

SCIENTIFIC OPINION

Updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Environmental Fate and Behaviour Studies¹

Scientific Opinion of the Panel on Plant Protection Products and their Residues

(Question No EFSA-Q-2009-00616)

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SUMMARY

The European Food Safety Authority (EFSA) asked its Panel on Plant Protection Products and their Residues to review the Opinions of the PPR Panel issued in 2006 and 2007 related to the revision of Annexes II and III to Council Directive 91/414/EEC (data requirements) concerning the placing of plant protection products on the market.

If not otherwise stated, the findings and recommendations given in the adopted EFSA 2007 Fate and Behaviour opinion (EFSA, 2007b) remain valid and applicable.

The Panel is of the opinion that the data requirement methodologies should not be too prescriptive. Also, new data may be needed due to the current development and updating of guidance documents by the Panel and other instances or due to new regulations which may include additional requirements in order to allow the application of new developments in risk assessment.

Some extra remarks and recommendations are given taking into consideration the comments provided by the Panel in its relevant Opinions made after its previous review (EFSA, 2007b):

- that data requirements for exposure calculations should not to be too detailed in the Annex II and III .

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- that the recommendations related to the use of compound-specific Q10 values in the EFSA opinion (EFSA, 2007e) should be taken into consideration
- that the Panel's conclusion that the trigger value (10%) for the formation percentages for environmental metabolites is a risk management decision should be taken into consideration
- that future developments in the area of nanomaterials used as/in plant protection products need to be considered and appropriately taken into account

Key words: Environmental fate and behaviour studies, plant protection product, pesticides, active substance, risk assessment, exposure assessment, data requirement, Annex II and III fate and behaviour, Directive 91/414/EEC.

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BACKGROUND AS PROVIDED BY EFSA

In November 2005, the Commission initially informed EFSA² that they are revising the data requirements for authorisation of active substances and plant protection products in the framework of Council Directive 91/414/EEC. The revision process involved Part A of Annexes II and III and had been organised in order to amend the directives³ laying down the data requirements for active substances and plant protection products. The Commission had prepared SANCO Working Documents⁴ containing the proposed data requirements to revise Annexes II and III to Directive 91/414/EEC and asked the PPR Panel to provide observations and/or possible recommendations, and in particular to verify that the methodology and the approaches presented in the draft data requirements were in line with the scientific state of the art in the relevant field and the extent of its applicability with respect to the risk assessment of plant protection products.

Between May 2006 and March 2007, the PPR Panel issued upon request of the Commission six opinions on the SANCO working documents related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (EFSA 2006a, b, c; EFSA 2007a, b, c).

Until now the Annexes II and III to Council Directive 91/414/EEC have not been finally amended, but meanwhile a new Regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC has been elaborated and may enter into force in 2009.

Following Art 8(4) of this new regulation, the data requirements shall contain the requirements for active substances and plant protection products as set out in Annexes II and III to Directive 91/414/EC and laid down in further regulations to be adopted.

² Letters P. Testori Coggi 21 Nov 2005 (requesting opinions on phys-chem. properties, analytical methods, residues); 03 Aug 2006 (fate and behaviour, toxicological and metabolism studies); 29 Sept 2006 (ecotoxicological studies)

³ 94/37/EC physical and chemical properties; 96/46/EC analytical methods; 94/79/EC toxicological and metabolism studies; 96/68/EC residues; 95/36/EC fate and behaviour in the environment; 96/12/EC ecotoxicological studies.

⁴ SANCO 10438, 10439, 10440, 10481, 10482, 10483

Therefore, the PPR Panel would like to revisit their opinions issued in 2006 and 2007 to make sure, that the data requirements for active substances and plant protection products are up to date at the time of their adoption under the relevant regulation.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Scientific Panel on Plant protection products and their Residues is asked by EFSA to review the Opinions of the PPR Panel issued in 2006 and 2007 related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

In January 2007, the PPR Panel adopted upon request of the Commission its opinion on the SANCO working documents related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Environmental fate and behavior studies (EFSA 2007b).

Annexes II and III to Council Directive 91/414/EEC have not been finally amended, but meanwhile a new Regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC was adopted by the European Parliament in January 2009 and is expected to enter into force in 2009.

Therefore, the PPR Panel is amending its opinion issued in 2007 to ensure that the data requirements for active substances and plant protection products are up to date at the time of their adoption under the relevant Regulation.

It is not the intention to replace the existing opinion (EFSA, 2007b) but to add some further comments and recommendations based on new EFSA opinions and guidance. If not otherwise stated, the findings and recommendations given in EFSA 2007 remain valid and applicable.

2. General remarks and recommendations

The PPR Panel takes the opportunity to emphasise the conclusions which were stated in its previous review of Annexes II and III data-requirements for Environmental Fate and Behaviour (EFSA, 2007b).

In this Opinion only additional remarks and recommendations are given, taking into consideration the comments provided by the Panel in its relevant Opinions made after the previous Opinion on Annex II and Annex III.

