Attachment - Testbiotech reply to EFSA statement on maize 1507

Table: Comparison - Testbiotech findings and EFSA statement of 20 October

Testbiotech findings	Explanation	EFSA statement	Testbiotech comment	Conclusion
Risks for non-target organisms				
EFSA risk assessment is based largely on analogies and conclusions drawn from other Bt toxins (Cry1Ab) which differ in their mode of action as well as their effects from the Cry1F produced in maize 1507. EFSA did not correctly assess scientific data indicating the high risks posed by 1507 maize to non-target organisms.	The most relevant publication in this regard is Hanley et al. (2003). It shows that Bt toxin Cry1F (as produced in maize 1507) is more toxic for certain butterflies than Cry1Ab. Cry1Ab (produced in other genetically engineered maize such as MON810) was used by EFSA in analogy as a key reference for assessing the risks posed by maize 1507 because more specific data on the toxicity of Cry1F are missing. The higher toxicity of Cry1F in comparison to Cry1Ab is observable in the greater wax moth (*Galleria mellonella*), a test organism in ecotoxicology. Since no other data on the susceptibility of European butterflies to Cry1F are available, this publication is a strong signal that there are adverse effects in European non-target butterflies (*Lepidoptera*). This fact is a crucial aspect in	EFSA does not refer to the most relevant publication (Hanley et al., 2003). The GMO panel does not even mention the risks for European non-target *Lepidoptera*. EFSA states that no new literature on adverse effects has been published since their opinion in 2005. They do not mention that their 2005 opinion overlooked the findings from 2003 (Hanley et al.). Instead EFSA refers to other publications dealing with completely different issues: Wolt et al. (2005) looked at the risks to a specific butterfly in Asia. Further EFSA refers to Gaspers et al (2010) whose findings deal with the susceptibility of target pest insects (corn borer), and to Perry et al (2010) dealing with models to assess the exposure of lepidoptera to Cry1Ab. None of these publications deals with the	Testbiotech concerns were not addressed. There are no experimental investigations on the susceptibility of the non-target European *Lepidoptera*. The only relevant publication, dealing with non-target *Lepidoptera* shows adverse effects in relevant test organisms.	EFSA has chosen a pick and choose strategy and fails to give proper scientific reasoning. It only refers to selected papers that support the panel's line of argumentation. As long as no other investigations are available on risks for non-target European *Lepidoptera*, the risk manager has to reject market authorisation.

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	the overall risk assessment of maize 1507.	issue stressed by Testbiotech.		

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High content of Bt in pollen				
1507 maize produces high amounts of Bt toxin in pollen. For example, the toxin content is much higher than in MON810. Many non-target organisms are exposed to this part of the plant therefore a detailed investigation of its toxicity is necessary.	Testbiotech addresses two facts: (1) a very high content of Cry1F in the pollen of the plants (2) In the opinions concerning maize 1507, EFSA gave confusing statements about the toxin content in pollen as well as its biological relevance.	EFSA does not mention this issue.	The high content of Bt toxin in pollen indicates higher risks for non-target organisms than those from other Bt maize lines such as MON810.	EFSA completely fails to address the issue raised by Testbiotech. Again, as long as no other investigations are available on risks for non-target organisms, the risk manager has to reject market authorisation.

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Unintended changes in the plants				
During the process of gene transfer, numerous fragments of the gene construct as well as other genetic material were transferred unintentionally along with the construct.	Additional unintended changes in the structure of the genome can cause unintended effects in the plants.	EFSA explains that unintended effects can be observed on the level of the genomic structure and biological activity, but does not see a risk. EFSA explains that the comparison of the plant's components does not raise any safety concerns. Data from releases under varying	The observed unintended effects on the genome level are difficult to assess from a risk perspective. Further investigations such as extended metabolic profiling could help to provide a clearer picture. Further, the plants should be tested systematically for genetic stability and unintended compounds under defined	EFSA does address this issue raised by Testbiotech. EFSA and Testbiotech come to different conclusions. Testbiotech urges extended profiling of the plants´ metabolism.

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		regional conditions did not show relevant findings.	environmental conditions (see model of 'Stress-Test' as proposed by Testbiotech).	

