
HEAD OF THE LEGAL AND REGULATORY AFFAIRS UNIT

Parma, 15 February 2012
Ref. CR/LV/DD/rl (2012) - **out-6259987**

Mr Hans Muilerman
Pesticide Action Network
PAN Europe
Rue de la Pépinière 1
B-1000 Brussels
Belgium

E-mail: hans@pan-europe.info

**Subject: Your confirmatory application for access to documents of 28 December 2011
Documents related to the draft Scientific Opinion on exploring options for providing
preliminary advice about possible human health risks based on the concept of
Threshold of Toxicological Concern (TTC)**

Dear Mr Muilerman,

Further to our letter dated 24 January 2012, I am writing to you regarding your confirmatory application dated 28 December 2011 in compliance with Regulation (EC) N° 1049/2001 for access to documents of EFSA on the subject matter of Threshold of Toxicological Concern (TTC).

Your confirmatory application of 28 December 2011 additionally refers to two further documents, namely:

- a. *'The agenda/minutes/presence list and the report of the joint meeting of 8 June 2011 with Commission Scientific Committees as mentioned in your letter of April 14, 2011'*: as mentioned in our previous letter dated 24 January 2012, I am aware that you have received this document directly from the European Commission ;
- b. *'The report presented by Pavan/Fioravanzo in the 14th meeting'*: I should draw your attention to the fact that this report is publicly available on the EFSA website since June 2011 when the meeting took place and during which it was discussed¹.

Furthermore, I should inform you that considering that the decision-making process is still on-going on the subject matter of Threshold of Toxicological Concern (TTC), EFSA is at this moment not in a position to release some of the requested documents in addition of those already released on the occasion of our initial reply of 08 December 2011:

1. Notes summarizing the comments made during the 17 meetings of the EFSA Working Group on TTC and prepared as follow-up of the meetings (*corresponding to point 11 of PAN-Europe's initial access request*) ;
2. The drafts of the EFSA opinion on TTC (*corresponding to point 14 of PAN-Europe's initial access request*).

¹ Please consult EFSA website: <http://www.efsa.europa.eu/en/supporting/pub/159e.htm>.

Having carefully carried out a concrete examination of each individual document falling in the two groups indicated hereinabove, EFSA maintains that the documents are intended for internal use and relate to a matter where the decision has not yet been taken in application of Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001.

In order to live up to its mission as a European risk assessor EFSA pays due attention to the need to identify at an early stage potential sources of divergences between its scientific opinions and scientific opinions by other bodies carrying out similar tasks. In that respect EFSA has been in contact with the non-food Committees of the European Commission, which are finalising an opinion on the same subject, in order to reach a common understanding on the possible use of the TTC approach in the food and feed area as well as in non-food consumer products, in particularly cosmetics. The EFSA draft opinion on TTC was presented and discussed at the last Scientific Committee plenary (7 - 8 February 2012), and the Scientific Committee identified that despite the ongoing communication and liaison with the non-food Committees diverging views remain. Therefore EFSA decided to postpone the adoption in order to follow the process described in Article 30 of its Founding Regulation (EC) No 178/2002.

A disclosure of the requested documents at this stage of the process will effectively undermine the EFSA decision-making process as in absence of the final published opinion of EFSA the disclosure carries the concrete risk of leading to misunderstanding in the public of the scientific and very technical discussion that has not arrived to a conclusive end and exposes EFSA and its experts to external pressures that will adversely affect the quality of the decision-making process and would undermine the role attributed to EFSA in particular to carry out its tasks in independence and objectivity. As long as the relevant decision-making process is still on-going, the requested notes and the draft opinions on TTC , in all their parts, fall in their full extent under the exception provided in Article 4(3) first subparagraph of Regulation (EC) 1049/2001. Therefore it needs to be concluded that also partial access cannot be granted at this stage.

EFSA has specifically undertaken the balance of the interests at stake in application of Regulation (EC) No 1049/2001 and verified that no overriding public interest on disclosure applies to this request. In particular and as concerns your argument that TTC qualifies as environmental information in the sense of Regulation (EC) No 1367/2006 please consider that TTC is a specific probabilistic screening method already applied in other scientific areas.

In this context, it should be highlighted that in order to ensure full transparency and openness in the delivery of EFSA's work a draft opinion on TTC has been subject to open consultation, from the 12 July 2011 until the 23 September 2011. Furthermore a dedicated discussion on the draft opinion was organized at the Stakeholders Platform meeting on the 17 November 2011. As it emerges from the above, EFSA put in place all means at its disposal to grant full availability of the draft opinion to the public.

After the formal adoption of the *Scientific Opinion on exploring options for providing preliminary advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)* and its publication on the EFSA website, EFSA shall further analyse the requested documents that are considered to be protected at this stage.

I should inform you on the fact that you may challenge the present decision before the Court of Justice of the European Union by virtue of Article 263 of the Treaty on the Functioning of the European Union or submit a complaint to the European Ombudsman.

Yours sincerely,



Dirk Detken