

DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY CONCERNING PESTICIDES RISK ASSESSMENT PEER REVIEW

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| EFSA – European Food Safety Authority | Decision of the Management Board/Executive Director concerning Pesticides Risk Assessment Peer Review | Decision No.: 14461368 |
| | Effective Date: 18/09/2015 | |

| Approvals | Signature | Name |
|--------------------|--------------------------|-----------------|
| Lead Author | <i>Signature on file</i> | Jose Tarazona |
| Reviewer | <i>Signature on file</i> | Juliane Kleiner |
| Executive Director | <i>Signature on file</i> | Bernhard Url |

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| Introduction | <p>In accordance with Article 12 of Regulation (EC) No 1107/2009, EFSA performs an independent scientific peer review of the assessment report produced for each pesticide active substance by designated rapporteur Member State.</p> <p>EFSA's pesticides peer reviews are to be performed in cooperation with all Member States to ensure consistency in the evaluations within the EU.</p> <p>Where appropriate, EFSA is required to organise a consultation of experts, including experts from the rapporteur Member State.</p> <p>As a result from the peer review of the active substance risk assessment, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge.</p> |
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| Description | This Decision lays down the rules to be followed by the Authority in the framework of the pesticides peer review consultation process. |
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| References | <ul style="list-style-type: none"> • Articles 15, 168, 298 of the Treaty on the Functioning of the European Union • Article 41 Charter of Fundamental Rights of the European Union • Regulation (EC) No. 178/2002 • Regulation (EC) No. 1107/2009 • Decision of the Executive Director concerning the selection of members of the scientific committee, the scientific panels and the selection of external experts to assist EFSA with its scientific work • Decision of the Management Board of the European Food Safety Authority of 15 March 2012 concerning the establishment and operations of the Scientific |
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| | <p>Committee, Scientific Panels and of their Working Groups</p> <ul style="list-style-type: none"> • EFSA’s Policy on Independence and Scientific Decision-Making Processes • Decision of the Executive Director on Declarations of Interests • Decision of the Executive Director laying down the rules on the reimbursement of expenses incurred by third parties from outside EFSA invited to attend meetings in an expert capacity (Experts’ Compensation Guide) |
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Abbreviations

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| ED | Executive Director |
| EFSA | European Food Safety Authority |

Decision History

| Date | Revision No. | Description of Change |
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| | 0 | Initial ED Decision |

DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY CONCERNING PESTICIDES RISK ASSESSMENT PEER REVIEW

THE EXECUTIVE DIRECTOR,

HAVING REGARD to the Treaty on the Functioning of the European Union¹, and in particular Articles 15, 114, 168, 298,

HAVING REGARD to Article 41 of the Charter of Fundamental Rights of the European Union²,

HAVING REGARD to the Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety³, and in particular to Article 28 thereof,

HAVING REGARD to Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market⁴, and in particular to Article 12(2) thereof,

HAVING REGARD to the Decision of the Executive Director concerning the selection of members of the scientific committee, the scientific panels and the selection of external experts to assist EFSA with its scientific work⁵,

HAVING REGARD to the Decision of the Management Board of the European Food Safety Authority of 15 March 2012 concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups⁶,

HAVING REGARD to EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interests⁸,

HAVING REGARD to the Decision of the Executive Director laying down the rules on the reimbursement of expenses incurred by third parties from outside EFSA invited to attend meetings in an expert capacity (Experts' Compensation Guide)⁹,

WHEREAS:

- 1) In accordance with Article 12 of Regulation (EC) No 1107/2009 EFSA performs an independent scientific peer review of the assessment reports produced for each pesticide active substance by designated rapporteur Member State.
- 2) As a result from the peer review performed by EFSA, the Authority adopts a conclusion in the light of current scientific and technical knowledge. The

¹ OJ C 326, 26.10.2012, p 1-390.

² OJ C 326, 26.10.2012, p. 391-407.

³ OJ L 31, 1.2.2002, p. 1-24.

⁴ OJ L 309, 24.11.2009, p. 1-50.

⁵ EFSA/SCER/DEC/14562383/2015.

⁶ MB 15 03 2012 – item 8 doc 7.

⁷ Policy on Independence and Scientific Decision-Making Processes, mb 15 12 11 –adopted.

⁸ Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests, EFSA/LRA/DEC/02/2014.

⁹ EFSA/FIN/POL/1/2013.

conclusion should include details concerning the evaluation procedure and the properties of the active substance.

- 3) EFSA's pesticides peer reviews should be performed in cooperation with all Member States in order to ensure consistency in the evaluation within the EU.
- 4) EFSA should circulate the assessment report received from the rapporteur Member State to the applicant and the other Member States and make it available to the public for the submission of written comments.
- 5) Where appropriate EFSA should organise a consultation of experts, including experts from the rapporteur Member State.
- 6) For the purpose of coordination with the Member States and in view of the implementation of the new regulatory framework introduced by Regulation (EC) No 1107/2009 a Pesticides Steering Network (PSN, formerly Pesticide Steering Committee, PSC) has been established by EFSA as a network responsible for the management and planning of pesticide risk assessment process.
- 7) Without prejudice to Article 28(9) of Regulation (EC) No 178/2002 and to the Management Board Rules of Procedures, and in particular to Articles 1, 22 and 23 thereof, external experts who possess particular scientific knowledge may be invited to contribute on a regular or *ad hoc* basis to the work of EFSA.
- 8) Due to the timelines set in Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, the limited control over the incoming workflow, the need for a focussed peer review and streamlined conclusions, and in view of the limited number of meetings in the peer review process, the organisation of a specific call for experts for the peer review consultation would be disproportionate to the objective pursued therewith.
- 9) It is necessary to establish the rules governing the peer review consultation process as prescribed in Article 12(2) of Regulation (EC) No 1107/2009.

