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,

Recommendation of the European Ombudswoman in case 428/2016/JAS and risk assessment of genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122

We are writing to inform you that we have received the recommendation of the EU Ombudswoman in case 428/2016/JAS on the European Commission's response to a request for internal review of its decision to grant market authorisation for a genetically modified oilseed rape. The recommendation states: "*The Commission should, with a view to complying with the statutory time limits applicable to requests for internal review under the Aarhus Regulation, review its procedures for dealing with such reviews as well as the resources it requires in that regard. This review of procedures and resources should, in particular, take account of the fact that many such reviews will involve complex scientific assessments such as authorisations of products containing genetically modified organisms.*"

In the light of this recommendation, we hope that the EU Commission will indeed revise its procedures and improve them. However, we also hope this review will not only deal with formalistic aspects such as deadlines. In this regard, it is worth taking a step back to not only consider the processes under the Aarhus convention, but also to look at other steps in the process of risk assessment and authorisation of genetically engineered plants.

As you are aware, Testbiotech frequently comments on EFSA opinions on the risk assessment of genetically engineered plants using procedures established by the EU Commission. However, we have not at any time received any meaningful response. Instead, what we see is the EU Commission and EFSA dealing with the underlying scientific questions in a mostly formalistic and legalistic manner. Accordingly, we think this process needs to be improved substantially to attain any significant results, involving the risk assessor as well as the risk manager.

Please see attached our latest comment on the EFSA opinion on risk assessment of maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 (with apologies since we did not manage to file this during the official time period). This maize produces six insecticidal toxins and is resistant to two herbicides as well as being capable of withstanding higher spray dosages of glyphosate. It is clear that there are various gaps in risk assessment and the overall process of risk analysis, in this regard e.g. health risks were never investigated in any of the feeding trials. It is evident that our comment is not only relevant for the risk assessment as performed by EFSA but also for the EU Commission. Comments addressing the overall risk analysis can not be handled by just sending them to EFSA.

Perhaps you can use this example to let us know what could be done to establish a more productive process regarding the discussion of the relevant scientific findings and arguments. This would also be helpful in clarifying scientific arguments if, for example, a request for internal review is filed under the Aarhus convention.

In this context we would like to announce that, in 2018, the research project RAGES (www.testbiotech.org/en/rages/projekt) which is evaluating the current risk assessment of genetically engineered plants, plans to present its conclusions next year and will invite the EU Commission as well as EFSA to discuss its findings. We will let you know the details as soon as possible.

With kind regards

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Annex: Testbiotech Comment on EFSA opinion on risk assessment of maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122