Maize 3272

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
Allergenicity

EFSA says "In relation to the allergenic potential of AMY797E protein and considering all possible food and feed uses of maize 3272, the GMO Panel concludes that the information provided does not fully address the concerns previously raised by the Panel in 2013. Owing to the nature and the knowledge available on this protein family (or functional class of enzymes), it is still unclear whether under specific circumstances the alpha-amylase AMY797E has the capacity to sensitise certain individuals and to cause adverse effects. In addition, the applicant provided thorough information relevant for the allergenicity assessment of a specific product, the dried distiller grains with solubles (DDGS) which is the main product of interest for importation into the European Union. Having considered the information provided on this product, the GMO Panel is of the opinion that under the specific conditions of use described by the applicant, DDGS produced from maize 3272 does not raise concerns when compared to DDGS from non-GM maize."

You are not thinking holistically, I'm afraid. You believe that cattle feed (DDGS) can't cause allergies, but it's all part of GM maize, isn't it? Why should the latter suddenly not cause reactions? We ingest it via meat and milk, don't we?

Others

Fragment: "Lastly, we wish to point out that there is no logical basis for citing the economic importance of amylopectine-potatoes obtained by genetic modification. People can quite reasonably accept a degree of risk in return for an expected benefit (risk analysis). After all, what we have here is a mutant potato with certain desired properties. But such properties can be created, risk-free, in any variety, using traditional grafting methods. Why this isn't already being done is a total mystery."

https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/bezwaarschrift-tegen-verlenen-van-vergunning-voor-teelt-van-genetisch-veranderde-aardappelrassen/

Our comment: The same applies to GM maize.

We read: "DDGS (Distiller`s Dried Grains with Solubles) is released when alcohol is obtained from grain. Depending on the type of grain used, it is either wheat DDGS or maize DDGS." Source: https://www.weidseblik.nl/producten/grondstoffen/tarweglutenvoer

Why does it have to be GM maize?

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4. Conclusions and recommendations

How can people who wish to leave a comment be well-informed if the consultation is only held in English, and not in other EU languages, not even major ones like German, French or Spanish? This oversight must be remedied! This is why there are so few comments from countries where English is not spoken! We repeat: We don't want GM maize! Even the Dutch CA is dubious!

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5. Others

PDF] Agrobacterium & Morgellons Disease, A GM Connection? MW Ho, J Cummins - Sci. Soc, 2008 - Citeseer … Agrobacterium tumefaciens in agroinfected plants. Molecular Plant – Microbe Interactions 1993, 6(50), 673-5. 19. Ho MW and Cummins J. Horizontal gene transfer from GMOs does happen. Science in Society 38. The association of Morgellons Disease with dirt and soil where Agrobacterium lives, the widespread use of Agrobacterium in genetic engineering of plants, and the ability of Agrobacterium to infect human cells, all point towards a possible role of genetic engineering in the aetiology of Morgellans disease via Agrobacterium.
http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.604.6877&rep=rep1&type=pdf

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6. Labelling proposal

If you were to take the terrible decision not to ban this genetically modified maize (which by definition can never be the same as "ordinary" maize, given that it's been, well, modified), then the most effective label would be a skull inside a warning triangle. And not only starting at 0.9% of ingredients, but wherever GM organisms are present.

These replies are being sent to you jointly on behalf of Stichting Ekopark, NL.

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
b. Food Safety Assessment:
Toxicology

29-11-2019. Third supplement. Microbial Ecology in Health and Disease. 2009; 21: 172–174

New evidence links CaMV 35S promoter to HIV transcription

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“Abstract

New evidence raises the possibility that the CaMV 35S promoter in practically all transgenic crops grown commercially may enhance multiplication of disease-associated viruses including HIV through induction of proteins required for their transcription. Key words: Cauliflower mosaic virus, transgenic crops, GM crops.”

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

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a. Assessment:
4. Conclusions and recommendations

Supplement to 4-12-2019. Quote: After so many years of EFSA’s poor implementation and partial disregard of repeated EU Parliament requests to fix its independence policy, the new Parliament would be wise to step up the pressure on this EU agency.
https://corporateeurope.org/en/2019/06/efsa-gene-drive-working-group-fails-independence-test

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Organisation: Testbiotech e.V. - Institute for Independent Impact Assessment of Biotechnology
Country: Germany
Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

In order to assess the sequences encoding the newly expressed proteins or any other open reading frames (ORFs) present within the insert and spanning the junction sites, it was assumed that the proteins that might emerge from these DNA sequences would raise no safety issues. Furthermore, other gene products, such as miRNA from additional open reading frames, were not assessed. Thus, uncertainties remain about other biologically active

substances arising from the method of genetic engineering and the newly introduced gene constructs.

