

mon-810-pollen

Organisation: Dr. Steisslinger Consulting

Country: Germany

Type: Consultant

a. Assessment:

3. Environmental risk assessment

GMO plants do not belong into the environment!!! Safety has never been properly established. I oppose vehemently any release into the environment.

Organisation: E3D

Country: France

Type: Association

a. Assessment:

Molecular characterisation

The implanted genes are truncated and therefore their expression is not identical to that produced and expressed by *Bacillus Thuringensis* as an insecticide.

b. Food Safety Assessment:

Toxicology

No studies covering a period longer than three months have ever been produced by the breeder (Monsanto). A study over at least two years should have been necessary for the maize to gain approval. Why is the pollen not tested over two years?

Allergenicity

Ditto

Nutritional assessment

Substantial equivalence is a complete fraud, accepted by the of the US Food and Drug Administration. Why?

3. Environmental risk assessment

No studies have ever been produced by Monsanto.

4. Conclusions and recommendations

Definitive prohibition of any GMO on which a full study spanning at least two years (rats) has not been conducted.

6. Labelling proposal

Irelevant.

Organisation: Conservation Engineering Ltd

Country: United Kingdom

Type: Individual

a. Assessment:

4. Conclusions and recommendations

Please keep GM pollen out of the EU. Reject this proposal and application

Organisation: Testbiotech

Country: Germany

Type: Non Profit Organisation

a. Assessment:

Molecular characterisation

The EFSA risk assessment suffers from a lack of data on the actual Bt content in pollen. The original data from Monsanto are around 20 years old. Since then only very few data were made available.

Further, the methods for measuring the Bt content were never evaluated for reliability and comparability (Szecaks, et al., 2011). It is known that environmental conditions can influence the content of the Bt in the plants – but no data are available for Bt content in pollen under defined environmental conditions (Then & Lorch, 2008).

Thus, the whole risk assessment is based on insufficient data.

Székács, A., Weiss G., Quist, D., Takács, E., Darvas, B., Meier, M., Swain T., Hilbeck A., (2011): Inter-laboratory comparison of Cry1Ab toxin quantification in MON 810 maize by

enzyme-immunoassay, Food and Agricultural Immunology,
DOI:10.1080/09540105.2011.604773.

Then, C. & Lorch, A., 2008, A simple question in a complex environment: How much Bt toxin do genetically engineered MON810 maize plants actually produce?, in: Breckling, B., Reuter, H. & Verhoeven, R. (eds), 2008, Implications of GM-Crop Cultivation at Large Spatial Scales, Theorie in der Ökologie 14. Frankfurt, Peter Lang, <http://www.mapserver.uni-vechta.de/generisk/gmls2008/index.php?proceedings=ja&call=ja>

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

The EFSA risk assessment suffers from a complete lack of data on compositional analysis of the pollen. Without data for compositional analysis, no comparative risk assessment can be applied (as performed by EFSA).

The complete lack of any data on compositional analysis should have led EFSA to reject the assessment of this application as long as no data are available.

b. Food Safety Assessment: Toxicology

The mode of action of the Bt toxin still is not known in all its details (Vachon et al 2012). The impact on human cells was described recently (Mesnage et al., 2012). Since no reliable data are available for the Bt content in the pollen and no final conclusion can be drawn upon the safety of the pollen.

Mesnage R., Clair E., Gress S., Then C., Székács A., Séralini G.-E., 2012, Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide, Journal of Applied Toxicology, <http://onlinelibrary.wiley.com/doi/10.1002/jat.2712/abstract>

Vachon, V., Laprade, R., Schwartz, J.L., 2012, Current models of the mode of action of *Bacillus thuringiensis* insecticidal crystal proteins: A critical review, J. Invertebr. Pathol. (2012), <http://dx.doi.org/10.1016/j.jip.2012.05.001>

Allergenicity

The opinion of EFSA ignores the findings on immune reactions triggered by Bt plants. There are already several studies showing that genetically engineered plants producing Cry proteins interact with the immune system in vertebrates. Such examples include fish (Sagstad et al., 2007), pigs (Walsh et al., 2011), mice (Finamore et al., 2008), and rats (Krogsho et al., 2008). Further, Gu et al (2012) suggest that Bt-maize can potentiate oxidative cellular stress

in immune-sensitised animals (fish), thus specific attention should be paid to interactions of the Bt proteins with other food components and the immune status of the individual.

