Parma, 12 December 2011

Mr Hans Muilerman
Pesticide Action Network
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1000 Brussels
Belgium

Mr Vito A. Buonsante
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E-mails: hans@pan-europe.info
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Re: Confirmatory application of 23 December 2010 regarding the draft Guidance on the Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009

Dear Messrs. Muilerman and Buonsante,

By decision of 10 February 2011\(^1\) I replied to your confirmatory application of 23 December 2010 in application of Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to documents\(^2\). Whereas the European Food Safety Authority (“EFSA”) decided before to grant partial access to the requested documents, with this decision I upheld the refusal to provide you access to the draft versions of the Guidance on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (hereinafter “the Guidance”). I also confirmed that documents listed in points 7) to 9) of your initial request did not exist.

WITHDRAWAL OF THE CONTESTED DECISION OF 10 FEBRUARY 2011

Considering the commitment of EFSA to its core values of independence, scientific excellence, transparency and openness and in view of the recent clarifications provided by the Court of Justice of the European Union and following an internal re-evaluation of your request, I decided to reconsider the position contained in the confirmatory decision of 10 February 2011.

Against this background, I re-evaluated your request and decided to withdraw the previous decision and to adopt the present new decision in reply to your confirmatory application of 23 December 2010.

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\(^1\) Ref: DD/LV/v1 (2011) – out-5528282.
NEW CONFIRMATORY REPLY

The present decision replaces and annuls the decision adopted on 10 February 2011.

Please find enclosed a CD ROM with the requested documents listed as follows:

1. n°13. The document on the structure of the Guidance (meeting n° 1),
2. n°14. The draft Guidance (meeting n° 2),

Please note that concerning your request in item n°14 of your initial application, the “outlining tasks and deadlines” are listed in the action notes of the minutes of the Working Group meeting n°2 already provided with our letter dated 1st December and the documents already disclosed.

3. n°15. The draft Guidance sent to PPR and PSC (meeting n° 3)
4. n°19. The draft Guidance (meeting n° 5).
5. n° 17. The full feedback documents (e-mails, memo’s, letters, or other document including names of those sending feedback) received from PPR and PSC members to EFSA/AMU (meeting n° 4).

Please be aware that the names of the experts cannot be disclosed for protection of personal data in application of Article 4(1)(b) of Regulation (EC) No 1049/2001 and taking into account the legislation of the Union concerning the protection of personal data, and in particular Regulation (EC) No 45/2001. The disclosure of the names of individuals is to be considered as a transfer of personal data in the sense of Article 8 of Regulation (EC) No 45/2001. With regard to your confirmatory application of 23 December 2010, EFSA maintains that the conditions for the personal data transfer laid down in the aforementioned provision are not fulfilled.

As regards the request of access to documents listed in points n°7 to n°9 of your initial request concerning internal meetings, I hereby confirm that items n°7 to n°9 do not exist. Indeed internally at EFSA there were no formal meetings organised between AMU and PRAPeR EFSA staff. The exchanges were made by telephone calls and direct exchanges during informal meetings between colleagues aimed at exchanging information on the dates and objective of the discussions of the Working Group meetings. No minutes were taken and therefore the requested documents do not exist.

Finally, I should draw your attention on the possibilities for appeal provided for in Article 263 of the Treaty on the Functioning of the European Union as well as the possibility for lodging a complaint with the European Ombudsman.

Yours sincerely,

Catherine Geslain-Lanéelle

Enclosures: Documents listed in points 1 to 5.
Cc.: Hubert Deluyker, Dirk Detken.

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