Public comments - Soybean BPS-CV127-9

Organisation: Testbiotech
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The original version of this event contained various copies of the additionally inserted gene sequences. These copies were removed by backcrossings. This in effect means that EFSA did not assess the original version of the event but only the event after backcrossing which is supposed to show only copy at one integration site. To avoid uncertainties about unexpected effects from the process of genetic engineering in the plants, data from the original event should have been taken into account and included a comparison to the event after backcrossing.

Further, the molecular characterisation shows that „a disruption of an endogenous gene may have occurred in BPS-CV127-9 as a result of the insertion and/or chromosomal rearrangements in the proximity of the insertion site. The annotated gene has no known function“. EFSA not assess the potential impact of this finding in detail. For example, RNAi molecules that can emerge from the process of DNA insertion and new open reading frames should have been assessed in regard to their potential to be transferred as biologically active substances at the stage of consumption.

In the light of these findings and taking into account that various differences in compositional analysis and agronomic performance in comparison with isogenic plants and null segregants were observed, much more data on the effects of the additional DNA on the plants genome, transkriptome, proteome and metabolome should have been requested and defined environmental stress conditions taken into account.

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

Various differences in compositional analysis and agronomic performance in comparison with isogenic plants and null segregants were observed. Only one field trial was conducted in the US, with an outcome showing large differences compared to those conducted in Brazil, indicating environmental x genome interaction. According to EFSA, seed weight and tocopherol content could not be established as being equivalent to comparators and references. In conclusion, several unexpected changes in plant metabolism were found that might point to other unexpected and currently undetected changes. In consequence, EFSA should have requested much more data from all parts of the plants and a complete set of data on phenotypical characteristics. Instead, EFSA accepted a dossier with no reliable data from many parts of the plants such as forage, and without phenotypical data from very important

characteristics such as pollination, nodulation and seed germination. EFSA was of the opinion that these data would only be relevant for the environmental risk assessment for cultivation of the plants. This reasoning has to be rejected since these data are absolutely essential to make a judgment on the real dimension of unintended effects in the plants that might have an impact on health.

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b. Food Safety Assessment:
Toxicology

The applicant carried out a 90-day subchronic study but this was not taken into account by EFSA because of several flaws. The GMO panel did not request a new 90-day study. Thus, there is no feeding study with the whole plants available to assess effects on health.

EFSA states that, “the occurrence of an unintended effect in seed weight cannot be ruled out”. Therefore EFSA sees the need for further considering the “the potential consequences of the observed difference in seed weight”. This observation should have prompted also further investigation into potential effects on health from the soybeans. There should, for example, have been a request for feeding studies with the whole plant. However, unexpected effects in seeds were only considered in regard to environmental impacts and not in the context of effects on health. This is another major flaw in the overall risk assessment of the soybeans.

Allergenicity

EFSA (2010) requests detailed investigations into allergenic risks for infants and individuals with impaired digestive functions. “The specific risk of potential allergenicity of GM products in infants as well as individuals with impaired digestive functions (e.g. elderly people, or individuals on antacid medications) should be considered, taking into account the different digestive physiology and sensitivity towards allergens in this subpopulation.” However, these specific risks were left aside during EFSA risk assessment.

Further, the soybeans were tested with sera from small groups of individuals known to react to allergens from soybeans. Differences were observed but not deemed relevant. As the minutes of a meeting of the working group (WG) “Self Task on Allergenicity” of 24 September 2007 shows, EFSA has serious doubts about the reliability of the investigations with such a small number of patients conducted in this case. “More sera from patients are needed but they also need to be well characterised. Statistical calculations have been done showing that 60-70 well characterised sera are needed based on variability. Since this might not be feasible, the WG has to consider the reliability of studies with a lower number of sera.” Therefore, the assessment conducted by EFSA is inadequate. EFSA should have requested more detailed investigations taking into account possible changes in the content of all relevant allergens known to occur in soybeans. Further, no other non-IGE-mediated immune reactions were taken into account, although these effects hve to considered as being relevant (Mills et al., 2013).

EFSA (2010) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed.

EFSA Journal 2010; 8(7):1700. [168 pp.] doi:10.2903/j.efsa.2010.1700. Available online: www.efsa.europa.eu

EFSA (2007), Minutes of the meeting of the EFSA working group (WG) “Self Task on Allergenicity” of 24 September 2007

Mills, E.N.C., Marsh, J.T., Boyle, R., Hoffmann-Sommergruber, K, DuPont, D., Bartra, J., Bakalis, S., McLaughlin, J., Shewry, P.R. (2013) Literature review: ‘non-IgE-mediated immune adverse reactions to foods’, EFSA supporting publication 2013:EN-527.

Others

As a recent legal dossier compiled by Professor Ludwig Kraemer shows, the decision not to monitor effects on health at the stage when genetically engineered food is consumed, violates the requirements of EU regulations. This is especially relevant in this case, because the suggested maximum residue levels for residues from spraying are higher for these herbicide resistant soybeans than for others (EFSA, 2013). Directive 2001/18 and Regulation 1829/2003 both require that potential adverse effects on human health from genetically modified plants are monitored during the use and consumption stage, including in those cases where such effects are unlikely to occur. Monitoring also has to include residues from spraying with the complementary herbicide. Thus, the EFSA opinion that monitoring of effects on health is unnecessary is wrong and contradicts current EU regulations.

EFSA (2013) European Food Safety Authority, Reasoned opinion on the setting of a new MRL for imazapic in genetically modified soya bean. EFSA Journal 2013;11(10):3426, 26 pp. doi:10.2903/j.efsa.2013.3426

Kraemer, L. (2012) The consumption of genetically modified plants and the potential presence of herbicide residues, legal dossier compiled on behalf of Testbiotech, http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

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4. Conclusions and recommendations

The risk assessment is inconclusive and market authorisation for import and usage in food and feed cannot be given because there are gaps in the data and several indications for unintended effects in the genetically engineered soybeans have been observed.
