

EXECUTIVE DIRECTOR

Parma, 03/03/2011
Ref. CGL/sc (2011) - out-**5611423**

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

Re: EFSA rejects criticism from the Pesticide Action Network Europe since they are baseless and a misrepresentation of the fact.

Dear Mr Muilerman

The European Food Safety Authority (EFSA) rejects criticism from the Pesticide Action Network (PAN) of its newly-published guidance for applicants submitting dossiers on active substances used in pesticides. EFSA considers these allegations to be baseless and a misrepresentation of the facts.

EFSA published a guidance document for applicants submitting dossiers on active substances in order to support applicants in meeting a new requirement of the EU's new legislation on pesticides concerning the submission of scientific peer-reviewed open literature published within the 10 years prior to the application being made. Applications concerning active substances used in pesticides have thus far consisted of studies conducted by and paid for by industry. Traditionally, these are expected to meet Good Laboratory Practice (GLP) standards. The new legislation requires applicants in addition to conduct a review of peer-reviewed open literature. This does not replace the requirement for applicants to provide a dossier which includes GLP safety studies. The legislation tasked the European Food Safety Authority to provide the guidance for this part of the application. This guidance was published on 28th February 2011 following extensive public consultation (<http://www.efsa.europa.eu/en/efsajournal/doc/2092.pdf>.)

After publication of the guidance on EFSA's website, the Pesticide Action Network issued a statement and press release alleging that EFSA has taken the "side of big industry". EFSA rejects this criticism of its newly-published guidance:

1. PAN alleges that GLP studies are being favoured in the selection of peer-reviewed literature. In reality, the guidance states very clearly that all peer-reviewed scientific literature should be considered by applicants, whether or not

these studies are carried out according to GLP. It can be expected that most of these peer-reviewed studies will not have followed GLP standards.

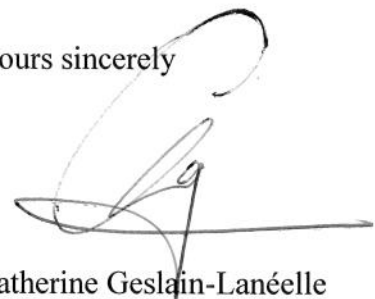
2. PAN alleges that EFSA's guidance on how applicants should determine the reliability of scientific publications is skewed towards industry interests. In fact, the very purpose of EFSA's guidance is to ensure that inappropriate information cannot be used as relevant scientific evidence and to avoid that relevant scientific information is excluded. EFSA's guidance sets out the principles that must be used to include peer-reviewed literature in the documentation submitted with applications.

Furthermore, EFSA's guidance makes clear to applicants that they need to document extensively and transparently the process they used in the search and selection of the studies in peer-reviewed scientific literature and the reporting of the results for every individual study. This will allow experts in the Member States and at EFSA to assess the rigour of the selection process to prevent any possible bias, including whether any publications were unjustifiably excluded. The guidance even foresees that applicants must be prepared to submit excluded studies on request.

3. PAN alleges that EFSA "continues to place industry/GLP studies at the highest level of reliability". On the contrary, EFSA's guidance emphasises that compliance with GLP standards should not be considered as a guarantee of reliability. It states that "study reliability must be judged solely on the basis of the accuracy and reproducibility of the facts reported. The main difference between GLP and non-GLP peer-reviewed studies is in the background information reported and the potential access to raw data that may be lacking in the latter type of studies".

Finally, EFSA would like to point out that PAN had made similar comments during the public consultation on the EFSA guidance. A technical report summarising the consultation outcomes can be found at the following link: <http://www.efsa.europa.eu/en/supporting/pub/125e.htm>

Yours sincerely

A handwritten signature in black ink, appearing to read 'Catherine Geslain-Lanéelle', written over a horizontal line.

Catherine Geslain-Lanéelle