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Risks for soil organism				
There is an almost complete lack of studies on the effect of Cry1F on soil. The EFSA assessment on the effects of 1507 maize on soil is therefore highly speculative.	It is known that some Bt plants exudate Bt toxin into the soil. Furthermore, residues from roots and other plant material will be left on the field after crop harvesting. Bt toxins can be found for months after maize cultivation. There is some discussion on the potential accumulation of the toxins in the soil. As far as 1507 and the Bt toxin Cry1F are concerned, none of these issues were properly assessed because the only field data stems from maize producing Cry1Ab.	EFSA agrees with Testbiotech that hardly any data are available with regard to 1507 and Cry1F. EFSA is of the opinion that these data are not necessary.	Without knowing how much Bt toxin is released into the soil during 1507 cultivation, no conclusions can be drawn on the impact on soil organisms. This constitutes a major gap in EFSA risk assessment.	Without assessment of the actual risk for soil organisms no market authorisation can be given.

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Risks of application of Glufosinate				
The effects of the use of glufosinate have not been evaluated by the EFSA‘s GMO panel.	Glufosinate, a broad-spectrum herbicide, can be applied to the plants because 1507 has been engineered to be resistant to the herbicide (brand names Basta or Liberty). No data are available on possible interaction between the herbicide and the Bt toxin. Glufosinate is known to be detrimental to health. The registration of the substance therefore ceases in 2017 unless new risk assessments can prove the current hazard classification wrong.	EFSA explains that compositional analyses of the maize were performed after cultivation with and without spraying.	The GMO panel at EFSA is of the opinion that risks associated with herbicides have to be assessed by the EFSA Plant Protection Panel (PPR-Panel). While this is correct for the assessment of general toxicity and environmental impact, there are specific issues such as residues and metabolites of the toxins in the plants and their interaction with the plants metabolism. EFSA did not investigate the amount of residues from glufosinate in the plants under varying conditions in weed management. EFSA also did not assess the environmental impact of changes in weed management.	The EU Commission explicitly requests that the interface between the usage of herbicides and the cultivation of herbicide-tolerant plants must be addressed by the EFSA GMO panel. No market authorisation can be granted without prior assessment of the specific risks involved in the cultivation and usage of products derived from herbicide tolerant plants.

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Resistance in pest insects				
Recently published scientific data shows that the cultivation of 1507 maize has led to field resistance in certain target organisms after only a short time period. Resistance to plant pests is a major risk in Bt crops, as is pest replacement - also observed with Cry1F.	There are recent observations in the US, Asia and South Africa that pest organisms become resistant or tolerant to Bt toxins. Further, new pest infestation was observed in the US and China after cultivating Bt plants over a longer time period.	EFSA says it is unlikely that resistance to Cry1F will occur in European pest insects. Further, EFSA points out that shifts in pest infestations are also caused by other forms of weed management and thus the problem is not specific for insect resistant genetically engineered plants.	Testbiotech disagrees with the EFSA conclusions because the insecticidal protein is produced throughout the whole period of vegetation and the toxin is also abundant on the field after the harvesting. Testbiotech is of the opinion that, in comparison to other methods of insect management, insect resistant plants are causing a higher risk for the development of resistance, tolerance and shifts in pest organisms.	The risk manager has to take a decision as to whether Bt technology is compatible to sustainable agriculture or if it will lead to a situation, where there is a steadily increasing exposure to insecticides. Meanwhile in the US, plants are being grown that produce six different Bt toxins in one plant (brand name SmartStax). There is growing pressure to combat infestations from new and old pest insects. Further industry even proposes to use additional insecticides to combat newly emerging pest infestations.

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Health risks				
Feeding studies that were not thoroughly assessed by EFSA indicate detrimental effects on health.	Industry presented a 90-day feeding study that investigated potential health effects in rats. While Pioneer and EFSA are of the opinion that these trials do not reveal any adverse effects, two more recent evaluations (Dona & Arvanitoyannis, 2009; Seralini et al., 2009) conclude there are indications that health may be affected and more investigations are necessary.	EFSA has not considered the recent studies mentioned by Testbiotech.	Contrary to EFSA, Testbiotech is of the opinion that feeding studies with genetically engineered plants should be conducted before these plants are placed on the market. Ethical questions related to the use of animals must be integrated in risk assessment. If market authorisation is being considered, long term feeding studies will be necessary to observe effects over more than one generation.	The existing data on 1507 are not sufficient to exclude health risks for wildlife, livestock and humans. The market application should be rejected.