European Commission

Vytenis ANDRIUKAITIS
Member of the European Commission

Berl 08/369
Rue de la Loi, 200
B-1049 Brussels - Belgium
Tel. 00.32.2.295.41.59
e-mail: vytenis.andriukaitis@ec.europa.eu

Mr Christoph Then, Executive Director, Testbiotech
e-mail: christoph.then@testbiotech.org

Ms Helen Wallace, Director. GeneWatch UK
e-mail: helen.wallace@genewatch.org

Brussels, 08. 01. 2016
ARES(2016)

Your letter on the authorisation of genetically engineered herbicide resistant soybeans for import – Ares(2015)5118894

Dear Mr Then, dear Ms Wallace,

Thank you for your letter dated 16 November 2015, which outlines your concerns about the authorisation of three genetically engineered soybeans for import.

The European Food Safety Authority (EFSA) has issued favourable opinions for these GMOs, which are the basis for the Commission's risk management decisions. The Standing Committee on Plants, Animals, Food and Feed on 18 November 2015 voted on the draft authorising decisions presented by the Commission, with 'no opinion' as a result and Member States will vote again on these drafts in the Appeal Committee of 11 January 2016.

Regarding the pesticide risk assessment, as highlighted in your letter, EFSA conducted a peer review of the pesticide risk assessment of the active substance glyphosate, in close cooperation with experts from the 28 Member States. This assessment, which was carried out in the context of the procedure for a possible renewal of the approval of glyphosate and according to the provisions of the EU legislation on plant protection products (thereafter PPP ; Regulation (EC) No 1107/2009), focused on five representative uses, all of which are on conventional crops. Given the absence of

cultivation of glyphosate-tolerant crops in the EU, uses on conventional crops can indeed be considered representative for the EU. Consequently, data on glyphosate tolerant GM crops were not included in the dossier submitted by the applicant, and EFSA's assessment is limited to the five representative uses.

This however does not mean that uses on GM crops will not be evaluated to the same level of scrutiny. If a glyphosate-containing PPP were to be used on a glyphosate tolerant GM crop cultivated in a Member State of the EU, an applicant would first have to submit relevant data to that Member State to obtain an authorisation for that product. A risk assessment would then have to be carried out by that Member State based on the uniform principles for evaluation and authorisation of PPPs laid down in Commission Regulation (EU) No 546/2011, to which Member States must adhere when carrying out such assessments, and taking into account the List of Endpoints for the active substance provided in the Appendix A to the EFSA Conclusion.

If a glyphosate-containing PPP is used on a tolerant GM crop cultivated in a third country, and the resulting residue level is not be covered by the maximum residue levels (MRLs) already established by the Commission, an applicant would first have to submit relevant data on good agricultural practices. This submission would then enable Member States and EFSA to assess the resulting residue levels and whether such residues are safe for consumers. The requested MRL could then be set by the Commission and only then would the import of such crop within the EU be possible.

Food to be placed on the market in the EU has to comply with all MRLs set under Regulation (EC) No 396/2005, not only for glyphosate, but also for isoxaflutole, dicamba and any other substance in the scope of that Regulation. Residue levels up to the MRL are safe for consumers.

It is true that the legislation requires cumulative and synergistic effects of pesticide residues to be considered in the MRL setting, but only when the methods for assessment will be available. This is not yet the case and the legislation recognises that further work in this respect is needed. The Commission is working with the Member States, EFSA and other scientists to develop such a methodology for cumulative risk assessment. This is a very complex work which requires more time. I would like to emphasize that this issue is not specific to GM crops but pertains to all uses of PPPs, as it may also be necessary in conventional agriculture to treat a crop with PPPs containing different active substances, either as a result of pest pressure from different organisms or to manage possible resistance.

As regards the co-formulant POE-tallowamine, the Commission has asked EFSA to provide an assessment of that substance. The assessment was published on 12 November 2015. My services are now carefully examining the EFSA Statement.

Regarding your request for internal review of three nutritionally modified GM soybeans, I would like to refer you to the Commission's response dated 16 November 2015 (Ref. Ares(2015)5145741).

Yours sincerely,