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Testbiotech comment on Selection of Comparators for risk assessment

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Testbiotech demands new concept for risk assessment of genetically engineered plants

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Testbiotech comments on: *EFSA Panel on Genetically Modified Organisms (GMO); Guidance document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 20YY; volume (issue):NNNN. [19 pp.] doi:10.2903/j.efsa.20YY.NNNN. Available online: www.efsa.europa.eu/efsajournal.htm*

As a recent Testbiotech background paper shows (Then & Bauer-Panskus, 2010), the EFSA concept of *comparative assessment* was developed to a great extent by industry and the International Life Sciences Institute (ILSI) between 2001 and 2003. During this period, Harry Kuiper and Gijes Kleter (both members of the EFSA GMO Panel) were active within the ILSI *Task Force* as experts and authors of relevant scientific publications. In 2004, the concept was adopted in the food and feed Guidance (EFSA 2004) document. Accordingly, the concept meets the needs of the industry by providing a streamlined and flexible process for market authorizations, but does not provide sufficient levels of protection for either consumers or the environment.

The main problem with comparative assessment as proposed by EFSA is that genetically engineered plants are not seen to be basically different from conventionally bred plants. Therefore, genetically engineered plants are not assessed (*per se*) as technical products inheriting specific risks and technical qualities. On the contrary, they are assessed by comparing them with plants derived from conventional breeding. This has a huge impacton the overall process of risk assessment: Comparative assessment largely influences and substantially narrows the outcome of *hazard identification* and *hazard characterization* at an early stage of risk assessment.

More specific investigations are crucial to risk assessment because genetic engineering in plants is the only technology in the plant breeding sector that does not rely on the plant's own genome regulation, but on technically enforced gene activity. In many cases, it also involves the insertion of additional genetic information from other species. In using comparative assessment, EFSA Guidance fails to provide an adequate scientific concept for generating and assessing data prerequisite for hazard identification and hazard characterization.

As Testbiotech shows (Then, 2010; Then & Bauer-Panskus, 2010; Then & Potthof, 2009), the

comparison of genetically engineered plants and their conventional counterparts can be seen as an important tool, but should not be used as *starting point* or *concept* of risk assessment. Instead, a broad range of non-biased and specific technical data should be generated by subjecting the genetically engineered plants to a range of standardized conditions. These data should, for example, cover genetic stability, interactivity between the genome and the environment, the potential impact of climate change and reactions to specific abiotic and biotic stressors. Metabolic profiling, measurement of gene activity and determining the content of decisive components (such as Bt toxins or metabolites from the application of herbicides) can serve as a starting point for risk assessment. In 2009, Testbiotech presented this concept as a *stress test* or *crash test* for genetically engineered plants (Then & Potthof, 2009).

By extending the concept of comparative assessment to *stacked events* or plants that have been subjected to *complex genetic manipulation*, risk assessment moves more and more towards extrapolations, interpretation and speculation not based on facts and adequate empirical investigations. The EFSA panel is even proposing to use genetically engineered plants as comparators for stacked events (for example line 375ff.) and comes to the conclusion that in some cases plants from different species might be accepted as comparators (see line 568 ff.). This means that uncertainties, inaccuracies and mistakes that emerge from the risk assessment of the single events will increase. This kind of approach will not provide sufficient levels of protection for human health and the environment.

In conclusion, *risk assessment per se* should be applied in each individual case (see line 572 ff.). The elements of *risk assessment per se* must be discussed and defined further (see Testbiotech 2010, Ten points for better risk assessment). A stress test concept could be used as a starting point to develop more adequate hypotheses for the later stages of risk assessment.

References:

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