Maize MZIR098

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

Science of The Total Environment Volume 741, 1 November 2020, 139953

Review Pesticide residues in honey and their potential reproductive toxicity YasserEl-Nahhal

Quote of abstract: 'The results showed that 92 pesticide residues were found in honey samples from 27 countries. Six residues belong to class IA toxicity, eight residues belong to class IB toxicity, 42 residues belong to class II, 35 residues belong to class III and one residue belong to class IV toxicity.' Comment: 'In conclusion, consumption of honey as one of many food items contaminated with #pesticide residues may induce male and female reproductive toxicity in consumers.'

https://www.sciencedirect.com/science/article/pii/S0048969720334732?via%3Dihub ----------

PEER-REVIEWED STUDY: Glufosinate Ammonium (GLA), the herbicide sprayed on Bayer's herbicide tolerant Liberty Link GMO crops, has been found to induce austism-like symptoms in mice after their mothers were exposed to low doses - both pre and post-natal. The study raises fundamental concerns about the ability of current safety testing to assess risks of pesticide exposure during critical developmental periods. Another toxic herbicide in your GMO food.

Pre- and postnatal exposure to low dose glufosinate ammonium induces autism-like phenotypes in mice Quote of abstract: 'Glufosinate ammonium (GLA) is one of the most widely used herbicides in agriculture. As is the case for most pesticides, potential adverse effects of GLA have not been stud-ied from the perspective of developmental neurotoxicity. Early pesticides exposure may weaken the basic structure of the developing brain……'more see link and cause permanent changes lead-ing to a wide range of lifelong effects on health and/or behavior.'

Anthony Laugeray 1*, Ameziane Herzine1, Olivier Perche1,2, Betty Hébert 1, Marine Aguillon-Naury 3, Olivier Richard1,3, Arnaud Menuet1,3, Séverine Mazaud-Guittot 4, Laurianne Lesné4, Sylvain Briault 1,2, Bernard Jegou4, Jacques Pichon1,3, Céline Montécot-Dubourg1,3 and Stéphane Mortaud 1,3 1 Immunologie et Neurogénétique Expérimentales et Moléculaires – UMR7355 CNRS – 3b, Orléans, France 2 Département de génétique, Centre

Hospitalier Régional, Orléans, France 3 Université d'Orléans, Orléans, France 4 IRSET INSERM U 1085, Université de Rennes I, Rennes, France Edited by: Francesca Cirulli, Istituto Superiore di Sanità, Italy Reviewed by: Gregg Stanwood, Vanderbilt University, USA XiaomingWang, Duke University, USA *Correspondence: Anthony Laugeray, INEM INSERM – UMR7355 CNRS – 3b, rue de la Férollerie, Orléans 45071, France e-mail: alaugeray(a)yahoo.fr

https://www.frontiersin.org/articles/10.3389/fnbeh.2014.00390/full ----------

Induction of micronuclei and nuclear abnormalities in tadpoles of the common toad (Rhinella arenarum) treated with the herbicides Liberty (R) and glufosinate-ammonium Article in Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 769 · April 2014 with 268 Reads DOI: 10.1016/j.mrgentox.2014.04.009 · Source: PubMed Rafael C Lajmanovich o 34.3 o Universidad Nacional del Litoral • Mariana Cabagna o 23.71 o Universidad Nacional del Litoral • + 3

Andrés M Attademo o 32.31 o Universidad Nacional del Litoral • Celina M Junges Via Twitter: #Nuclear abnormalities in #herbicides #exposed #toad (R. arenarum) http://researchgate.net/publication/261920235_Induction_of_micronuclei_and_nuclear_abnormalities_in_tadpoles_of_the_common_toad_(Rhinella_arenarum)_treated_with_the_herbicides_Liberty…()_and_glufosinate-ammonium via @researchgate

Abstract, Quote:

Our study demonstrates that the commercial formulation of a GLA-based herbicide induces micronucleus formation in R. arenarum tadpoles, in contrast to the active ingredient. According to these results, the inert ingredients of the commercial formulation played an important role in the production of genotoxic damage in erythrocytes of amphibian tadpoles.'

Bt Toxin Kills Human Kidney Cells Cry1Ab biopesticide kills human cells at low doses as does Roundup herbicide Dr Eva Sirinathsinghji Excerpt from Water Carnival - the images of organisms discovered in Mae-Wan Ho's laboratory within a quantum jazz soundscape. Download the full video from the online store. A new study shows that low doses of Bt biopesticide CryA1b as well as the glyphosate herbicide, Roundup, kill human kidney cells. The Bt biopesticide conferring insect resistance and the glyphosate tolerance trait tied to the use of glyphosate herbicides account for almost all the GM crops grown worldwide. Bt crops already constitute 39 % of globally cultivated genetically modified (GM) crops, yet this is the first study that provides evidence on the toxicity of Bt protein in human cells.

https://www.i-sis.org.uk/Bt_Toxin_Kills_Human_Kidney_Cells.php ----------

Noorwegen: Høringsuttalelse av søknad om markedsføring av genmodifisert mais MZIR098 EFSA/GMO/DE/2017/142 Under EU forordning 1829/2003 Sendt til Miljødirektoratet av GenØk-Senter for biosikkerhet Oktober 2017 Quote: ' Pat and glufosinate-ammonium The maize event MZIR098 contains the transgene pat-08, which codes for the enzyme phosphinothricin acetyltransferase that makes this maize line tolerant towards glufosinate-

ammonium, a chemical toxic substance used in herbicide products. All herbicides based on glufosinate-ammonium are prohibited for usage in Norway due to its negative effects. Glufosinate-ammonium is harmful by inhalation, swallowing and by skin contact. Serious health risks may result from exposure over time (read more under the part on Herbicides, p.17).'

The GMO Panel of the Norwegian Scientific Committee for Food Safety (22) also writes that: 'There are many knowledge gaps related to assessment of adjuvants. Most of the immunologic adjuvant experiments have been performed using Cry1Ac. Whether the other Cry proteins have similar adjuvant properties is unknown'.

And; 'The possibility that Cry proteins might increase the permeability of the intestinal epithelium and thereby lead to 'bystander' sensitization to strong allergens in the diet of genetically susceptible individuals cannot be completely excluded.' http://genok.no/wp-content/uploads/2017/10/GenOk__H_142.pdf Wij zijn het eens met het commentaar van Noorwegen. (Denk aan 'Starlink' waar mensen ernstig last van kregen! 22. (VKM) NSCfFS. Summary of the health risk assessment of the adjuvant effects of Cry proteins from genetically modified plants used in food and fodder. In: Mikalsen A, Aasma Finne M, Haraldsen T, editors. Opinion of the Panel on Genetically Modified Organism of the Norwegian Scientific Committee for Food Safety. Oslo: Vitenskapskomitteen for Mattrygghet; 2012. p. 29. ----------

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Others

See for all our comments www.gentechvrij.nl

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4. Conclusions and recommendations

Not for human consumption! Not for animal feed!

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6. Labelling proposal

No. Not to place on the EU market and any other market! These comments are also from Stichting Ekopark, Lelystad, 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

9-07-2020. Supplement to our previous objections, and those from Stichting Ekopark, Lelystad: EFSA: 'The GMO Panel concludes that maize MZIR098 is as safe as the conventional counterpart and non-GM maize reference varieties tested, and no post-market monitoring of food/feed is considered necessary.' page 1, conclusion

Our comment:

How can reach this conclusion when there is no information about MZIR098? Moreover, a difference was in fact found (neutral detergent fibre (NDF), 3.4.6, Nutritional assessment of endogenous constituents).

EFSA does not assess the impact of spraying GLA or Bts. So your research is not complete. It is known that, in animal intestines, food sprayed with GLA reverts to the original GLA. METABOLISM OF 14C-GLUFOSINATE AND 14C-N-ACETYL-GLUFOSINATE IN LACTATING GOATS AND LAYING HENS.
http://www.inchem.org/documents/jmpr/jmpmono/v99pr06.htm

We still remember the issue with Starlink in 2000 only too well.

Wikipedia: 'StarLink is a genetically modified maize, containing two modifications: a gene for resistance to glufosinate, and a variant of the bacillus thuringiensis (Bt) protein called Cry9C.'

Product recalls

In 2000, Genetically Engineered Food Alert was launched by seven organizations (Center for Food Safety, Friends of the Earth, Institute for Agriculture and Trade Policy, National Environmental Trust, Organic Consumers Association, Pesticide Action Network North America, and The State PIRGs) to lobby the FDA, Congress and companies to ban or stop using GMOs.'

https://en.wikipedia.org/wiki/StarLink_corn_recall

EFSA:

'Since no specific consumption data were available on commodities containing, consisting of or obtained from MZIR098 maize grains, a conservative scenario with 100% replacement of conventional maize by the GM maize was considered. Consumption figures for all relevant commodities (e.g. corn flakes, sweet corn, popcorn, etc.) were retrieved from the EFSA Comprehensive European Food Consumption Database'. (EFSA consumption database).40

Corn oil was excluded from the assessment since no proteins are expected to be present in the oil.

3.4.6. Nutritional assessment of endogenous constituents

The intended traits of maize MZIR098 are herbicide tolerance and insect resistance, with no intention to alter nutritional parameters. However, neutral detergent fibre (NDF) in treated grains was significantly different from its conventional counterpart and showed a lack of equivalence with the set of non-GM reference varieties (Section 3.3.6). The biological relevance of NDF, the role of maize as contributor to its total intake and the magnitude and direction of the observed change were considered during the nutritional assessment.' Pag. 19 EFSA SO

Organisation: Gentechvrije Burgers
Country: The Netherlands
Type: Individual

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a. Assessment:
6. Labelling proposal

This is my only comment: label it at least clearly on the products in the shops, so that I as a consumer can decide wether of not I choose to be poisoned by this kind of manipulated maize. I will never give it my children, because I hope they will grow up as a normal adult, safe and sound, not as a victim of moneymakers. There are natural alternatives!

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

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a. Assessment:
Others

21-07-20. Follow-up to our previous objections and those issued by the Lelystad-based Stichting Ekopark.

Please read these old letters, they are very much worth reading! Reproduced with permission.

Comments on article from de Volkskrant newspaper: *Landbouwer blieft geen genmais meer* [Farmer please no more GM maize] Date 10.03.2001

Amsterdam, 27 March 2001

Rik Nijland, ‘de Volkskrant’, Postbus 1002, 1000 BA Amsterdam

Dear Mr Nijland,

Regarding the article: *Landbouwer blieft geen genmais meer* [Farmer please no more GM maize].

Your article in de Volkskrant of 10.03.2001 was recently brought to my attention. I believe I have to write to you to clarify the situation.

One comment: if there really are too many weeds (in the maize field), then you in any case need less herbicide, because the maize plant has an umbrella effect on account of its larger leaves.

Aventis refers to the effect of Liberty on the surrounding flora and fauna, but momentarily forgets ‘people’ who have to deal with e.g. the effects of ‘drift’ (and the herbicide residues in the food chain!).

It is inaccurate to talk about ‘the product Liberty’. It should really be: the active substance in Liberty, namely GLA technical (phosphinothricine or glufosinate ammonium), a product - like Roundup - developed from a phosphorus compound. This ‘technical’ GLA is the active substance in other herbicides produced by Hoechst, including for example Basta, Finale, Finale SL (including SL14). All these herbicides have the active substance GLA ‘technical’ in common.

Various ‘excipients’, such as propanediol, anti-foaming agents, etc., and (and this is serious) alkyl ether sulphate (AES), which affects the cardiovascular system (vasodilation, vasoconstriction - depending on the dose - blood pressure, etc.), are added to the active substance. The product as such - the commercial product - is called the ‘formulation’. GLA technical is often used in laboratory tests.

Basta, for example, contains 30% AES. And that’s a big deal.

About six months ago, I noticed that the Dutch Pesticides Act mentions only the ‘active substance’ and its metabolites, and not the other substances in the consumer product, the formulation. (For the record: I found only one mention in the Act of ‘excipients’.)

I have asked that the words: ‘the added substances, such as surfactants and solvents, together known as: the formulation’ be added to the Act.

At the beginning of April this is to be discussed in the Standing Parliamentary Committee for Agriculture, Nature and Food, and I have tried to obtain information on the additions to the active substance (this also applies to other herbicides) but this is reserved for the *College Toelating Bestrijdingsmiddelen (CTB)* [Pesticide Authorisation Committee]; however, guidelines prevent the exact composition from being communicated. By a process of reduction and deduction, I have arrived at 60% of known substances in Basta. The *Rijks Kwaliteitsinstituut voor Land- en Tuinbouwproducten (RIKILT)* [Institute for Food Safety]

does not know the composition of the herbicides either. This is serious. This is why I don't want any Liberty (or other herbicides!).

Herbicides are acetylated in the plant and deacetylated in the gut, and thus the original herbicide is reconstituted.

It is claimed that it is completely broken down. But this is not the case. 6% is not broken down and has a half-life of six minutes. The other 94% has quite some time to pass through the gut wall. No chronic toxicity tests have ever been conducted! I have some valid information indicating that residues are found in meat, milk and eggs.

All this is why I appealed to the *College van Beroep voor het Bedrijfsleven* [Trade and Industry Appeals Tribunal] against the CTB's decision granting a licence for the application of Liberty (until June 2003), because I think the public has the right to learn about the substances in herbicides that are damaging to health. This is not the place for obligations of confidentiality!

This is why I am so happy about a major case being examined by the *Landsadvocaat* [State Advocate] The amazing thing is that nobody has previously stuck their neck out on this! For example, I have submitted around 55 objections, commentaries and appeals to the Council of State.

My hair stood on end when I read the Opinion of the Scientific Committee on Plants on the authorisation of GA 21 maize applied for by Spain. So far as I can see, they are relying on feed tests from 1986, and an analysis from the same year, and 'including' them in the current assessment. How is that possible? That simply can't be!

Yours sincerely, L. Eijsten PS: My last letter to you was dated 16.8.00!! It concerned two serious instances of misrepresentation.

https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/commentaar-op-volkskrantartikel-landbouwer-blieft-geen-genmais-meer/

'Continuation of comments on the article '*landbouwer blieft geen genmais meer*' from de Volkskrant': Consumer confidence; continuation of comments on the article '*landbouwer blieft geen genmais meer*' from de Volkskrant'

The letter below was also submitted for publication to de Volkskrant.

Amsterdam, 16 April 2001

Rik Nijland, 'de Volkskrant', Postbus 1002, 1000 BA Amsterdam

Dear Mr Nijland,

Consumer confidence

On 27 March 2001, I wrote to you in response to the article '*landbouwer blieft geen genmais meer*' that appeared in the newspaper on 10 March 2001, but unfortunately I have not had any reply. An article in the paper of 4 April last by Mr Trommelen struck me in particular.

In the report by ‘experts’ from alternative and ordinary agriculture - who are those experts? Are they ‘manufactured’ experts, as a result of a study commissioned by the Ministry for Economic Affairs and written by Schenkelaars Biotechnology, entitled ‘*Risico’s van genetisch gemodificeerde organismen*’ [Risks of genetically modified organisms], on the basis of CCRO research programmes from 1991 to 1998, the aim being ‘to gain and deepen the understanding that policy-makers and scientific advisers need in order to assess the potential risks of genetically modified organisms’, in the words of Professor P.G. de Haan in the foreword? They were seeking a short-term risk assessment and it was impossible to say that major risks had been identified - or they had been overlooked. But what about long-term risks?

In the piece about the need for knowledge in order to be able to conduct a risk analysis, the fact that a literature review is being conducted was mentioned 5 (five) times. Analyses had been conducted, mathematical models developed, the possible consequences simulated, experience gained using the safety assessment of field trials, etc., etc. All relating to the agricultural impact.

And people? Adverse health effects? Is there a decision tree for those too? No doubt the policy officers at the Ministry of Economic Affairs will have an answer to that too! Let us hear it! (I see that the Ministry of Health, Welfare and Sport did not take part in this study).

The report from the Ministry of Agriculture, Nature and Food Quality states: ‘the risk of statutory ‘doses of pesticides’ being exceeded ...’ - should that not be:

the standards for pesticide residues referred to in the Pesticides Act? The report is said to show (first paragraph of your article) that the food safety of common products is guaranteed. By whom? Bla, bla - which insurance provider? Government?

Standards have been set for residues in food, e.g. for glufosinate in potatoes it is 0.5 mg/kg (ppm), for glyphosate in wild mushrooms 50 ppm, in soybean 20 ppm, in pigs’ kidneys 0.5 ppm, in cows’, goats’, and lambs’ kidneys 2 ppm, etc. The latest update from the EPA in the USA gives the following limits for glyphosate, for example: grain 20 ppm, sugar-beet pulp 25 ppm, rapeseed meal 15 ppm, rapeseed 10 ppm, etc., all without AMPA.

And the limit for glyphosate residues in the kidneys of cattle, goats, hogs, horses, sheep is 4 ppm, and for the liver of these animals 0.5 ppm. The liver and kidneys of poultry (a lot of which are eaten) are permitted to contain 0.5 ppm of glyphosate residues.

All this is calculated on the basis of the lifetime consumption of a ‘normal’ person. You can’t go overboard then! Very small children, who have to eat more than would be normal per kg/own body weight, don’t get a very good deal.

HOWEVER ... the standards are based on the active substance, i.e. glufosinate technical and glyphosate technical, and not on the added substances which together constitute the formulation. I have a lot of documents on this. In the USA, the EPA thus sets standards that are also important for us, because of imported products, such as animal feed.

As you have already stated, the substances in the formulation are more harmful than the active substance alone. This is true of Finale, Liberty, Basta and indeed Roundup. The active

substances are often used in laboratories. Their harmfulness for e.g. skin, eyes, breathing, etc. is indicated using classes: I, II, III and IV, class I being the most toxic.

There is no misunderstanding, the EPA data on this are clear. For example, Basta - and therefore Liberty too probably - contains 30% AES (alkyl ether sulphate) which has cardiovascular effects and is class I toxic (Iskandarova).

The College Toelating Bestrijdingsmiddelen (CTB) [Pesticide Authorisation Committee] is supposed to analyse all additives before granting approval!

But what do I read in the Pesticides Act, on pages 143 and 144 (part 2)?

'It is generally sufficient to perform these tests with the main formulation type to be authorised'. What do the experts say now? Either insufficient analyses have been done or the Government is NOT concerned about the harmfulness. Which is all to the detriment of the consumer - i.e. all of us.

You can consult the documents in question at any time at my place.

Yours sincerely, L. Eijsten.

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

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a. Assessment:
5. Others

22.07.2020 Improvement of text of 21.07.2020. Also sent on behalf of Stichting Ekopark, Lelystad

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As you have already stated, the substances in the formulation are more harmful than the active substance alone. This is true of Finale, Liberty, Basta and indeed Roundup. The active substances are often used in laboratories. Their harmfulness for e.g. skin, eyes, breathing, etc. is indicated using classes: I, II, III and IV, class I being the most toxic.

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Yours sincerely, L. Eijsten.

https://www.gentechvrij.nl/dossiers/archief-lily-eijsten/consumentenvertrouwen/

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

Glufosinate ammonium

In GM maize, the herbicide GLA is converted into acetylated glufosinate ammonium which does not metabolise further in the plant but is stored in the plant tissue.

This product is thus definitely present in the plant when used as feed, as a result of the genetic manipulation.

Deacetylation of this metabolite

The issue is that acetylated glufosinate - a metabolite (which occurs only in the manipulated plant) - is again deactivated in the gastrointestinal tract of rats, goats and chickens (the test animals used), so that the herbicide is again released in the gut and enters the human consumption chain in contaminated milk, eggs and meat.

GLA toxicity tests suggest that in developing embryos GLA activates the apoptosis gene in the developing brain
(https://www.sciencedirect.com/science/article/abs/pii/S0304394097133304).

Further studies show that the herbicide has many unexpected and unpleasant effects, particularly at very low doses (Prof. Fujji, Tokyo, behavioural abnormalities in young mammals,
https://www.researchgate.net/publication/244754595_Alterations_in_the_Response_to_Kainic_Acid_in_Rats_Exposed_to_Glufosinate_Ammonium_a_Herbicide_during_Infantile_Period

... Rats exposed to low doses of glufosinate in the first week of life were tested at six weeks and found to have an enhanced response to kainic acid, which stimulates glutamate receptors in the brain [342]. Glufosinate exposure of mouse dams has been shown to induce autistic-like behaviour in the pups [343].

Copied with permission from a letter from Ms L. Eijsten, Amsterdam.

Others

23.7.20 Next supplement to our previous objection. Also sent on behalf of Stichting Ekopark, Lelystad.

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

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a. Assessment:
Others

26.7.20 Supplement to our previous objections

A question and a look back in time:

Members of the Scientific Committee on Plants (SCP), can you not just prohibit this GM maize like you did in 1998 with the GM potatoes Apriori and Apropos, so that they could not be planted in trial fields?

7. OVERALL ASSESSMENT

The Committee is of the opinion that insufficient risk assessment has been carried out with respect to specific genes or gene elements (some of unknown function) incorporated into the GM lines under the control of bacterial promoters. This is particularly the case for the nptIII gene, which confers resistance to amikacin, a clinically important antibiotic. Without an adequate risk assessment of the potential consequences of horizontal gene transfer from the GM plants to humans, animals and the environment, the Committee considers that it is not possible to fully assess the safety of the transgenic potato lines in question under Directive 90/220/EEC.

Quote of:

Opinion of the Scientific Committee on Plants regarding submission for placing on the market of genetically modified high Amylopectin potato cultivars apriori and apropos notified by Avebe (Notification C/NL/96/10) - SCP/GMO/044 - (Opinion adopted on October 2, 1998)

1. TITLE

Application for consent to place on the market genetically modified high amylopectin potatoes (Notification C/F/95/12-01/B)

https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scp_out24_en.pdf

AVEBE nonetheless wanted to plant them in the Netherlands, and wanted to use an authorisation held by a different company (Hettema) to do so. Jan Pronk, the former Minister of Housing, Spatial Planning and the Environment (VROM) put a stop to that.

Ms Eijsten and Mr van der Meulen (among others) were bold enough, as concerned members of the public in Amsterdam, to help ensure that the trial fields were not permitted to be established on Dutch land, by lodging objections with the then Minister of VROM and appealing to the Council of State. The result was a moratorium.

https://www.trouw.nl/nieuws/avebe-teelt-ondanks-verbod-toch-gen-pieper~b1b75fd3/

Statement of objection

GRANTING AUTHORISATION FOR THE CULTIVATION OF GENETICALLY MODIFIED POTATO VARIETIES

'Objection to the granting of authorisation for the cultivation of genetically modified potato varieties'; concerns the potato varieties Apriori and Apropos, with the genes KGZ and nptII being expressed. The applicant is Hettema Zonen Kweekbedrijf BV.
_____ Amsterdam, 11 January 2000

BGGO 99/13

BY REGISTERED MAIL

To: Ministry of VROM

Directoraat-General Milieubeheer [Directorate General for Environmental Management]

Directie Stoffen, Veiligheid, Straling [Directorate for Substances, Safety, Radiation] ic 655

attn. P.J. van der Meer

Postbus 30945

2500 GX THE HAGUE

Dear Sirs,

This concerns the application for the planned introduction into the environment of GMOs, i.e. the application for authorisation to propagate, cultivate and process potato varieties whose starch composition has been genetically modified (two specific potato varieties, called Apriori and Apropos in the advisory report of 12.1.99 from the *Commissie Gentechnische Modificatie (COGEM)* [Commission on Genetic Modification] to be granted to Hettema Zonen Kweekbedrijf BV, reference No BGGO 99/13. Genes to be expressed: as-KGZ and nptII.