Further, the weight of evidence brought forward by EFSA is based on investigations that do not allow the assessment of digestion of the protein under realistic conditions. For example, feeding studies with pigs conducted by Chowdhury et al. (2003) as well as Walsh et al. (2011) found that Cry1A proteins can frequently be found in the colon of pigs. This shows Cry1A proteins can show much higher stability in monogastric species than predicted by current *in vitro* digestion experiments. It should also be taken into consideration that pollen is likely to resist digestion more than other foodstuff and as result the Bt proteins are likely to survive to an ever higher percentage than in other food.

In this context, risk assessment should also include the exposure via the respiratory system, because this question was not fully investigated in the risk assessment of MON810 for cultivation.

Thus, no conclusion can be made upon the safety of the pollen in regard to the immune system.

Chowdhury, E. H., Kuribara, H., Hino, A., Sultana, P., Mikami, O., Shimada, N., Guruge, K. S., Saito, M., Nakajima, Y. (2003). Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11. *J. Anim. Sci.* 81: 2546-2551.

Finamore, A., Roselli, M., Britti, S., Monastra, G., Ambra, R., Turrini, A. & Mengheri, E., 2008, Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice. *Journal of Agricultural and Food Chemistry* 56: 11533–11539

Gu, J., Krogdahl A., Sissener, N.H., Kortner, T.M., Gelencser E., Hemre G.I., Bakke A.M. (2012) Effects of oral Bt-maize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic salmon, *Salmo salar* L., *British Journal of Nutrition*, doi:10.1017/S000711451200325X

Krogsho, S., Madsen, C., Poulsen, M., Schrøder, M., Kvist, P.H., Taylor, M., Gatehouse, A., Shu, Q., Knudsen, I., 2008, Immunotoxicological studies of genetically modified rice expressing PHA-E lectin or Bt toxin in Wistar rats. *Toxicology*. 245, 24-34.

Sagstad, A., Sanden, M., Haugland, O, Hansen A.C., Olsvik P.A., Hemre G.I., 2007, Evaluation of stress- and immune-response biomarkers in Atlantic salmon, *Salmo salar* L., fed different levels of genetically modified maize (Bt maize), compared with its near-isogenic parental line and a commercial suprex maize, *Journal of Fish Diseases*, 30: 201–212

Walsh, M.C., Buzoianu, S.G., Gardiner, G.E., Rea M.C., Gelencsér, E., Jánosi A., Epstein M.M., Ross, R.P., Lawlor, P.G. (2011) Fate of Transgenic DNA from orally administered Bt MON810 maize and effects on immune response and growth in pigs. *PLoS ONE* 6(11): e27177, doi:10.1371/journal.pone.0027177.

Nutritional assessment

The EFSA risk assessment suffers from a complete lack of nutritional data.

Pollen is seen as a health food and dietary supplement, so it is astonishing that EFSA has not even tried to assess the nutritional quality of pollen that contains Bt-toxins.

EFSA should have undoubtedly requested data from the applicant.

3. Environmental risk assessment

Risk assessment should also include the exposure via the respiratory system since so far no detailed investigations are available, while some data indicate risks for human health (Bernstein et al., 1999; Doekes et al., 2004).

Bernstein, I. L.; Bernstein, J. A.; Miller, M.; Tierzieva, S.; Bernstein, D I.; Lummus, Z.; Selgrade, M. K.; Doerfler, D. L.; Seligy, V. L. (1999) Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides. *Environ. Health Perspect*, 107, 575–582.

Doekes, G.; Larsen, P.; Sigsgaard, T.; Baelum, J. (2004) IgE sensitization to bacterial and fungal biopesticides in a cohort of Danish greenhouse workers: the BIOGART study. *Am. J. Ind. Med.*, 46, 404–407.

4. Conclusions and recommendations

The risk assessment of EFSA is not based on any reliable data. Further, the opinion of EFSA does not identify the true range of uncertainties (as requested by Regulation 178/2002) and the current limits of knowledge. The risk manager should therefore reject this opinion.
