Testbiotech, Frohschammerstr. 14, 80807 Munich, Germany

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

Open letter

12 December 2017

Dear Mr Andriukaitis,

Market authorisation for genetically engineered soybeans with triple resistance to herbicides

We have some deep concerns about the latest reply from DG SANTE (Ref. Ares(2017)6030603 – 08/12/2017) to our communication on the risk assessment of genetically engineered soybeans FG72 x A5547-127 and DAS-44406-6. These crops are the first genetically engineered soybeans that are resistant not only to one or two herbicides, but which inherit triple herbicide resistance. The herbicides that can be applied to these specific crops (but not spayed onto other soybeans) are glyphosate, glufosinate, 2,4-D and isoxaflutole.

Testbiotech has examined documents from applications submitted by Bayer and Dow AgroSciences for the approval of genetically engineered soybeans and found that important areas of risk assessment were not taken into account.

In our updated backgrounder "*Checking the facts final version: Genetically engineered soybeans from Bayer and Dow with triple resistance to herbicides*" (attached) we provide evidence that market authorisation for the soybeans with triple resistance cannot be issued on the basis of EFSA´s opinion. Our arguments not only concern pesticide regulation (as the reply from DG SANTE appears to insinuate) but are also closely related to GMO regulation.

EU risk assessment requests that field trials and risk assessment have to take the application of the complementary herbicides into account. It is seemingly self-evident that applications of the herbicides must be in accordance with the dosage and the number of applications under farming conditions. However, as we are now able to show in detail, the application for approval submitted by Bayer completely fails this test.

It is known that the composition of plant constituents and their agronomic characteristics can be changed by the dosage and the number of applications of the complementary herbicides. There are many potential reasons for these effects, such as dose-dependent effects emerging from the newly introduced DNA constructs and gene products. Such changes in plant composition and phenotype are crucial elements of the comparative risk assessment performed by EFSA and cannot be omitted. However, the data provided by the applicant do not allow any conclusions to be drawn on actual health risks.

The field trials performed by Dow are much closer to real farming conditions, but do not cover all relevant herbicides. Further, the sub-chronic feeding study presented by Dow is not in accordance with necessary scientific standards. For example, no conclusion on dose-related effects can be drawnfrom these data, since only one (relatively low) dosage of soybeans was fed to the rats. From

our understanding of EU regulations, animal feeding studies that do not fulfill the relevant scientific standards should be rejected by EFSA as long as no very specific reasons are given. Finally, we have indications that the plant material used was not sprayed with the complementary herbicides as applied during the field trials; this material appears to have been sprayed with much lower dosages. This detail is not evident from the EFSA opinion and was also not clear to many experts from EU Member States. Furthermore, EFSA has as yet not provided access to the data of this feeding study. We are concerned that it is intended to conceal the actual risks to health from consumption of these soybeans.

As you are aware from our previous interventions, we have raised further objections to the market authorisation of these plants. As we have already shown in detail, there is not enough data to assess the health risks of the new metabolites of isoxaflutole that occur in the genetically engineered soybeans. Further, as far as we know, there are also major gaps in the risk assessment of the relevant metabolites emerging form the usage of 2,4-D and glufosinate on the genetically engineered soybeans. DG SANTE is responsible for both pesticide regulation and GMO regulation and has to ensure that all relevant data are available and fully assessed before genetically engineered herbicide resistant plants are allowed for import or cultivation.

As you are also aware from our previous interventions, we see no possibility for the EU Commission to allow imports of genetically engineered plants and products derived thereof if relevant combinatorial and cumulative health effects are not investigated.

To conclude, we urge you to halt the market authorisation of the soybeans FG72 x A5547-127 and DAS-44406-6 because the data provided is not sufficient to assess the health risks. In addition, there are well-established facts showing that adverse effects are not unlikely if the respective food and feed is ingested.

We would be very happy to receive your comments or provide you with information if required.

With kind regards

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Annex:
Checking the facts final version: Genetically engineered soybeans from Bayer and Dow with triple resistance to herbicides, Testbiotech December 2017