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

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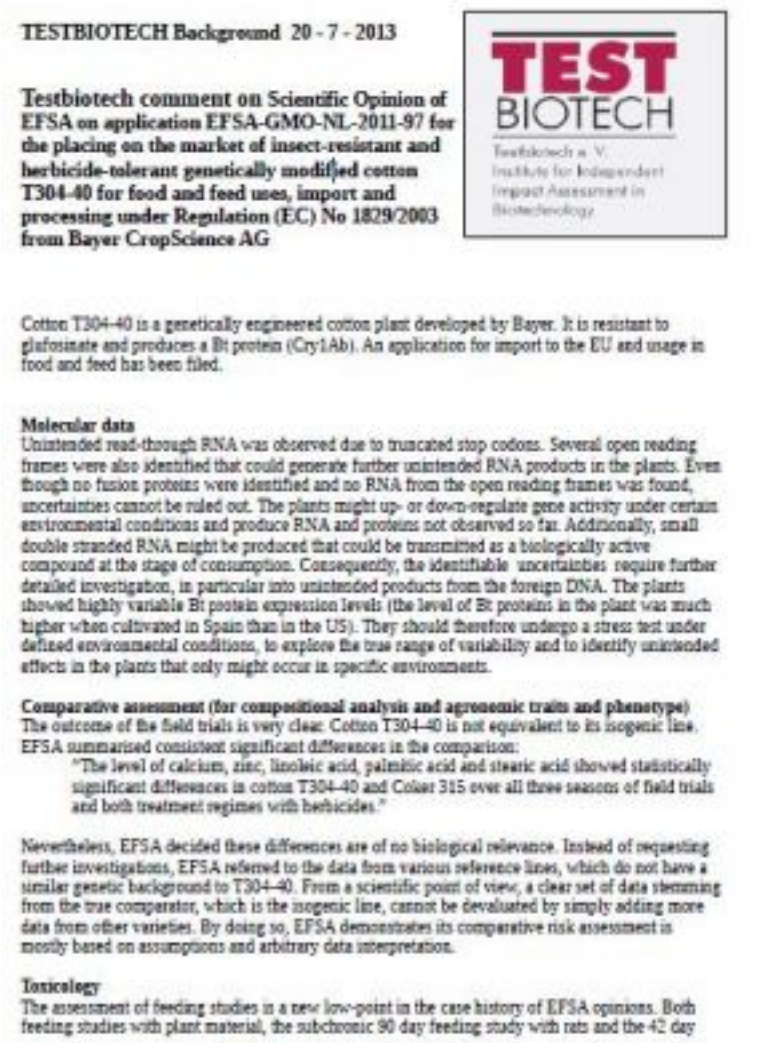

TESTBIOTECH Background 20 - 7 - 2013

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

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

Publication year: 2013
File attachments: Attachment — Size
TBT Comment_Cotton 304_40_Import_2013.pdf [1] — 64.78 KB

Projekt: EU-Zulassungen [2]

efsa-gmo-nl-2011-97-placing-market

Links
[1] https://www.testbiotech.org/sites/default/files/TBT%20Comment_Cotton%20304_40_Import_2013.pdf
[2] https://www.testbiotech.org/en/node/1499