TESTBIOTECH Background 18- 3 - 2013

Testbiotech comment on EFSA GMO Panel´s Scientific Opinion on application (EFSA-GMO-NL-2010-87) for the placing on the market of genetically modified herbicide tolerant oilseed rape GT73 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape GT73 under Regulation (EC) No 1829/2003 from Monsanto

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Summary:
This comment concerns a genetically engineered, herbicide-tolerant (glyphosate) oil seed rape, GT73, which produces two different enzyms that confer herbicide resistance (CP4 EPSPS and GOX proteins).

EFSA did not request a new investigation into GT73, but instead based its opinion mostly on studies that are 10-20 years old. In the light of the many significant findings in compositional analysis and feeding studies, much more investigation is needed before any conclusion can be drawn on the safety of this product. Further, EFSA did not take into account the true potential for persistence and invasiveness of the genetically engineered plants that will emerge from spillage. Residues from spraying with herbicides were not assessed.

The EFSA risk assessment is not based on sufficient and sufficiently reliable data. Further, it does not identify the true range of uncertainties (as requested by Regulation 178/2002) and the current limits of knowledge. The risk manager should therefore reject this opinion.

Molecular characterisation
The data as presented are not conclusive. The molecular characterisation of GT73 oilseed rape does not meet current scientific standards. Some of the investigations were performed more than ten years ago and should have been complemented by recent data. There was no inclusion of methods to screen the transcriptom, metabolom and proteome, and the ELISA tests used to measure the expression rate of the additional proteins were not validated in ring tests.

Comparative analysis
The data as presented are not conclusive. The outcome of the field trials showed many statistically significant differences in composition, which should have triggered further investigations into the relationship between the identified difference and the genetic modification process and interaction with the environment. Further, the dossiers presented by industry are around 10 -20 years old and do not meet current scientific standards. These deficiencies concern the validity and quality of the submitted sets of data as well as its quantity. The dossiers of industry should have been complemented by much more recent data.

Furthermore, since glyphosate is a chelating agent, data on the micronutrient content of the GMO grown with and without glyphosate application and a comparison to its non-GM counterpart are necessary for the nutritional assessment.

Toxicology
The scientific standards of the studies are severely deficient. For example, in the rat feeding studies with GT73, it is unclear whether the plants were sprayed with glyphosate during growth. Some of the control material was contaminated with GT73, and it was not demonstrated that the GT73 test substance was not contaminated with other transgenic oilseed rape varieties, and that the control/ reference groups were free from GMO. The studies that were repeated followed different scientific designs so that the results cannot be compared properly. Some of the studies revealed indications of ill effects on health such as increased liver weights.

The residues from spraying were not assessed. Since there are two different enzymes in the plants that make it resistant to glyphosate, it would be necessary to run detailed investigations into residues, metabolites and possible interactions.

Allergenicity
Digestion of the additional proteins was not assessed under practical conditions. Changes in the expression of endogenous genes were not assessed by profiling methods. Thus, the risk assessment cannot be regarded as conclusive.

Nutritional assessment
Several nutritional studies were conducted that differed in methodology, scientific standards, animal species and results. No conclusion concerning the safety of the plants can be drawn from these data.

Environmental risk assessment
Spillage of whole seeds can lead to unintended cultivation of rape seed along transport lines. Pollen drift can create viable crossings with crops in the fields and wild relatives. Gene flow between *Brassica napus* that is known to hybridize with *Brassica rapa* and closely related species as well as the introgression of the transgenes of feral genetically engineered rape seed to certain wild relatives have already been confirmed in several publications. The assessment of persistence and invasiveness did not take into account the fact that glyphosate is a very common herbicide in the EU, and therefore the plants will foster selective advantage derived from herbicide application.

Moreover, feral oilseed rape populations will open up an opportunity for genetic recombination, stacking of genes, and the evolution of genotypes that could lead to not only an increase in the cost of weed control in the future, but also to phenotypes with new environmental risks such as enhanced invasiveness. These effects will also be influenced by glyphosate exposure that can extend beyond crop field boundaries. Herbicide drift could function as a selective agent contributing to increased transgene persistence in the environment.

Importing whole kernels cannot be allowed since spillage during transport is inevitable.

Monitoring
Monitoring has to be performed at the consumption stage and take into account the residues from spraying. Further, there must be case specific monitoring to make sure that no viable seeds are imported and/or released into the environment.

Conclusion:
The opinion of EFSA must be rejected.