

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 – Analytical methods¹

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

(Question No EFSA-Q-2009-00618)

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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 PPR Panel considers that since the publication of its previous opinion, one OECD guidance document in the field of analytical methods has become available. This merits consideration.

Guidance Document on Pesticide Residue Analytical Methods (Series on Pesticides, No. 39; Series on Testing and Assessment, No. 72) (OECD, 2007).

The OECD document contains more detailed information concerning validation parameters e.g. on number of samples for fortification experiments. Under confirmatory techniques e.g. the characteristics of the UV spectrum, it is mentioned that samples should be spiked at the limit for quantification. The OECD (2007) document should therefore be referenced in the Annexes.

¹ For citation purposes: Scientific Opinion of EFSA prepared by the Panel on Plant Protection Products and their Residues (PPR) on the review of 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 – Analytical methods, *The EFSA Journal* (2009) 1174, 1-6

The PPR Panel cannot at present give a definitive opinion 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.

The PPR Panel emphasises that the recommendations given in the previous opinion are still valid.

Key words: Directive 91/414/EEC, data requirement, Annex II and III analytical methods, plant protection product, pesticides, active substance.

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
Assessment.....	5
1. Introduction	5
2. General remarks and recommendations	5
3. Conclusion.....	5
References	5
List of acronyms.....	6

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.

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 2006 - 2007, the PPR Panel reviewed the proposed revisions of analytical data requirements in Annex II and III of Directive 91/414/EEC, as set out in Commission Working Document, SANCO/10439/2005 and issued an opinion on the subject on 17 May 2006 (EFSA 2006b). 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. General remarks and recommendations

The PPR Panel considers that since the publication of its previous opinion, one OECD guidance document in the field of analytical methods has become available. This merits consideration.

Guidance Document on Pesticide Residue Analytical Methods (Series on Pesticides, No. 39; Series on Testing and Assessment, No. 72) (OECD, 2007).

The OECD document contains more detailed information concerning validation parameters e.g. on number of samples for fortification experiments. Under confirmatory techniques e.g. the characteristics of the UV spectrum, it is mentioned that samples should be spiked at the limit for quantification.

The PPR Panel takes this opportunity to emphasise the scientific recommendations made in its previously adopted opinion (EFSA, 2006b).

The PPR Panel cannot at present give a definitive opinion on the analytical methods required for nanopesticides. Certainly, the data requirements in Annex II and III are insufficient for the analysis of this complex group of materials. There is a large variety of nanomaterials. They differ in size, shape, composition and origin and they can comprise organic or inorganic, crystalline or amorphous particles. They can be found as single particles, aggregates, powders or dispersed in a matrix, over colloids, suspensions and emulsion among others. The unique properties of nanomaterials is challenging, affecting sampling, extraction and final analysis. As such, an assessment would likely require substantial efforts and resources and would need a specific mandate.

3. Conclusion

The PPR Panel emphasises that the recommendations given in the previous opinion are still valid (EFSA, 2006b), and in addition recommends that the OECD Guidance Document on Pesticide Residue Analytical Methods (2007) is referenced in the Annexes

REFERENCES

EFSA, 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, 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 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, 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, 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, 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.
- OECD (2007) Guidance Document on Pesticide Residue Analytical Methods. Series on Testing and Assessment number 72. Series on Pesticides number 39. (ENV/JM/MONO(2007)17.
[http://www.olis.oecd.org/olis/2007doc.nsf/LinkTo/NT00002F06/\\$FILE/JT03230940.PDF](http://www.olis.oecd.org/olis/2007doc.nsf/LinkTo/NT00002F06/$FILE/JT03230940.PDF)

LIST OF ACRONYMS

DG SANCO	Directorate General for Health and Consumer Affairs
EEC	European Economic Community
EFSA	European Food Safety Authority
OECD	Organization for Economic Cooperation and Development
PPR	Plant Protection Products and their Residues