Testbiotech, Frohschammerstr. 14, 80807 Munich, Germany

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

Open letter

4 March 2016

Dear Mr Andriukaitis

Market authorisation for genetically engineered soybeans with residues stemming from spraying with glyphosate, isoxaflutole and dicamba

We refer to our previous letters regarding the safety of the genetically engineered soybean plants 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), which currently are in the process of authorisation for import and usage in food and feed in the EU. We would like to restate that market authorisation cannot be granted to these products due to serious concerns regarding the residues from spraying with the complementary herbicides:

- The EFSA opinions on glyphosate (EFSA 2015) and on tallowamine (EFSA 2015b) can in no way be understood to mean that the residues from spraying herbicide resistant plants with glyphosate are safe as long as they are below the relevant MRL (maximum residue level). On the contrary, it has to be concluded that a lot more data on the residues from the herbicide formulations actually being sprayed onto the plants would be needed before any conclusion could be drawn.
- The Reuter dossier (2015) we sent to the EU Commission shows that the safety of the combination of the herbicides cannot be presumed even if the MRLs of the single substances are not exceeded.

EFSA now has presented its peer review of the pesticide risk assessment of the active substance isoxaflutole (EFSA 2016). This has only served to heighten our concerns since:

- Carcinogenicity and developmental toxicity were confirmed for the active substance.
- In soybean seeds three different metabolites of isoxaflutole were found, most of them at higher levels compared to uses in other species.
- Risk assessment for food and feed could not be concluded, and no MRL could be determined due to lack of data.
- There were further data gaps concerning the method for the determining residues in food and feed of plant origin.

In your previous answers you explain that further risk assessment of these soybeans would not be needed since an MRL was set for the residues from spraying. However, it is now evidently clear that currently no MRL can be set for residues stemming from isoxaflutole. So according to your own criteria, no market authorisation can be granted for the respective soybeans. From our point of view, the same is true for soybeans that are resistant to glyphosate, since the EFSA was similarly unable to conclude on risk assessment and safety for consumers.

Further, we would like to restate our concerns regarding the combined toxicity of glyphosate and isoxaflutole as well as glyphosate and dicamba. As you point out in your letter of January 2016, “it is true that the legislation requires cumulative and synergistic effects of pesticide residues to be considered” but then you go on to explain that no methods are available as yet for this purpose. The Reuter dossier (2015) provides evidence that residues in plants from spraying with a combination glyphosate and dicamba or isoxaflutole are likely to cause adverse effects on health such as genotoxicity, liver toxicity and tumours. Both consumers and farm animals may be exposed to a combination of these substances that are highly likely to be found as residues in the harvest of the crops made resistant to a combination of the herbicides. However, so far the combined toxicity of the residues from these herbicides has never been assessed.

To conclude, EU regulations require the highest standards to be met to protect consumers and the environment. In the case of the genetically engineered plants discussed here, the precautionary principle must be applied and the application rejected. Recent resolutions passed by EU Parliament and adopted in February 2016 support the same conclusion. Therefore, we urge you to ensure that the process for market authorisation for these herbicide resistant genetically engineered soybeans is stopped now.

With kind regards

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The Reuter toxicology dossier: www.testbiotech.org/node/1485
Our previous technical Background: www.testbiotech.org/node/1440
The recent EFSA assessment: www.efsa.europa.eu/en/efsajournal/pub/4416

Text of the EU Parliament resolutions:
www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bMOTION%2bB8-2016-0135%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bMOTION%2bB8-2016-0134%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bMOTION%2bB8-2016-0133%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN