



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the Food Chain
Pesticides and Biocides

**WORKING GROUP of the ADVISORY GROUP ON THE FOOD CHAIN,
ANIMAL AND PLANT HEALTH on a Technical guidance document on the
interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No
1107/2009**

25 June 2015, 14.30h – 17.30h

Centre Albert Borschette, rue Froissart 36, Brussels

SUMMARY REPORT

Participants:

European Commission:
DG Health and Food Safety (DG SANTE), unit E3

Present Members of the Advisory Group:
COPA-COGECA, ECCA, ECPA, FoEE, FOODDRINKEUROPE, PAN EUROPE

Non-members of the Advisory Group:
EPPA, Greenpeace, HEAL,
UK Pesticide Campaign (apologies)

The objective of the meeting was to consult stakeholders on the draft *Technical guidance document on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009*, in particular to listen to their opinions. Organisations which are part of the Advisory Group were invited, and in addition the non-member organisations mentioned in the list of participants above. During the meeting stakeholders were invited to send written comments by 24 of July, 2015. The comments may be published.

Following the welcome and introduction by Michael Flüh, Head of Unit SANTE E.3, the draft guidance document (GD) was presented.

The Commission informed that the draft GD was developed by an expert group appointed by Member States (MS). This expert group met 5 times from September 2013 onwards. As preparation for these meetings, MS sent input regarding how to address

negligible exposure and this input served as starting point for the WG. The Commission reminded that active substances approved under the provisions of negligible exposure would be candidates of substitution.

Beside the stakeholder consultation initiated during the current meeting, the Standing Committee was updated regularly and consulted on the present draft GD at its last meeting.

The GD is intended to be adopted as a Commission Notice. Internal procedures are initiated.

The following **clarifications** were made based on questions posed:

- HEAL was wondering about the provisions in annex II (points 3.6.3 to 3.6.5), in particular if the provision referring to residues refers to the conditions excluding contacts with humans, or to these and closed systems. COM explained it will be cross checked.
- Greenpeace asked for clarification on the formal process. COM explained that it has started and that an inter-service-consultation will be part of the process before adoption of the Commission Notice.
- PAN mentioned that the definition of "closed system" means no escape into the ecosystem. COM mentioned that technically even high-tech greenhouses are not 100 % closed (referring to EFSA publications), and that therefore a technical definition of negligible exposure is needed.
- FoEE mentioned the need for guidance to implement Article 4.7 in particular regarding how to interpret "serious danger to plant health", which they see as a priority. COM reminded that this Article is out of the scope of the presented draft GD.

Stakeholders were invited to **comment via a tour-de-table**. The comments are briefly summarised below. In addition, stakeholders were invited to send it detailed written comments by 24 of July 2015.

- Copa Cogeca agrees with the need for a guidance to implement negligible exposure and asks that all possible measures should be used to reduce exposure. They reminded PPPs are needed to control pest and diseases and are part of economic activities of small enterprises (farmers); since PPPs have biological activity some impacts are expected. Negligible exposure cannot be zero by definition, but other measures to reduce risks should be taken into account. Copa Cogeca reminded the provisions under the Sustainable Use Directive 2009/128/EC (SUD), by which training and protection of operators, workers and environment are increased via several provisions. They also reminded that mitigation measures are already in place to reduce exposure of operators and workers.
- PAN wonders that the concept of speeding up the approval process for active substances via the hazard ("cut-off") approach will be lost by re-introducing negligible exposure assessment. PAN also wonders if the draft GD would trigger more animal testing requirements. PAN suggests to better develop the section on environmental exposure, in particular because the sensitivity of non-target organisms may be higher.
- Greenpeace mentioned the discrepancy between the sections of the GD dealing with human health and environment, respectively. The environmental section needs to be further developed, or else not published. Greenpeace wonders if the

PPPs would be limited to professional users, and COM clarified it is recommended in the draft.

- HEAL recognized that provisions in sections 3.6.3 to 3.6.5 are not categorical and that there is a need to provide a common sense approach regarding "negligible exposure". However, exceptions should be very well controlled and not become the rule. HEAL suggested some changes regarding the drafting of the document, for example a flow chart explaining in detail the steps / process which may be helpful. HEAL was wondering about the issue of thresholds in the context of section 3.6.5. HEAL mentioned that non-dietary routes could be covered better (ground water, long transport).
- FoEE mentioned this is an important guidance which touches key requirements and conditions. FoEE mentioned that there are still residues of PPPs in humans and in food, that accidents with PPPs may happen, and that not all farmers have access to neither high technology nor adequate training and that this needs to be considered. FoEE was asking to consider residents and Art 4.7 too. COM agreed that the issues raised are very important, but reminded that regarding dietary exposure (residues) the legislation is very clear and protective (technical zero), that PPPs may be only authorised for professional uses, that exposure of residents is already considered both in the legislation and the draft guidance, and that MS have to ensure all farmers are trained by end of 2015 (SUD).
- ECCA appreciates the clear distinction between 3.6.2 (complete ban) and negligible exposure under 3.6.3/4/5 (negligible exposure is accepted). Regarding defining "danger to plant health", they refer to the working document on emergency situations (SANCO/10087/2013¹). ECCA wonders if professional use is considered equivalent to negligible exposure, which COM clarified this is not the case.
- ECPA asks for focusing the discussion during this meeting on this guidance document and not on other more general issues, and will send further comments.
- EPPA believes it is a timely document with a balanced approach which fits the Better Regulation concept. EPPA mentioned Member States are looking for a clear document on how to proceed and agrees that a complete zero exposure is not possible and shares the approach taken in the draft guidance.
- Food Drink Europe appreciated the opportunity to comment. So far it has no particular comments for the moment but may send in written comments if necessary.

The Chairman thanked for the comments and invited again to send written comments by July 24.

¹ WORKING DOCUMENT ON EMERGENCY SITUATIONS ACCORDING TO ARTICLE 53 OF REGULATION (EC) No 1107/2009. SANCO/10087/2013 rev 0. 1st February 2013.