that the approach outlined above is a decision-making tool and not an accurate predictor of actual effects in the field.

For this reason, the Joint Working Group proposes to review the operation of this guidance and the outcomes achieved after two years. At that time the EFSA Secretariat will

approach Member State Competent Authorities and others involved with this guidance for an assessment of the success or otherwise of this guidance document.