Environmental stress can cause unexpected patterns of expression in the newly introduced DNA (see, for example, Trtikova et al., 2015). The data presented in the original dossier assessed by EFSA (2013a), show a high amount of AMY797E is produced in the kernels with a wide range of concentration, from 1004 – 3365 µg/g dw (EFSA, 2013b). Only a very low number of individual maize plants were analysed, which do not allow a solid statistical analyses (EFSA, 2013b). No further expression data were presented in the statement for complementation of the opinion (EFSA, 2019), even though new field trials were performed by Syngenta.

From the data presented, it cannot be concluded to which extent specific environmental conditions, such as those caused by climate change, will influence the overall concentration of the enzymes in the plants.

In regard to expression of the additionally inserted genes, Implementing Regulation 503/2013 requests "Protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown".

However, the few data presented between 2003 and 2007 (EFSA, 2013a) do not represent the conditions in which the plants would be grown, since no extreme weather conditions were taken into account.

While in the previous assessment (EFSA, 2013a), the old EFSA guidance was applied, there is no excuse why EFSA (2019), after being requested by the EU Commission in 2017, did not use Implementing Regulation 503/2013, which has to be applied to all applications filed after December 2013.

Whatever the case, the plants should have been subjected to a much broader range of defined environmental conditions and stressors to gather reliable data on gene expression and functional genetic stability, taking into account more extreme drought conditions. In addition, they should have been tested in the maize producing countries in South America. EFSA should also have requested data from several varieties, including those cultivated in South America. Furthermore, data from the parental plants need to be presented.

The material derived from the plants should have been assessed by using omics techniques to investigate changes in the gene activity of the transgene and the plant genome, as well as changes in metabolic pathways and the emergence of unintended biologically active gene products. Such in-depth investigations should not depend on findings indicating potential adverse effects, they should always be necessary to come to sufficiently robust conclusions to inform the next steps in risk assessment.

References:

EFSA (2013a) Scientific Opinion on application (EFSA-GMO-UK-2006-34) for the placing on the market of genetically modified maize 3272 with a thermotolerant alpha-amylase, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. EFSA Journal 2013; 11(6):3252, 27 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3252

EFSA (2013b) Application EFSA-GMO-UK-2006-34, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin

EFSA (2019) Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-UK-2006-34) for authorisation of food and feed containing, consisting of and produced from genetically modified maize 3272. EFSA Journal;17(11): 5844, 15 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5844

Trtikova, M., Wikmark, O.G., Zemp, N., Widmer, A., Hilbeck, A. (2015) Transgene expression and Bt protein content in transgenic Bt maize (MON810) under optimal and stressful environmental conditions. PloS one, 10(4): e0123011. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123011

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

For the assessment published by EFSA (2019), new field trials for compositional and agronomic assessment of maize 3272 were conducted in the US during one year only (2014) and not in any other relevant maize production areas, such as Brazil or Argentina.

The statistical analysis presented (EFSA, 2019) showed several significant differences between the conventional comparator and maize 3272, some of these were in the highest category.

No data were presented to assess the overall fitness of the plants (for example, seed dormancy, germination rate and survivability at higher or lower temperatures).

Overall, it is not plausible that the data as presented are sufficient to assess the real biological characteristics of the plants, since the production of the two enzymes in the kernels (one of them in high amounts) is likely to change more than one metabolic pathway in the plants.

Under these circumstances, it is not acceptable that EFSA failed to require further studies even though: • No data from omics (proteomics, transcriptomics, metabolomics) were used to assist the compositional analysis and the assessment of the phenotypical changes. • No field trials were conducted for the final assessment that lasted more than one season. Thus, based on current data, site-specific effects can hardly be assessed. • Further, no data were generated representing more extreme environmental conditions, such as those caused by climate change. • No data were generated that represent the growing conditions in other relevant maize growing regions outside the US.

In addition, more varieties carrying the transgenes should have been included in the field trials to see how the gene constructs interact with the genetic background of the plants. Based on the available data, no final conclusions can be drawn on the safety of the plants.

References:

EFSA (2019) Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-UK-2006-34) for authorisation of food and feed containing, consisting of and produced from genetically modified maize 3272. EFSA Journal;17(11): 5844, 15 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5844

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b. Food Safety Assessment:
Toxicology

As mentioned, the original opinion of EFSA was published in 2013. However, it was found to be non-conclusive due to missing data. In 2017, the EU Commission asked EFSA to finalise the risk assessment. The statement complementing the opinion was published in 2019 (EFSA, 2019).

While in the previous assessment (EFSA, 2013a), the old EFSA guidance was applied, there is no excuse why EFSA (2019), after being requested by the EU Commission in 2017, did not apply Implementing Regulation 503/2013, which has to be applied to all applications filed after December 2013.

