



EU Commissioner Mr Vytenis Andriukaitis, European Commission Directorate General for Health and Food Safety B - 1049 Brussels Belgium

cc Mr Jean-Claude Juncker President of the Commission and Mr Frans Timmermans First Vice-President of the Commission Rue de la Loi 200/Wetstraat 200 B- 1049 Brussels Belgium

Open letter

19 January 2016

Dear Mr Andriukaitis,

<u>Market authorisation for genetically engineered soybeans showing combined toxicity; your letter of</u> *January 2016* 

We appreciate your attempt in the letter to resolve the open question regarding the safety of herbicide resistant plants that can be sprayed with a combination of complementary herbicides.

However, may we say that our conclusions regarding the safety of the plants under discussion MON87708 x MON89788 (resistance to glyphosate and dicamba), FG72 (resistance to glyphosate and isoxaflutole) and MON87705 x MON89788 (double resistance to glyphosate and change in oil content) are very different for the following reasons:

- The opinion of EFSA on glyphosate (EFSA 2015) and tallowamine (EFSA 2015b) cannot be
  interpreted to mean that the safety of residues from spraying with glyphosate in herbicide
  resistant plants is assured just because the maximum residues level (MRL) is not exceeded.
  On the contrary, it has to be concluded that much more data would be needed on residues
  from the herbicide formulations actually being sprayed on the plants before any conclusion
  can be drawn.
- The Reuter dossier (2015) which we recently provided to the EU Commission (but which was not mentioned in your letter) shows that the safety of combined herbicides cannot be concluded just because MRLs of the single substances are not exceeded.

Thus, your assessment, which is largely based on the assessment of MRLs, leads to the wrong conclusions. Your statement that "it is true that the legislation requires cumulative and synergistic

effects of pesticide residues to be considered" only serves to heighten our concerns since you then go on to say that as yet there are no methods available for this purpose.

The Reuter dossier provides new evidence that residues stemming from spraying the plants with glyphosate together with dicamba or isoxaflutole will lead to adverse effects on health, such as genotoxicity, liver toxicity and tumours. Consumers and farm animals could be exposed to a combination of these substances that may be found as residues in the harvest of these crops. Moreover, the dossier as well as your letter provide evidence that the combined toxicity of the herbicides was never assessed by EU authorities.

If the EU Commission and EFSA are unable to assess health effects of these mixtures because there are no methods available, then market authorisation should not be granted. EU regulations require the highest standards for the protection of consumers and the environment. In the case of the genetically engineered plants under discussion, the precautionary principle has to be applied and the application has to be rejected.

Therefore, we once again kindly ask you to ensure that the process for market authorisation for these herbicide resistant genetically soybeans is stopped.

With kind regards

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Annex: Dossier on combined risks of the complementary herbicides