The PPR Panel recommends that the revised Annex II and III environmental fate data requirements should be flexible enough to allow new developments (test guidelines, guidance documents, Opinions and legislation) to be implemented when necessary. Given the imminent adoption of a new Regulation concerning the placing of plant protection products on the

market,⁵ the Panel anticipates that additional data may be needed in order to perform the requested risk assessments. New Regulations may include additional requirements for certain items e.g. coformulants.

3. Specific remarks

The PPR Panel recommends that the Annexes II and III: Fate and behaviour in the environment should be revised and updated taking into consideration the comments and conclusions provided by the Panel in Opinions published since the previous Opinion on the data-requirements (EFSA, 2007b). The Panel concluded that its Opinion on the Focus Air Report (EFSA, 2007d) does not necessitate any extra requirements for inclusion in Annex II and Annex III. On the other hand, its Opinion on Q10 (EFSA, 2007e) does contain some elements that are new since the previous Opinion (EFSA, 2007b). Additionally, some further proposals are likely to arise from guidances currently being developed by the Panel.

The following recommendations are formulated:

3.1 Recommendations from the PPR Q10 opinion

The revised Q10 opinion (EFSA, 2007e) contains detailed recommendations for estimating compound-specific values of the Arrhenius activation energy. These recommendations should be considered as a further clarification of the comment that the Panel made on the influence of temperature on degradation in Annex II (EU No 7.2.2) on p. 12 of EFSA (EFSA, 2007b).

3.2 Calculations of PECs in depth of the soil layer

Annex III (e.g. EU No 9.1.3 to 9.2.3) prescribes details of the procedure for the calculation of PECs (bulk density of 1.5 kg/L, depth of the soil layer, time window, etc). The prescription of such details of the exposure assessment for soil organisms is likely to lead to conflicts with the guidance that the PPR Panel is currently developing for this risk assessment. The Panel recommends that the Annex II and Annex III data requirements should not be prescribed in too much detail.

3.3 Comments on the trigger values for metabolites

The current annexes refer in several places (e.g. current EU no 7.1.1.2.1) to a trigger value of 10% for the percentage of metabolite formation. For metabolites that are formed above this trigger value, further data are required that enable adequate exposure assessments (e.g. for leaching to groundwater and exposure of aquatic organisms). For metabolites whose formation percentage remains below this trigger, no further risk assessment is required. The PPR Panel points out that this trigger value is a risk management decision because it cannot be excluded that metabolites with formation percentages below 10% may pose unacceptable risks to e.g. groundwater and aquatic organisms. Furthermore, in regulatory practice the trigger is linked to results obtained with a molecule radiolabelled at a specific atom, which implies that not all metabolites are necessarily covered. The Panel recommends taking into consideration these remarks for the update of the data requirements.

⁵ Regulation (EC) No .../2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Expected to be published by 2009.

3.4 Nanomaterials used as/in pesticides

Although to date there are no registered pesticides on the market which contain nanomaterials, progress of science indicates that this might not be the case in the future, in particular since there are already biocides with these characteristics. Regarding the assessment of risks in nanotechnology, the Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has already published several opinions (SCENIHR, 2006, 2007, 2009). The latest one, published in January 2009, indicates that methodologies to assess exposure to manufactured nanomaterials to humans and the environment and the identification of potential hazards require further development, that more research is needed and that risk assessment should be performed case-by-case for each nanomaterial.

Also, EFSA's Scientific Committee (SC) has published a scientific opinion on nanoscience and nanotechnologies in relation to food and feed safety (EFSA, 2009). The SC concluded that established international approaches to risk assessment can also be applied to engineered nano materials (ENM). A case-by-case approach would be necessary and that, in practice, current data limitations and a lack of validated test methodologies could make risk assessment of specific nano products very difficult and subject to a high degree of uncertainty.

The PPR Panel recommends that future developments in this area need to be considered and appropriately taken into account when risk assessments of these kinds of material are needed. Until then, these risk assessments will need to be performed on a case by case basis until appropriate guidance is available.

CONCLUSIONS AND RECOMMENDATIONS

The PPR Panel recommends:

- that the recommendations of its previous Opinion are taken into consideration (EFSA, 2007b)
- that the revised Annexes II and III data requirements should not be too descriptive and should be made flexible enough to allow new developments in risk assessment
- that data requirements for exposure calculations should not to be too detailed in the Annex II and III
- that the recommendations related to the use of compound-specific Q10 values in the EFSA opinion (EFSA, 2007e) should be taken into consideration
- that the Panel's conclusion that the trigger value (10%) for the formation percentages for environmental metabolites is a risk management decision should be taken into consideration
- that future developments in the area of nanomaterials used as/in plant protection products need to be considered and appropriately taken into account

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LIST OF ACRONYMS

DG SANCO	Directorate General for Health and Consumer Affairs
EEC	European Economic Community
EFSA	European Food Safety Authority
ENM	Engineered nano materials
PPR	Plant Protection Products and their Residues
Q ₁₀	Q ₁₀ is defined as the ratio of pesticide degradation rate coefficients (k_2/k_1) at a temperature T_1 that is 10°C lower than a temperature T_2 (see EFSA, 2007e)
SC	Scientific Committee
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks