

Testbiotech comment on Scientific Opinion of EFSA on application EFSA-GMO-NL-2011-97 for the placing on the market of insect-resistant and herbicide-tolerant genetically modified cotton T304-40 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG

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Impact Assessment in
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Cotton T304-40 is a genetically engineered cotton plant developed by Bayer. It is resistant to glufosinate and produces a Bt protein (Cry1Ab). An application for import to the EU and usage in food and feed has been filed.

Molecular data

Unintended read-through RNA was observed due to truncated stop codons. Several open reading frames were also identified that could generate further unintended RNA products in the plants. Even though no fusion proteins were identified and no RNA from the open reading frames was found, uncertainties cannot be ruled out. The plants might up- or down-regulate gene activity under certain environmental conditions and produce RNA and proteins not observed so far. Additionally, small double stranded RNA might be produced that could be transmitted as a biologically active compound at the stage of consumption. Consequently, the identifiable uncertainties require further detailed investigation, in particular into unintended products from the foreign DNA. The plants showed highly variable Bt protein expression levels (the level of Bt proteins in the plant was much higher when cultivated in Spain than in the US). They should therefore undergo a stress test under defined environmental conditions, to explore the true range of variability and to identify unintended effects in the plants that only might occur in specific environments.

Comparative assessment (for compositional analysis and agronomic traits and phenotype)

The outcome of the field trials is very clear. Cotton T304-40 is not equivalent to its isogenic line. EFSA summarised consistent significant differences in the comparison:

“The level of calcium, zinc, linoleic acid, palmitic acid and stearic acid showed statistically significant differences in cotton T304-40 and Coker 315 over all three seasons of field trials and both treatment regimes with herbicides.”

Nevertheless, EFSA decided these differences are of no biological relevance. Instead of requesting further investigations, EFSA referred to the data from various reference lines, which do not have a similar genetic background to T304-40. From a scientific point of view, a clear set of data stemming from the true comparator, which is the isogenic line, cannot be devaluated by simply adding more data from other varieties. By doing so, EFSA demonstrates its comparative risk assessment is mostly based on assumptions and arbitrary data interpretation.

Toxicology

The assessment of feeding studies is a new low-point in the case history of EFSA opinions. Both feeding studies with plant material, the subchronic 90 day feeding study with rats and the 42 day

feeding study with poultry, were completely or largely rejected by EFSA because of flaws in the design of the study. At the same time, EFSA did not ask for any new investigations. The Food Authority simply assumed that the new proteins as expressed in the plants were safe and at the same time ignored the observed differences in plant composition. Any further testing of the whole plant material was deemed unnecessary. The lesson for industry was, of course: Products can easily escape detailed risk assessment by providing data with no scientific value from feeding trials.

Allergenicity

Under normal circumstances, EFSA bases its weight of evidence approach on methods such as the pepsin test, which are known to be unreliable. No conclusions can be drawn from the pepsin test on the degradation of the foreign proteins under realistic conditions if the proteins are ingested with many other components.

Further, no tests were performed to investigate adjuvant effects that can enhance immune reaction to known endogenous plant allergens.

As a result, the allergenicity risk assessment is not conclusive.

Nutritional Assessment

see Toxicology

Environmental risk assessment

Testbiotech agrees with the comments of several Member States that spillage, persistence and invasiveness are relevant risks in certain countries. No viable seed should be imported into countries or regions where cotton plants can survive and spread into the environment, such as Italy, Greece and Spain.

Others

Residues from spraying with glufosinate are plant constituents that are relevant for the risk assessment of these plants. T 304-40 raises specific safety concerns such as combinatorial effects with the insecticidal protein, which are not addressed by pesticide regulation. EFSA has not carried out such an assessment.

Conclusion and recommendations:

This risk assessment is a new low-point in the case history of EFSA opinions. The opinion should be rejected completely. Instead of identifying uncertainties and knowledge gaps and requesting relevant investigations as requested by experts from several EU Member States, EFSA is simply hiding behind the wording of its controversial Guidance. As a result, the opinion is an attempt to window dressing the issue but not a reliable risk assessment.