

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 – Residues.¹

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

(Question No EFSA-Q-2009-00617)

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PANEL MEMBERS

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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.

The present opinion is an update to the existing opinion on Annex II & III – Residues (EFSA, 2006c).

The PPR Panel notes that since the publication of its previous opinion, eight OECD test guidelines and four OECD guidance documents in the field of residues have become available and recommends this new information be thoroughly considered in the establishment of the data requirements in annexes II and III to Directive 91/414/EC.

Moreover, when the new Regulation of the European Parliament and of the Council on the placing of plant protection products on the market is in place, it may again be necessary to define additional requirements to address certain issues e.g. pesticides which may disrupt the endocrine system, safeners and synergists, co-formulants.

In addition, the PPR Panel cannot at present give a definitive statement on whether or not the data requirements given in Annex II and III are sufficient to gauge risks of nanopesticides, since such an assessment would require substantial scientific efforts and time which could not be provided within the frame of the present mandate.

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

Key words: annex II and III, data requirements, Directive 91/414/EEC, plant protection products, pesticides, residues

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BACKGROUND AS PROVIDED BY EFSA

In November 2005, the Commission informed EFSA² that they are revising the data requirements for the 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 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.

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.

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

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.

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EVALUATION

1. Introduction

In 2006, the PPR Panel reviewed the proposed revisions of residue data requirements in Annex II and III of Directive 91/414/EEC, as set out in Commission Working Document, SANCO/10440/2005 rev. 6 and issued an opinion on the subject on 18 May 2006 (EFSA 2006c). 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 notes that since the publication of its previous opinion, eight OECD test guidelines and four OECD guidance documents in the field of residues have become available and recommends this new information be thoroughly considered in the establishment of the data requirements in annexes II and III to Directive 91/414/EC.

New OECD Test Guidelines are:

Metabolism in Crops (TG 501)

Metabolism in Rotational Crops (TG 502)

Metabolism in Livestock (TG 503)

Residues in Rotational Crops (Limited Field Studies) (TG 504)

Residues in Livestock (TG 505)

Stability of Pesticide Residues in Stored Commodities (TG 506)

Nature of Pesticide Residues in processed Commodities - High Temperature-Hydrolysis (TG 507)

Magnitude of Pesticide Residues in Processed Commodities (TG 508)

New OECD Guidance Documents are:

Definition of Residue (Series on Pesticides, No. 31; Series on Testing and Assessment, No. 63)

Overview of Residue Chemistry Studies (Series on Pesticides, No. 32; Series on Testing and Assessment, No. 64)

Guidance Document on Pesticide Residue Analytical Methods (Series on Pesticides, No. 39; Series on Testing and Assessment, No. 72)⁵

Guidance Document on Magnitude of Pesticide Residues in Processed Commodities (Series on Testing and Assessment, No. 96).

In addition, several activities concerning the development or updating of guidance documents are ongoing by the PPR Panel and within OECD, e.g. an opinion on the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment (EFSA 2008a), a guidance document on the use of probabilistic methodology for modeling dietary exposure to pesticide residues (EFSA 2008b), and a guideline on field trials for residues in crops (OECD). In addition, OECD is currently elaborating a calculator to harmonize the way MRLs are derived from the residue field trial data and will develop a guidance document to accompany this calculator. After completion of these activities, revision of the data requirements may again 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 is in place, it may also be necessary to revisit the Annexes to define additional requirements to address certain issues e.g. pesticides which may disrupt the endocrine system, safeners and synergists as well as coformulants.

The PPR Panel is of the opinion that at present no definitive statement can be made as to whether or not the current data requirements in Annex II and III are sufficient to carry out risk assessments for nanopesticides⁶. Such an assessment would likely require substantial effort and resources, and would need a specific mandate.

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

⁵ See also 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 – Physical and Chemical properties. *The EFSA Journal* (2009) 1172, 1-6

⁶ For a definition of nanomaterials, see EFSA 2009

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

EFSA(European Food Safety Authority), 2008a. Terms of Reference (Scientific opinion of the Panel on Plant Protection Products and their Residues on evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment).

EFSA(European Food Safety Authority), 2008b. Terms of Reference (The use of probabilistic methodology for modeling dietary exposure to pesticide residues: Guidance document of the Panel on Plant Protection Products and their Residues).

EFSA(European Food Safety Authority), 2009. Scientific Opinion of the Scientific Committee on The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, 10 February 2009, *The EFSA Journal* (2009) 958, 1-39.

OECD(Organisation for Economic Cooperation and Development), documents http://www.oecd.org/document/41/0,3343,en_2649_34383_42409449_1_1_1_1,00.html.