HAS DECIDED AS FOLLOWS:

ARTICLE 1

Subject matter and scope

1. This decision lays down rules for the scientific peer review consultation process in accordance with Article 12(2) of Regulation (EC) No 1107/2009.
2. These rules shall also apply to the peer review consultation process in the framework of the procedure for the renewal and review of active substances approvals.

ARTICLE 2

Definition and role

In the course of the peer review performed by the European Food Safety Authority of the assessment report produced for each pesticide active substance by designated rapporteur Member State, the Authority where appropriate may organise a consultation of experts, including experts from the rapporteur Member State. The process includes a set of targeted expert consultations involving experts from the rapporteur Member State, other experts nominated by the Member States or selected by EFSA as external experts; as well as different

observers. This decision provides the framework for the meetings and teleconferences organised for these consultations as follows:

- the different participants and their roles are described in Article 3;
- the selection of Member States representatives and external experts under Article 4;
- the chairing, organisation and reporting under Articles 5, 6 and 7, respectively;
- the indemnities and compensations in Article 8;
- the independence and confidentiality provisions under in Articles 9 and 10, respectively.

ARTICLE 3

Composition of the peer review consultation meetings/groups

1. Peer review consultation meetings are composed of EFSA staff members, national experts nominated by Member States and external experts, as appropriate.
2. The relationship between the participants to the peer review meetings shall be governed, respectively, by the provisions of the Staff Regulations and Conditions of Employment of other servants of the European Union for EFSA staff, the Decision concerning the establishment and operation of Networks of scientific organisations for national experts nominated by Member States, and the ED Decision concerning the selection of members of the Scientific Panels, and the selection of external experts for the external experts.
3. The composition of the peer review consultation meetings/groups shall be established in accordance with the expertise required on the basis of the items to be discussed as established in the draft agenda.
4. Experts nominated by the Rapporteur Member State for the substances included in the draft agenda shall be invited by default. EFSA may invite more than one expert from the same Rapporteur Member State if deemed appropriate or necessary, for instance where three or more substances from the same Rapporteur Member State are to be discussed.
5. EFSA may invite additional Member States expert representatives, and external experts not nominated by the Member States, where their specific expertise justifies it.
6. Other experts or representatives of EU institutions may be invited as observers. Observers shall not in any way participate or intervene in the discussions, in the drafting or in other activities carried out in the meetings they attend.

ARTICLE 4

Selection and appointment of the experts participating in the consultation

1. Member States expert representatives are appointed by the Head of the Pesticides Unit following the proposal from the respective Team Leaders among those nominated by Member States, on the basis of the items to be discussed as established in the draft agenda circulated to Member States contact points prior to the organisation of the consultation meetings. The selection process should consider the comments submitted by the nominating Member State to the items in the agenda and the expertise of the expert as indicated in the nomination.

2. External experts not nominated by Member States are selected when needed on the basis of their expertise regarding the items in the agenda, and appointed by the Head of the Pesticides Unit in consultation with the Head of the Regulated Products Department in accordance with the selection procedure provided in the Decision of the Executive Director concerning the selection of members of the scientific committee, the scientific panels and the selection of external experts to assist EFSA with its scientific work. These experts should submit a declaration of commitment as set out in Annex II of EFSA's DoI rules for external experts.

ARTICLE 5

Chair and Secretariat of Meetings and Teleconferences

1. Meetings and Teleconferences shall be chaired by EFSA or by an external expert invited as chair on the basis of the items to be discussed.
2. EFSA shall provide the Secretariat.

ARTICLE 6

Minutes/Meeting report

1. EFSA shall prepare a meeting report of the meetings and teleconferences.
2. A non-confidential version of the meeting report shall be published as a background document to EFSA's conclusion in accordance with the confidentiality requirements laid down in Article 63 of Regulation (EC) No 1107/2009.

ARTICLE 7

Mission expenses of the participants and indemnities

1. Unless covered by reimbursements from the relevant Member State organisation, travel and subsistence expenses incurred by participants not employed by EFSA in connection with peer review consultation meetings shall be reimbursed by the Authority in accordance with the scales laid down in the Authority's expert compensation guide.

ARTICLE 8

Independence

1. Experts invited as chair and external experts not nominated by Member States and who are invited as members participating to meetings shall submit Annual Declaration of Interests and shall declare any interests which might be considered prejudicial to their independence in relation to the items on the agenda (Specific Declaration of Interests and Oral Declaration of Interests) in accordance with Article 8 of the Decision of the Executive Director on Declarations of Interests.
2. Experts nominated by Member States are invited to complete and submit an Annual Declaration of Interests for transparency reasons. In accordance with Article 10 of the Decision of the Executive Director on Declarations of Interests, no screening of the submitted ADOIs shall be performed by EFSA.
3. Observers attending meetings regulated in this decision are subject to Article 12 of the Decision of the Executive Director on Declarations of Interests.

ARTICLE 9

Confidentiality

Participants to the peer review consultation meetings shall:

- not divulge to third parties information identified by the Authority as “restricted” or “confidential”;
- without prejudice to obligations for Member States representatives, sign a written declaration that they will comply with the rules of confidentiality set out in this Article;
- be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.

ARTICLE 10

Entry into force

The present decision shall enter into force on the date of its signature.

Done at Parma,

Signed by,

Bernhard Url
Executive Director