

**Terms of Reference of the Working Group on Post  
Approval Issues from the Standing Committee on  
Animals, Plants, Food and Feed: section Pesticide  
Legislation**

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## Revision history

When	What
26 January 2017	Adoption of the ToR for the PAI group.
22 October 2019	Amendment of the ToR to include the figure of the vice-chairman/vice-chairwoman
23 October 2020	Amendment of the ToR in order to reflect the minutes to be provided to any third party

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The following are the terms of reference and working procedures for the Working Group on Post Approval Issues (hereafter 'PAI Group') from the Standing Committee on Animals, Plants, Food and Feed: section Pesticide Legislation (hereafter 'SCoPAFF').

## 1. BACKGROUND

In 2004, Member States set up a forum for discussion and harmonisation on the implementation of the provisions of Directive 91/414/EEC with regard to issues related to products or active substances after the latter were included in Annex I of the Directive ("re-registration"). Following the adoption of Regulation (EC) 1107/2009, it was decided to maintain this forum as the Post-Approval Issue Group, as it was considered an important and efficient way to better harmonise zonal and national implementation of EU procedures for plant protection products.

## 2. SCOPE OF WORK FOR THE PAI GROUP

The PAI group is a working group from the Standing Committee for Animals, Plants, Food and Feed. It is established to deal with **general non-zonal issues relating to the procedures for the authorisation of plant protection products** under Reg. (EC) No 1107/2009 for the approval and renewal of the approval of active substances.

- (1) In particular, it will:
  - (a) Provide a forum for discussion of **any procedural issues, not purely risk assessment based**, submitted by one or more of its members, by the SCoPAFF, by EFSA or by the Commission arising in relation to the authorisation and renewal of authorisation procedures unless they are regarded as strictly applicable to one zone only. Where a topic for discussion covers also risk assessment, the PAI group will liaise with the interzonal steering Committee (iZSC), which is the competent forum,
  - (b) Provide a forum for discussion of any issues submitted by one or more of its members, by the SCoPAFF, by EFSA or by the Commission, **not related to risk assessment or the peer-review procedure**, arising in relation to the approval and renewal of approval procedures unless they are regarded as strictly applicable to one zone only. Where a topic for discussion covers also risk assessment and in particular the peer-review processes, the PAI group will refer them to the Pesticides Steering Network (PSN),
  - (c) Develop harmonised positions in relation to issues raised and common solutions to problems identified; contradicting decisions in different Member States for comparable cases should be avoided. Where these harmonised agreements address a non-product-specific point, they should be reflected in a draft procedural guidance document (GD),
  - (d) Keep up-to-date the procedural GDs addressing the topics discussed under points a, b or c above.
  - (e) Ensure that proposed changes to the GDs always involve all MS via a commenting round, are properly documented and communicated via SCoPAFF, if suitable by use of a commenting table for clarity and transparency,
  - (f) Provide the SCoPAFF with recommendations for endorsement (with respect to GDs) and where necessary with information for decision making,
  - (g) Provide SCoPAFF with recommendations on how to draft and how to implement approval or renewal of approval regulations, even if the issues

- addressed are not strictly related to the authorisation of plant protection products, such as for instance the assessment of confirmatory data,
- (h) Address any request for new tasks sent by the SCoPAFF,
  - (i) Ensure transparency and give a formal feedback of its work to all MS via CIRCABC, and also communicate it to stakeholders via the public site of CIRCABC.
- (2) It will not:
- (a) Address issues related to risk assessment procedures on product authorisations. The iZSC is the competent forum.
  - (b) Address issues related to risk assessment or peer-review procedures on active substance approvals, including the renewal of these approvals. The PSN is the competent forum.
  - (c) Adopt any guideline and interpretation on topics falling in the scope described above. The SCoPAFF is the relevant forum.

Where a topic is also relevant for other fora such as the IZSC or the PSN, the PAI group should liaise with these groups and work in close cooperation with them to produce documents agreed by the competent groups to be forwarded to the SCoPAFF for endorsement.

