European Food Safety Authority

HEAD OF THE LEGAL AND POLICY AFFAIRS

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Dear Mr Then,

Thank you for your continuous interest in EFSA's activities.

Testbiotech has made a number of inaccuracies in its 1st December 2010 statement in its references to the European Food Safety Authority (EFSA) both with respect to the scientific approach followed by EFSA in assessing the safety of GM plants – in particular requirements for performance of animal feeding trials and the processes in place to ensure the independence of its scientific advice.

Animal feeding trials are used by EFSA for the toxicological and nutritional evaluation of GM plants. The toxicological impact of any changes resulting from the genetic modification is assessed on a case-by-case basis depending on the GM plant/trait combination. Such changes are first assessed through a comparative analysis of molecular structures, composition and phenotypes. In addition, any newly-inserted gene sequence is thoroughly investigated, for example through bio-informatic data analysis, in order to detect possible similarities with known toxic and allergenic substances.

Furthermore depending on the available data, toxicological experiments using laboratory animal species may be required in order to conclude on the safety of newly-expressed proteins and of plant constituents of which the levels may have been altered.

Moreover in case the results of the molecular, phenotypic and compositional analysis would indicate the potential occurrence of unintended effects which could not be characterized fully, the whole GM plant derived food/feed should be tested using animal feeding trials. Thus the assertion that EFSA does not demand animal feeding trials with GM plant derived food/feed is incorrect.

The GMO Panel adopted a report on the role of animal feeding trials in the safety and nutritional assessment of GM plants and derived food and feed which was published in the peer-review journal Food and Chemical Toxicology in 2008 following three years' work which involved technical meetings with experts from Member States and a public consultation. Here is the link to this report on EFSA's website: http://www.efsa.europa.eu/en/scdocs/scdoc/1057.htm.

The safety assessment of GM plants and derived food and feed follows the approach widely accepted by international organisations such as the FAO/WHO, CODEX Alimentarius and the OECD. It is based on comparison with conventional counterparts to identify intended and unintended differences. EFSA's report argues that this remains an appropriate basis for deciding when animal feeding studies are needed for the safety and nutritional assessment of GM food and feed. This document serves as guidance to applicants in this respect. The Panel routinely reviews data from animal trials when it assesses GM applications.

To this regard, you may be interested to know EFSA will organise next year a consultative workshop on its draft scientific opinion on the choice of comparators for GM risk assessment. The GMO panel recently launched this opinion for public consultation, after which the working group will evaluate all comment and proposals. The working group will also meet concerned stakeholders during the consultative workshop. In the draft opinion the Panel has strengthened its guidance in this area, recognising the importance of selecting an appropriate comparator, the cornerstone of GM safety assessment. We hope that you will accept the invitation to join us on this occasion and participate in this important scientific discussion and opportunity to further your own understanding of how EFSA carries out its risk assessment work in this area.

We would like to draw your attention to the ongoing work of EFSA's Scientific Committee regarding animal feeding trials with whole GM food/feed and other novel foods with the scope of harmonizing experimental designs and test protocols, and (statistical) approaches for analysis of the results obtained. This will help foster a consistent approach across all areas of EFSA's work, and contribute to harmonization at the international level.

This work will be submitted to a public consultation before it is adopted in 2011.

Finally, we would draw your attention the rigorous procedures and processes in place at EFSA to ensure both the high quality and independence of its scientific advice. EFSA has very stringent policies in place to allow it to anticipate, prevent and proactively manage any potential conflicts of interest in relation to its scientific work. However, the Authority is never complacent in this area and is currently working on an overall policy on independence-building on the key pillars which support our independence today including our existing policy on declarations of interest, our current rules on the selection of experts and the legally prescribed collective decision making of panels. For further information on EFSA independence you can view this link:
www.efsa.europa.eu/en/topics/topic/independence.htm

We trust that these clarifications will help further your understanding of EFSA and its scientific work.

Yours sincerely,

Dirk Detken