

Testbiotech comment on EFSA Panel on Scientific Opinion on application (EFSAGMO-BE-2010-81) for the placing on the market of genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 × Rf3 for food from Bayer.

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Molecular characterisation

Due to the way the additional DNA was integrated, the event MS8 x Rf3 might produce fusion proteins, additional mRNA and also dsRNA. Also according to EFSA, the emergence of unintended fusion proteins cannot be excluded. Further endogenous gene activity might be changed. EFSA states that bioinformatics analyses of the DNA sequence at the insertion sites did not indicate changes in the expression of endogenous genes. However, no experiments were performed to find out if endogenous gene regulation is actually impacted. Further, the possible occurrence and biological relevance of unintended (short?) RNA molecules was not investigated. Despite the fact that some of the unintended effects caused by the insertion of the additional genes might occur under specific stress conditions, no investigations under defined environmental conditions were performed. Thus, the data as presented are not conclusive.

Comparative analysis

The data used for comparison came from Belgium, but Belgium is not the country that will be exporting the oil seed rape into the EU. The data from Canada that were presented, lack the isogenic line as a comparator. Therefore, the data as provided by the applicant are not sufficient and should not be accepted as reliable and sufficient.

Toxicology

The applicant explained that the purpose of this application concerned accidental unintentional presence of traces of oilseed rape Ms8, Rf3 and Ms8 × Rf3 seeds in food. However, according to EU legislation, market authorisation for food and feed is not restricted to a certain amount of commodities being marketed. Therefore, full risk assessment has to be conducted in every case. But no subchronic or chronic feeding study with the whole food was conducted by the applicant. In addition, to our knowledge, the parental plants were not assessed in any subchronic or chronic feeding study. Residues from spraying were not taken into account. So in conclusion, toxicological risks were not examined sufficiently.

Allergenicity

Immune reactions were not tested by experimental investigations, no tests were conducted with parental plants or the stacked events. The digestion of the PAT protein was not assessed under practical conditions. Changes in the expression of endogenous genes were not assessed by profiling methods. Thus, risk assessment cannot be regarded as being conclusive.

Nutritional assessment

The diets used in the 42 days broiler study were not properly described. No details are given as to whether further genetically engineered plants (such as soybeans) were part of the diet or about residues from spraying with glufosinate. Thus, the scientific standards of the nutritional study are not sufficient and its results should not be accepted.

Environmental risk assessment

Spillage of whole seeds can render unintended cultivation of rape seed along transport lines. Pollen drift can create viable crossings with crops in the fields and wild relatives. From field tests, there is an indication of slightly higher yield due to hybrid vigour. But no experiments were conducted to find out if offspring from unintended crossings (from parental plants or the stacked event) might have an increased potential for persistence and invasiveness. Thus, import of whole kernels cannot be allowed.

Monitoring

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

Others

The market authorisation of stacked events requires the risk assessment and market authorisation of the parental plants first. However, in this case, it appears that the parental plants were not assessed and authorised before the stacked event. Thus, there seems to be a procedural flaw in this process.

Conclusion:

The opinion of EFSA must be rejected.