### **3. MEMBERSHIP**

All Member States have the possibility to send experts to the working group. Members of PAI are experts from the designated competent authorities according to Art. 75(1) of Regulation (EU) No. 1107/2009. Experts from EFTA States are also entitled to take part to the PAI group according to the Council Decision 2014/675/EU<sup>1</sup>. Member States should normally nominate a permanent (regulatory expert) representative in the PAI group or appoint a representative on an *ad hoc* basis, depending on the meeting agenda of the group. The European Commission is a member of the PAI group. So is EFSA.

Member States should ensure that their experts provide a high level of expertise.

For consideration of specific issues, attendance may also be invited on an *ad-hoc* basis from stakeholders or other European agencies than EFSA.

### **4. WORKING ARRANGEMENTS**

#### **4.1. Chair, vice-chair and secretariat**

Members of the PAI group should appoint three members of the group/Member States delegates to act as a chair, vice-chair and a secretary by simple majority amongst them. The chairman/chairwoman, vice-chairman/vice-chairwoman and the secretary are appointed for 3 years. The chairman/chairwoman, vice-chairman/vice-chairwoman and the secretary should preferably not be represented the same Member State. These tasks should regularly rotate between the members of the group.

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<sup>1</sup> Council Decision 2014/675/EU of 25 September 2014 on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning an amendment to Annex II of the EEA Agreement (OJ L 283, 27.9.2014, p. 47)

The chairman/chairwoman will:

- (a) in close coordination with the vice-chairman/vice-chairwoman and secretary plan the work of the PAI group,
- (b) chair the meetings in a transparent and open way allowing for in-depth, fruitful discussions and consensual decisions. This may include written consultation of the group between two meetings.

The vice-chairman/vice-chairwoman will:

- (a) in close coordination with the chairman/chairwoman and secretary plan the work of the PAI group,
- (b) chair the meetings in case of absence of the chairman/chairwoman in a transparent and open way allowing for in-depth, fruitful discussions and consensual decisions. This may include written consultation of the group between two meetings.

The secretary will:

- (a) prepare the agenda in close coordination with the chairman/ chairwoman and with the vice- chairman/ chairwoman,
- (b) provide the group with the agenda and the working documents early enough to allow a well-informed discussion,
- (c) draft the minutes, including their public version<sup>2</sup>, in close cooperation with the chairman/chairwoman and vice-chairman/vice-chairwoman, taking into account feedback from the experts of the PAI group,
- (d) follow up the action points identified during the meetings of the PAI group, including collating written comments between two meetings,
- (e) upload on CIRCABC all documents related to the work of the PAI group, including the public version of the minutes (on the public part of CIRCABC), once agreed by the group.

## **4.2. Meetings**

Meetings will be held on a quarterly basis, usually in March, June, September and December, generally as a one-and-a-half-day face-to-face meeting in Brussels, adjacent to the half-day meeting of the iZSC. If necessary and upon IT availability, remote attendance may be possible. An invitation will be issued by the Commission.

## **4.3. Operations**

The PAI group shall work under the supervision of the SCoPAFF and liaise regularly with other relevant groups like the iZSC. The SCoPAFF shall be kept regularly informed of on-going work in the PAI group, as well as new areas of work where the group starts working. The SCoPAFF mandates the PAI group to address specific issues falling within the remit of the group.

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<sup>2</sup> The public version of the minutes contains all elements with the exception of the name of individual MS and those parts containing opinions for internal use, but reflecting the overall deliberation and its outcome.

Representatives from Member States, directly or via the ZSC and iZSC, are strongly encouraged to raise their questions to the PAI group in order to identify a common solution or interpretation at European level.

The PAI group should adopt their recommendations to the SCoPAFF by consensus. However where no consensus can be reached, the group may decide to forward a recommendation supported by the majority of the group. In this case, the state of the discussion, including the different options, should be clearly reflected in the minutes and the related documents made available to the SCoPAFF.

Minutes on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete.