

SCIENTIFIC OPINION

Updating the opinions 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 – Physical and Chemical Properties¹

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

(Question No EFSA-Q-2009-00619)

Adopted on 18 June 2009

PANEL MEMBERS

Damia Barcelo Culleres, Jos Boesten, Claudia Bolognesi, Alan Boobis, Arne Büchert, Ettore Capri, David Coggon, Anthony Hardy, Andy Hart, Herbert Köpp, Matthias Liess, Robert Luttik, Otto Meyer, Stella Michaelidou-Canna, Mark Montforts, Angelo Moretto, Markus Müller, Bernadette Ossendorp, Walter Steurbaut, Maria Tasheva, Christiane Vleminckx.

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.

The present opinion is an update to the existing opinion on Annex II and III – Physical and Chemical Properties (EFSA, 2006a).

The PPR Panel considers that there are no relevant new scientific findings, test guidelines or guidance documents in the field of identity, physical chemical properties and further information collectively called “physical and chemical properties” that presently merit an update of the previous opinion. Consequently an in-depth review is neither needed nor is it feasible considering the short timeline given for the mandate.

In this context the PPR Panel refers to the planned revision of the “Manual on development and use of FAO and WHO specifications for pesticides”. The data requirements for describing the identity and physical and chemical properties of pesticide active ingredients and

¹ For citation purposes: Updating the opinions 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 – Chemical and Physical Properties. *The EFSA Journal* (2009) 1172, 1-6

preparations in Annex II and III refer to this Manual. The new version is expected to be available in 2010 and will have bearing on the corresponding chapters in Annex II and III, respectively.

Furthermore, the new framework regulation on pesticides may have an impact on data requirements concerning physical and chemical properties.

The PPR Panel notes that the present data requirements on Physical and Chemical Properties would not underpin a risk assessment on nanopesticides, if such products would be developed and submitted for registration. A specific mandate to cover nanopesticides as well as nanoformulations would be appropriate, but this would be a resource intensive task.

The PPR Panel emphasises that the recommendations in its previous opinion still stand.

Key words: annexes II and III, data requirements, Directive 91/414/EEC, plant protection products, pesticides, physical and chemical properties

TABLE OF CONTENTS

Panel Members	1
Summary	1
Table of Contents	3
Background as provided by EFSA	3
Terms of reference as provided by EFSA	4
Acknowledgements	4
Evaluation.....	4
1. Introduction	4
2. Opinion	4
References	5

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).

Currently 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 will enter into force in spring 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

EFSA wishes to thank the members of the Residue Working Group for their contribution to the preparation of this statement: Markus Müller, Arne Büchert, Andy Hart, Stella Michaelidou-Canna, Mark Montforts and Bernadette Ossendorp. EFSA also would like to thank the colleagues from the PRAPeR Unit Laszlo Bura and Jeff Pim as well as Luc Mohimont and Hans Steinkellner from the PPR Unit.

EVALUATION

1. Introduction

In 2006, the PPR Panel reviewed the proposed revisions to data requirements concerning chapters 1, 2 and 3 respectively (Identity, Physical and Chemical properties, Further Information, collectively designated as “Physical and Chemical Properties”) of Annex II and III of Directive 91/414/EEC, as set out in Commission Working Document SANCO/10482/2006 and issued an opinion on the subject on 17 May 2006 (EFSA 2006a). At that time, in addition to specific comments and recommendations on various sections of the draft data requirements, the PPR Panel formulated a set of main recommendations.

2. Opinion

The PPR Panel considers that there are no major changes in the science, test guidelines or guidance documents in the fields of identity, physical-chemical properties and further information (Physical-Chemical Properties) that presently necessitate an update of the PPR Panel’s previous opinion. An in-depth review is neither needed nor feasible considering the extremely short timeline given for the mandate.

However, in its earlier opinion, the PPR Panel recommends that reference should be made to the “Manual on development and use of FAO and WHO specifications for pesticides”, March 2006 revision of the 1st edition. This FAO and WHO Manual is currently under revision and a new edition is expected to be publicly available in 2010. This will lead to changes to data requirements for physical-chemical properties of active ingredients and formulations, which will have a bearing on the Chapters 1, 2 and 3 of Annexes II and III of Directive 91/414.

When these amendments and changes are finalized and adopted by the Joint Meeting of Pesticide Specifications of FAO and WHO and published by these UN organizations, a revision of the data requirements will be necessary.

Moreover, when the new Regulation of the European Parliament and of the Council on the placing of plant protection products on the market will be in place, it will be necessary to revisit the Annexes to define additional requirements for certain items e.g. pesticides which may disrupt the endocrine system, safeners and synergists as well as coformulants.

The PPR Panel takes this opportunity to emphasise the scientific recommendations it made previously.

The PPR Panel notes that the present data requirements on Physical and Chemical Properties would not underpin a risk assessment on nanopesticides⁵, if such products would be developed and submitted for registration. A specific mandate to covering nanopesticides as well as nanoformulations would be appropriate, but this would be a resource intensive task.

REFERENCES

- EFSA(European Food Safety Authority), 2006a. Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission 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 - Physical and Chemical Properties. 17 May 2006. *The EFSA Journal* (2006) 361, 1-17.
- EFSA(European Food Safety Authority), 2006b. Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission 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 – Analytical methods. 17 May 2006. *The EFSA Journal* (2006) 363, 1-18.
- EFSA(European Food Safety Authority), 2006c. Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission 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 – Residues. 17 May 2006. *The EFSA Journal* (2006) 364, 1-27.
- EFSA(European Food Safety Authority), 2007a. Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission 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 – Toxicological and metabolism studies. 31 January 2007. *The EFSA Journal* (2007) 449, 1-60.
- EFSA(European Food Safety Authority), 2007b. Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission 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 – Fate and Behaviour in the Environment. 31 January 2007. *The EFSA Journal* (2007) 448, 1-17.
- EFSA(European Food Safety Authority), 2007c. Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of

⁵ For a definition of nanomaterials, see EFSA 2009.

plant protection products on the market – Ecotoxicological studies. 7 March 2007. *The EFSA Journal* (2007) 461, 1-44.

EFSA(European Food Safety Authority), 2009. Scientific Opinion of the Scientific Committee on a request from the European Commission on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. *The EFSA Journal* (2009) 958, 1-39.