We hereby lodge an objection to the granting of authorisation BGGO 99/13, for the following reasons:

=== Firstly:===

This introduction into the environment is a small-scale 'trial'. Class IV. As arbitrarily determined by the COGEM on 18.5.99 after a meeting on 23.3.99, LESS information would need to be known for the purposes of the risk assessment on account of the small scale of the trial, and because there is generally little information already available in the case of initially small-scale trials. Moreover, if new information should come to light and risks become clear, authorisations can be withdrawn in response.

We believe that if information on risks 'is available' it should already be taken into account as part of the assessment at this stage, even if it would arbitrarily play a role only in a subsequent large-scale trial. In this draft decision No 99/13, VROM wrongly failed to sufficiently evaluate risks and objections (which had come to light through large-scale experiments and an application for market authorisation (AVEBE, ref. C/NL/96/10)). The simple fact that these risks were known should have resulted in a thorough evaluation.

A discussion of the problems as they emerged from the subsequent Opinion of the Scientific Committee on Plants - meeting of 2.10.98 SCP/GMO/044 (enclosed) - would certainly have been appropriate.

We are referring to the unintended presence of the TOTAL vector in the potato, including origin of replication and a number of genes, including the antibiotic-resistant gene nptIII - resistant to Amikacin, Kanamycin, Neomycin, Paromomycin, Ribostamycin, Lividomycin, Butirosin, Gentamicin, Isepamicin) and, *inter alia*, TetR for Tetracycline Resistance Repressor, with bacterial promoters.

We object to this insufficient risk evaluation and the failure to consider, to all intents and purposes, the unintended insertions present by arbitrarily deciding that this was not necessary for a class IV trial!

=== Secondly:===

As it explicitly states in the application for market authorisation for this potato (see above), VROM bases its findings mainly on the genes to be expressed.

One of those is the antibiotic-resistant gene nptII, which is otherwise irrelevant as far as the intended purpose is concerned and should really be removed (the first objection concerned, among other things, a different antibiotic-resistant gene that is NOT expressed).

Currently (2000) it is widely believed that the presence of antibiotic resistant genes is undesirable, even if they are not expressed. This view is also represented in the COGEM.

Various governments prohibit the import of GMOs with these genes, e.g. Austria, Norway, etc. Professional bodies such as the British Medical Association have made their opposition to antibiotic-resistant marker genes clear. At European regulatory level, these genes are being 'phased out', even in products that have already been AUTHORISED.

In stark contrast to 2000, VROM's findings are based mainly on a report from 1991 (first edition) that was commissioned by VROM. That report really only address the ‘safety’ of nptII (Kanamycin resistance) as a marker gene, in the sense that plants with this gene would not have any selective advantage in the environment and thus could not become an ineradicable weed.

The way that VROM refers to the report suggests that it is health aspects that are being considered.

THIS IS PARTICULARLY MISLEADING.

There are many aspects that need to be looked at in a risk assessment of antibiotic-resistant marker genes.

* In September 1998, the EPA provided an inventory of these aspects and the various opinions of them in a ‘Guidance Document for Industry’, also providing a bibliography.

* As regards the nptII gene, the VROM report (1991) assumes a spectrum of two resistances (neomycin and kanamycin).

* The 1998 Guidance Document indicates a spectrum of SIX.

* The 1991 VROM report states that horizontal gene transfer from plant to bacteria is only theoretically possible and never demonstrated.

* In 1994, Kirsten Schlüter demonstrated the transfer from potato to the bacteria Erwinia.

* IN 1998, KIRSTEN SMALLA, of Braunschweig, DEMONSTRATED horizontal gene transfer FROM SUGAR BEET TO THE BACTERIA ACINETOBACTER. Report enclosed.

* In 1999, Dany Mercer published the transfer of PLASMID DNA TO STREPTOCOCCUS IN HUMAN SALIVA. * TRANSFER IS THEREFORE NOT JUST THEORETICAL!!

However, the idea that such transfer might be irrelevant, given the high rate at which antibiotic resistance occurs naturally, is highly debatable.

* Firstly, a natural background is not always and consistently found, and little has been published on that natural background.

* Secondly, the rate of occurrence of antibiotic resistance can be determined only using cultivable bacteria (on a culture medium), and by no means all bacteria that occur in soil samples are cultivable.

* Thirdly, determining background resistance concerns phenotypic resistance (manifestation) and not specific genotypic (genetic characteristics) resistance; nor do we know whether resistance depends on a gene in the chromosome of the bacteria or on a gene in a plasmid.

=== Thirdly: ===

To summarise, we object to the occurrence of an expressed antibiotic-resistance gene and to the unintentional presence of an antibiotic-resistant gene that is NOT expressed.

THIS PUTS AT RISK THE PURPOSES FOR WHICH ANTIBIOTICS CAN BE USED. In the case of the nptII gene, we need to stop new applications of the gene.

In the case of the nptIII gene that is now emerging - and which has not really ever been discussed in the Netherlands - we must not even think about tolerating it, not least because it contains in its spectrum (9, listed on page 2) the antibiotic Amikacin, which many consider to be extremely important. The Opinion of the Scientific Committee on Plants refers to this.

The report on Amikacin drawn up by the *Rijksinstituut voor Volksgezondheid en Milieu* (RIVM) [National Institute for Public Health and the Environment] on behalf of the Dutch authorities (August 1999) used specific Dutch data. Did they forget that potatoes are also intended to be exported? Other countries won't be so happy with the potato in question.

Co-products of the potato can give rise to resistant pathogens through animal feed.

The RIVM report describes the importance of Amikacin in the fight against TB, a sickness that is becoming more prevalent.

We will close with a letter that was published in the newspaper 'Agrarisch Dagblad'; it speaks for itself. Finally, we would like to point out that there is no basis to assume an economic importance for the genetically modified amylopectine potato. You are supposed to be able to accept some risk in return for an expected gain (risk analysis).

There is already a mutant potato with the desired characteristics. Those characteristics can be achieved through traditional plant improvement of any variety without any risk at all. It is a major puzzle why this has not already been done. No authorisation as applied for must be granted for the genetically modified potato. J. van der Meulen, L. Eijsten.

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

== See also ==

* Kanamycin report critically reviewed

* media: *COGEM standpunt toelaatbaarheid van antibioticum resistentiegenen in transgene planten.pdf* [COGEM standpoint on admissibility of antibiotic-resistant genes in transgenic plants]

Ms Lily Eijsten was born in 1916 in Amsterdam. She died in May 2009.

She was:

• Executive secretary with various companies, including Stork Hijskranen • 1946/47 United Nations

• 1961 Freelance photographer

• including working as in-house photographer for the Hilton Hotel, Amsterdam

Following an unfortunate event in the Beatrixpark [in Amsterdam], when Lily was sprayed with the herbicide glufosinate ammonium (Finale SL14), and an occasion a year later when she came into contact with drift from the same herbicide, drift that remains in the air for much longer than many people know, Lily became allergic to this herbicide, an allergy that did not fade over the following years and manifested itself in ever more serious ways (including a leg that would not heal, and cancer); Lily then began working with Mr Han van der Meulen, a chemical literature researcher, to look into the first generation of genetically engineered crops that were made to resist various herbicides, including glufosinate ammonium and glyphosate, another much used herbicide.

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 regard to the 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'.

Environmental stress can indeed cause unexpected patterns of expression in the newly introduced DNA (see, for example, Trtikova et al., 2015). There is plenty of evidence that drought or heat can significantly impact the content of Bt in the plant tissue (Adamczyk & Meredith, 2004; Adamczyk et al., 2009; Chen et al., 2005; Dong & Li, 2006; Luo et al., 2008; Then & Lorch, 2008; Trtikova et al., 2015). Therefore, to assess gene expression, the plants should have been grown under conditions of severe drought, with and without irrigation, as well as compared to more moderately severe climate conditions. All relevant bioclimatic regions should have been taken into account.

Experiments under controlled and defined conditions should have been performed to gather sufficiently reliable data on gene expression and functional genetic stability. This would have to include exposure of the plants to all biotic or abiotic stressors which are relevant but which might have been absent in the field trials. The generation of these data should have taken all relevant patterns of herbicide application and the application of the complementary herbicides as well as various genetic backgrounds into account.

However, the data provided do not represent the conditions in which the plants were grown: (i) no extreme weather conditions which could be expected due to climate change were taken into account; (ii) the field trials did not take current agricultural management practices into account to the necessary extent (see below); (iii) the field sites were only in the US; no other

field trials in other GE maize producing countries (like Argentina or Brazil) were used to produce relevant data.

Therefore, the range of data provided for assessing genome x environment interactions is very limited and not representative of the conditions under which these crops will be grown. In addition, gene expression data was only provided for one variety. These poor data sets do not allow sufficiently reliable conclusions to be drawn on the expression of the additional gene constructs.

The need for more data is further underlined by the differences in MZIR098 gene expression compared to expression data from similar constructs of other events. Furthermore, the expression of mCry3A follows a strange pattern with pollen reaching extremely high concentrations. This alone should have highlighted the need for a much more detailed investigation. For example, the event should have been tested not just in one variety, but also in other genetic backgrounds in order to determine whether the pattern of gene expression is impacted.

It also has to be taken into account that the process of genetic engineering led to open reading frames (ORFs) that may give rise to biologically active molecules. One ORF is discussed in more detail because it might generate allergenic proteins. However, all potentially active molecules emerging from the genetic changes should undergo detailed assessment. This includes gene products besides proteins, such as dsRNA. Since detailed assessment is missing, uncertainties remain in regard to the risks of biologically active substances arising from the method of genetic engineering and the newly introduced gene constructs.

The data provided do not allow reliable conclusions to be drawn on gene expression and functional stability.

References:

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

In regard to the compositional analysis and agronomic traits and the characteristics of the GE phenotype, Implementing Regulation 503/2013 requests the assessment of whether the expected agricultural practices influence the outcome of the studied endpoints. According to the Regulation, this is especially relevant for herbicide resistant plants. Furthermore, the different sites selected for the field trials need to reflect the different meteorological and agronomic conditions under which the crop is to be grown.

Field trials for the compositional and agronomic assessment of maize MZIR098 were conducted in the US only at 8 (9) sites, but not in other relevant maize growing areas, such Brazil, Argentina, Paraguay or Uruguay. Data from only one year (2013) were used to generate data on the relevant meteorological conditions under which the plants may be grown. Due to ongoing climate change, the weather conditions at the same sites can be vastly different from year to year, and therefore data from just one year cannot be regarded as conclusive. Furthermore, data from the US cannot represent all relevant environmental impact factors from regions, such as Argentina or Brazil. Additional data from other sites and for more than one year would have been needed to draw conclusions on the impact of different meteorological and agronomic conditions on the measured endpoints and fulfill the requirements of Implementing Regulation 503/2013.

However, EFSA failed to request further studies, e.g. field trials lasting for more than one season and field sites in other maize growing regions. Furthermore, no data were generated representing more extreme environmental conditions, such as those caused by climate change.

In addition, experiments under controlled and defined conditions should have been performed to gather sufficiently reliable data on gene expression and functional genetic stability. This would have to include exposure of the plants to all relevant biotic or abiotic stressors which might have been absent in the field trials. The generation of these data should have taken all relevant patterns of herbicide application and the application of the complementary herbicides into account. Various genetic backgrounds should also have been tested to assess their impact on plant composition and phenotypical characteristics of the event.

However, no such data were made available. Therefore, no conclusion can be drawn on comparative analysis.

Furthermore, as the complementary herbicide, glufosinate, was not used in high doses as may be expected in the case of increasing weed resistance. Therefore, EFSA should have requested the applicant to submit more recent data from the field trials, also taking into account the highest dosage of glufosinate that can be tolerated by the plants, including repeated spraying. In response to comments made by Member States (2020b), EFSA simply stated that 'for the experimental treatments to be comparable between different locations, the application rate should not differ too strongly between them.' This statement is inadequate. To fulfill the requirements of Implementing Regulation 503/2013, additional data should have been requested to compare not only the treated and the non-treated plants, but also data allowing comparison within the group of treated plants. These data are necessary to conclude on the impact of the herbicide applications on gene expression, plant composition and the biological characteristics of the plant as requested by the Regulation. However, no such data were made available.

In addition, there were several significant findings on differences in composition, which should have been investigated in more detail and under the full range of expected agricultural and bioclimatic conditions, including various genetic backgrounds. These investigations should also include so-called 'omics' (transcriptomics, proteomics, metabolomics).

Further, experts from member states pointed to the fact that an analysis for many important maize constituents was missing, e.g. lutein, zeaxanthin, phytosterols, tocopherols or tocotrienols (EFSA, 2020b).

In summary, much more data would be needed to conclude on the comparative analysis and develop a sufficiently defined hypothesis on risk assessment in regard to the phenotypical characteristics and the compositional analysis of the maize.

References:

EFSA (2020b) Application EFSA-GMO-DE-2017-142, Comments and opinions submitted by Member States during the three-month consultation period, Register of Questions, http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?unit=GMO

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b. Food Safety Assessment:
Toxicology

Implementing Regulation 503/2013 requests: 'Toxicological assessment shall be performed in order to: (a) demonstrate that the intended effect(s) of the genetic modification has no adverse effects on human and animal health; (b) demonstrate that unintended effect(s) of the genetic modification(s) identified or assumed to have occurred based on the preceding comparative molecular, compositional or phenotypic analyses, have no adverse effects on human and animal health;'

'In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that: (a) the genetically modified food and feed has no adverse effects on human and animal health;'

In this regard, the mixed toxicity assessment is most relevant: it is known that maize produces protease inhibitors, which can delay the degradation of the Bt toxins and enhance their

toxicity in a synergistic way (MacIntosh et al., 1990). This may also be the case if the maize is mixed into a diet along with other plants such as soybeans, which produce an even higher amount and wider range of protease inhibitors (Pardo-López et al., 2009).

In addition, diets will typically contain residues from spraying with the complementary herbicide, which may also act in a synergistic way and enhance toxicity of the Bt proteins (since specific experimental data are missing, for general overview see Then, 2010).

It is evident that Bt toxins can survive digestion to a much higher degree than has been assumed by EFSA: Chowdhury et al. (2003) as well as Walsh et al. (2011) have found that Cry1A proteins can frequently and successfully still be found in the colon of pigs at the end of digestion when they were fed with Bt maize. This generally shows that Bt toxins are not degraded quickly in the gut and can persist in larger amounts until digestion is completed; there is therefore enough time for interaction between various food compounds.

Further, due to the various modes of action already described in literature (Hilbeck & Otto, 2015; Vachon et al., 2012) in particular in combination with additive or synergistic effects that cause enhanced toxicity, Bt toxins can be much lower in their selectivity than assumed (Then, 2010). Therefore, a much broader range of organisms might be affected. This observation may also be relevant for food and feed if exposed to the mixed toxicity of maize MZIR098.

In general, it is known that not all modes of action of the insecticidal proteins produced in the plants depend on the specific mechanisms occurring only in the target insect species. Only very few Bt toxins (especially Cry1Ab, for overview see, Then, 2010) were investigated in more detail in regard to their exact mode of action, and there is no data on the Bt toxins produced in the maize. On the other hand, several publications exist showing the effects of Bt toxins in mammals: some Cry toxins are known to bind to epithelial cells in the intestine of mice (Vázquez-Padrón et al., 1999, Vásquez-Padrón et al., 2000). As far as potential effects on health are concerned, Thomas and Ellar (1983), Shimada et al. (2003) Huffmann et al. (2004), Ito et al. (2004), Mesnage et al. (2013) and Bondzio et al. (2013) show that Cry proteins could potentially have an impact on the health of mammals. Two recent publications (de Souza Freire et al., 2014; Mezzomo et al., 2014) confirm hematoxicity of several Cry toxins, including those being used in genetically engineered plants such as Cry 1Ab and Cry1Ac. These effects seem to occur after high concentrations and tend to become stronger after several days. Such observations call for the study of effects after long-term exposure to various dosages.

Therefore, it should be acknowledged that, in regard to toxicology or potential combinatorial effects, the negative impacts of Bt toxins on human and animal health cannot be excluded a priori. Bt toxins have several modes of action and are altered in their biological quality; therefore, they are not identical to their natural templates (Hilbeck & Otto, 2015). It should not be overlooked that the mode of action of mCry3A as well as eCry3.1Ab was changed to become more effective in pest insects, therefore data from the naturally occurring Bt toxins are not sufficient. However, as shown in the outcome of the literature review conducted by the applicant (see above), there is a general lack of peer reviewed data on toxicology in regard to the newly synthesized Bt toxins produced by MZIR098.

In this context, there are very general gaps in risk assessment: if new toxins (insecticides) are introduced into the food chain, pesticide regulation requests a defined range of data to assess

toxicity, long-term persistence and effects on complex endpoints, such as the immune system and the reproductive system. However, it appears that no such data were made available in the case of the newly synthesized Bt toxins. These toxins were never assessed in accordance with EU pesticide regulation. Instead, in this case, the experts on the GMO Panel have taken it upon themselves to act as pesticide experts. This strongly goes against the GMO and pesticide regulation currently established in the EU.

Some of the few data provided by the applicant seem to indicate that the toxins produced in the plants are comparable to other variants of Cry3 toxins. However, as shown by the comments of the experts from member states (EFSA 2020b), these findings can be disputed since specific data on toxicity are missing and the testing methods are deficient.

Further, according to member states experts (EFSA 2020b), the analysis of the available bioassay data indicates that synergistic effects between eCry3.1Ab and mCry3A cannot be excluded: 'as the given LC50 value for a combination of eCry3.1Ab and mCry3A in a ratio 1.89:1 was estimated to be 0,61 µg/g diet and is substantially lower than estimates for each of the single toxins (e.g. 3.96 µg mCry3A /ml diet in TK0025294 and 9,5 µg eCry3.1Ab/g diet in TK0057497).' However, no specific experimental data on mixed toxicity were provided. No experimental data were provided on the synergistic and additive effects as described above, which can cause higher toxicity and lower selectivity.

In consequence, specific experimental data are indispensable for any conclusion to be drawn on risks to, e.g. the immune system, inner organs and the intestinal microbiome.