At the same time, EFSA did not request a 90-day feeding study as requested by Implementing Regulation 503/2013 for the complementation of its assessment.

According to EFSA (2019) the presence of the thermo-tolerant AMY797E protein in maize 3272 might result in processed food (e.g. ready-to-eat-cereals) and feed (e.g. canned pet food or by-products of the wet-milling) being different from that produced from conventional maize. Under certain processing conditions (e.g. temperature, moisture, pH), the AMY797E protein might cause the hydrolysis of maize starch into dextrins, maltose and other oligosaccharides, changing the composition and texture of the processed commodities as compared to those produced from conventional maize. Therefore, more specific data, for example, including feeding studies with ruminants, would have been necessary.

As a result, the toxicological assessment carried out by EFSA is not acceptable.

References:

EFSA (2013a) Scientific Opinion on application (EFSA-GMO-UK-2006-34) for the placing on the market of genetically modified maize 3272 with a thermotolerant alpha-amylase, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. EFSA Journal 2013; 11(6):3252, 27 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3252

EFSA (2019) Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-UK-2006-34) for authorisation of food and feed containing, consisting of and produced from genetically modified maize 3272. EFSA Journal;17(11): 5844, 15 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5844

Allergenicity

As experts from Member States (EFSA, 2013b) as well as EFSA (2013a and 2019) point out, allergenicity is a highly relevant topic for the assessment of maize 3272. It is well known that alpha amylase can trigger allergic reactions, especially via the respiratory system.

We support the conclusion from EFSA that in this regard, safety could not be demonstrated by the applicant and substantial uncertainties remain regarding the allergenicity of the newly introduced protein for which safe use is not reported: “The GMO Panel notes that previous concerns on the potential capacity for de novo sensitisation of the AMY797E still remain not completely addressed. An aspect for concern is the potential of this protein to sensitise and provoke respiratory disorders in humans. Furthermore, elicitation of allergic reactions upon oral ingestion of maize 3272 in potentially sensitised individuals to the AMY797E protein is unlikely to occur but it cannot be excluded. In the case of animals, the available literature on allergy to alpha-amylases is more limited.”

Therefore, the opinion of EFSA remains inconclusive and the application for market authorisation for import, covering all uses for food and feed, cannot be approved.

References:

EFSA (2013a) Scientific Opinion on application (EFSA-GMO-UK-2006-34) for the placing on the market of genetically modified maize 3272 with a thermotolerant alpha-amylase, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG. EFSA Journal 2013; 11(6):3252, 27 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3252

EFSA (2013b) Application EFSA-GMO-UK-2006-34, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin

EFSA (2019) Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-UK-2006-34) for authorisation of food and feed containing, consisting of and produced from genetically modified maize 3272. EFSA Journal;17(11): 5844, 15 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5844

Others

Being aware of the specific genetic changes in maize 3272 i.e. establishing unprecedented metabolic pathways in the plants and producing artificial proteins with any record of safe use, EFSA, after being requested by the Commission in 2017, should have requested a full new dossier, taking into account the criteria of Implementing Regulation 503/2013 and also requesting much more specific data to demonstrate safety for health and the environment.

3. Environmental risk assessment

Any spillage from the kernels has to be monitored closely. EFSA and Syngenta completely overlooked that populations of teosinte are abundant in Spain and France; these have to be considered to be wild relatives that enable gene flow and potential spread of the transgenes throughout the fields and the environment (Trtikova et al., 2017). Without detailed consideration of the hazards associated with the potential gene flow from maize to teosinte and from teosinte to maize, no conclusion can be drawn on the environmental risks of spillage from the GE maize.

Further, as shown by Pascher (2016), EFSA has also underestimated the risks posed by occurrence of volunteers from maize plants. Finally, the actual ability of maize 3272 to persist and propagate in the environment after spillage was not assessed, for example, data on dormancy and survivability are missing.

Consequently, environmental risk assessment carried out by EFSA is not acceptable.

References:

Pascher, K. (2016) Spread of volunteer and feral maize plants in Central Europe: recent data from Austria. Environmental Sciences Europe, 28(1): 30. https://link.springer.com/article/10.1186/s12302-016-0098-1

Trtikova, M., Lohn, A., Binimelis, R., Chapela, I., Oehen, B., Zemp, N., Widmer, A., Hilbeck, A. (2017) Teosinte in Europe – Searching for the Origin of a Novel Weed. Scientific Reports, 7: 1560. https://www.nature.com/articles/s41598-017-01478-w

4. Conclusions and recommendations

The EFSA risk assessment is still not conclusive. No approval for import can be issued.