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

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TESTBIOTECH Background 29 - 10 - 2012

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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.

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File attachments: Anhang — Größe
TBT comment_on_MS8_RF3.pdf [1] — 167.01 KB

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Projekt: EU-Zulassungen [4]

Links
[1] https://www.testbiotech.org/sites/default/files/TBT%20comment_on_MS8_RF3.pdf [2] https://www.testbiotech.org/users/andreas-bauer-panskus [3] https://www.testbiotech.org/users/christoph-then [4] https://www.testbiotech.org/projekt_zulassungen