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

04 January 2018

Dear Mr Andriukaitis,

Market authorisation for genetically engineered soybeans with triple resistance to herbicides DAS-44406-6 and FG72 x A5547-127 / Ares (2017)6318880 – 21/12/2017

We are writing to inform you that we have received a reply from DG SANTE regarding the process of market authorisation for genetically engineered soybeans with triple herbicide resistance (DAS-44406-6 and FG72 x A5547-127). In the letter dated 21 December 2017, it is stated that the EU Commission is of the opinion that our backgrounder has not revealed any data or evidence that would not have already been considered by the EFSA GMO Panel during its risk assessment.

We strongly reject this opinion and request that the market authorisation for the soybeans in question is halted.

We have, indeed, provided new evidence that there are gaps in risk assessment, which were not considered by EFSA, and not, or not fully, known at the time when Member States voted on the applications. The issues raised not only concern the risk assessment as conducted by EFSA, but the overall process of risk analysis. It is the task of the EU Commission to make sure that these gaps are closed before any final decision is made on market authorisation. In this regard and at this stage, the responsibility cannot simply be left with EFSA.

To summarise: we identified two larger gaps in the risk assessment of these plants:

(1) The first deals with the specific residues from spraying with the complementary herbicide and additives that can be expected in the plants and their combinatorial effects. In this respect we identified three areas of concern. We are aware that the EU Commission has already given some preliminary answers to these three areas. However, these answers do not re?solve the problems:

- We are aware that the EU Commission is of the opinion that the residues from spraying only have to be assessed under pesticide regulation. However, as we pointed out, the specific residues (including relevant metabolites) were neither assessed under pesticide regulation, nor under GMO regulation.
- We also are aware that the herbicide formulas and their additives as used in the countries of cultivation were never assessed by any EU authority. The EU Commission has admitted this problem in a letter to EFSA,[1] but the problem has still not been resolved.
- Further, the EU Commission is of the opinion that combinatorial effects have to be assessed. However, the Commission claims that there is no adequate methodology.[2] This is simply not correct. Suitable methodology to assess combinatorial effects that emerge from *simultaneous exposure* to a *fixed combination* of potential stressors via a *defined route of exposure* (as is the case with food and feed products derived from genetically engineered plants resistant to several herbicides) is available and widely used.

So in conclusion, there is evidence of crucial gaps in the risk assessment of these plants. It is the task of the risk manager to make sure that these gaps between pesticide regulation and GMO regulation are closed, and that risk assessment is performed in a coherent and meaningful manner. This problem cannot be left for EFSA to deal with. If the EU Commission fails to resolve this problem, the genetically engineered soybeans cannot be considered safe for consumption as required by the law.

1 www.testbiotech.org/node/1636
2 www.testbiotech.org/sites/default/files/11_letter_from%20Commission_August_2016.pdf

(2) The second gap in risk assessment concerns changes in plant composition and phenotypical characteristics caused by the application of the herbicides.

In accordance with EU guidelines and regulations, herbicide-resistant genetically engineered plants have to be sprayed with the complementary herbicides for the purpose of risk assessment. It is obvious that in this regard, the dosage, the number and the point in time of the sprayings are relevant. Depending on these criteria, the plant composition and other phenotypical characteristics might be changed substantially. These questions are crucial for the risk assessment of genetically engineered soybeans that naturally produce a wide range of biologically active compounds (such as phytoestrogens, allergens and many others), especially if an increasing number of complementary herbicides and / or increasing dosages are sprayed onto these plants.

In this context, we have provided new evidence (such as patent applications and several publications) showing the huge difference between what was applied in the field trials and what can be expected under practical conditions. Further, despite systematic investigations in this field, there is a distinct lack of data e.g. Zobiole et al. (2012) provide substantial evidence for the relevance of the underlying scientific questions. This evidence was published as far back as 2012 (see references in our backgrounder), but EFSA failed to take it into account in this context. Moreover, EFSA did not consider at all and/or discuss the impact of the dosage, the number or the point in time of the sprayings for the comparative assessment. EFSA also failed to consider and / or discuss the implications of other complementary herbicides being applied to the plants. Consequently, the impact of the new metabolic mechanisms on plant composition was – especially in the case of the Bayer soybean - not assessed under realistic conditions. The same is true for the feeding study performed by Dow.

These gaps in risk assessment concern the very basic principles of GMO risk assessment as conducted under the comparative approach. To conclude, risk assessment is necessarily considerably flawed if the application of the complementary herbicides is not tested under realistic conditions. It is the task of the risk manager to make sure that the risk assessment is actually performed taking into account all relevant aspects. In this respect, the EU Commission cannot rely on claims by EFSA that these issues were taken into account if there is no scientific basis for such claims.

In the light of these findings and in order to establish a meaningful process, we kindly ask you to consider the following questions in detail:

- If risk assessment of the residues from spraying with the complementary herbicides is absent or not finalised, does the EU Commission nevertheless regard the whole food and feed products derived from the respective genetically engineered plants to be safe?

- If, in the field trials, the herbicide-resistant genetically engineered plants are not sprayed with the complementary herbicides as would normally be the case under practical conditions, does the EU Commission nevertheless regard the data from these trials to be sufficient for risk assessment?

We urge the EU Commission to no longer deal with these questions in a mostly formalistic and legalistic manner. What is needed is discussion on the substance of the underlying scientific questions. Maybe it would be useful for the EU Commission to organise a face-to-face meeting to discuss the complex issues at stake and to improve common understanding.

We kindly ask you to come back to us if you need further clarification. Whatever the case, we still firmly maintain that market authorisation for the events in question cannot be granted. Based on the data available, no conclusion can be reached upon safety of these plants.

With kind regards

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