To some extent these questions could be answered by conducting animal feeding studies. They would allow the examination of the whole plant material, including, for example, protease inhibitors and residues from spraying. Therefore, we disagree with EFSA that subchronic feeding studies would not be needed. However, we do agree with comments requesting more data that would allow more specific hypotheses, e.g.: (i) substantial delay in the degradation of the Bt toxins in the plant material which might enhance adjuvant effects; (ii) lowered selectivity of the Bt toxins if combined with residues from spraying with glufosinate; (iii) significant changes in the intestinal microbiome due to exposure to the plant material. Many significant findings were reported from the 90-day feeding study, but without additional data it is difficult to interpret them correctly.

Overall, the data made available do not allow sufficiently reliable conclusions to be drawn on the safety of food and feed products derived from the maize.

In this regard, it also has to be considered that the concentration of the insecticidal proteins will be enriched in processed products such as gluten meal; the concentrations can also reach much higher concentrations compared to the kernels.

EU legal provisions such as Regulation 1829/2003 (as well as Implementing Regulation 503/2013) state that 'any risks which they present for human and animal health and, as the case may be, for the environment' have to be avoided. We conclude that the health risk assessment performed by EFSA is not sufficient to fulfill this requirement.

References:

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Allergenicity

Implementing Regulation 503/2013 requests: ‘In cases when known functional aspects of the newly expressed protein or structural similarity to known strong adjuvants may indicate possible adjuvant activity, the applicant shall assess the possible role of these proteins as adjuvants. As for allergens, interactions with other constituents of the food matrix and/or processing may alter the structure and bioavailability of an adjuvant and thus modify its biological activity.’

‘In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that: (a) the genetically modified food and feed has no adverse effects on human and animal health;’

There are several studies indicating that immune responses, such as adjuvanticity in mammals, can be triggered by Bt toxins and need to be considered: in this context, it is also a matter of concern that Bt toxins can cause non-allergic immune responses, such as adjuvant effects (Finnamore et al., 2008; González-González et al., 2015; Ibarra-Moreno et al., 2014; Jarillo-Luna et al., 2008; Guerrero et al., 2004; Guerrero et al., 2007; Legorreta-Herrera et al., 2010; Moreno-Fierros et al., 2000; Moreno-Fierros et al., 2013; Rubio-Infante et al., 2018; Rubio-Infante et al., 2016; Vázquez-Padrón et al., 1999) which might contribute to chronic disease or enhance immune responses. It is widely acknowledged that more data are needed

on adjuvant and other potential immune effects caused by Bt proteins (see, for example, Rubio-Infante, 2016; Santos-Vigil et al., 2018).

The synergistic effects described by MacIntosh et al. (1990) and other authors such as Pardo-López et al., 2009, causing higher toxicity of the Bt toxins are also relevant for risk assessment in regard to the immune system: the combination with protease inhibitors is likely to be associated with a delay in the degradation of the Bt toxins after consumption. This delay in degradation will lead to the intestinal immune system being exposed to Bt toxins for an extended period of time and might therefore trigger or enhance chronic inflammation, including allergies.

In this regard, it has to be further considered that the concentration of the insecticidal proteins will be enriched in processed products such as gluten meal and germ, and that they can reach much higher concentrations compared to the kernels.

In its risk assessment, EFSA did not consider that under real conditions and, contrary to what is suggested by the findings of in-vitro studies, Bt toxins will not be degraded quickly in the gut but are likely to occur in substantial concentrations in the large intestine and faeces (Chowdhury et al., 2003; Walsh et al., 2011). In addition, if mixed into a diet with soybeans, the immune system responses caused by the allergens in the soybeans might be enhanced by the adjuvant effects of the Bt toxins.

In general, it has to be taken into account that so far only very few Bt toxins produced in genetically engineered plants have been investigated in regard to their potential impact on the immune system. As yet, only two Bt toxins (Cry1Ac and Cry1Ab) have been tested in more detail for their possible effects on the immune system. This is especially relevant for mCry3A which has so far not been subjected to more detailed analysis regarding potential immunological effects. The same is true for eCry3.1Ab.

However, EFSA did not request the applicant to provide experimental data on the allergenic or immunogenic potential of mCry3A and eCry3.1Ab.

Given the fact that potential effects of Bt toxins on the immune system have been discussed for many years (for overview see, for example, Then & Bauer-Panskus, 2017), and already around 40 GE crop events producing Bt toxins have been approved for the EU market, any further delay in resolving these crucial questions cannot be accepted.

In accordance with EU Regulation 1829/2003, safety of whole food and feed has to be demonstrated before approval for import can be issued. Since this is not the case with maize MZIR098, the risk assessment is inconclusive and market authorisation cannot be granted.

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3. Environmental risk assessment

The appearance of teosinte in Spain and France (see Testbiotech, 2016; Trtikova et al., 2017) should have been considered in more depth. As Pascher et al, (2016) show, the volunteer potential of maize is higher than currently assumed. The hypothesis that hybrid offspring from maize MZIR098 and teosinte will show a higher fitness compared to conventional maize is plausible; this is because the Bt toxins may be present in the offspring and teosinte shows higher survival rates compared to maize.

EFSA should have requested data from the applicant to show that no adverse effects can occur through gene flow from the maize to teosinte and / or from teosinte to the maize volunteers. In the absence of such data, the risk assessment and the authorisation have to be regarded as not valid.

Further, it is surprising that EFSA did not assess recent findings of Diaz et al (2019) highlighting uncertainties regarding the origin and genetic makeup of teosinte in Spain.

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 stacked maize. Without experimental data on next generation effects (Bauer-Panskus et al., 2020), no conclusions can be drawn on

environmental risks of spillage of viable kernels. Consequently, environmental risk assessment carried out by EFSA is not acceptable.

Furthermore, the delay in degradation of the Bt toxins due to protease inhibitors produced in maize, raises questions on environmental exposure via manure or sewage.

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4. Conclusions and recommendations

The EFSA risk assessment cannot be accepted.

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5. Others

Monitoring: If approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. Thus, the monitoring report should, at very least, contain detailed information on: i) actual volumes of the GE products imported into the EU; ii) the ports and silos where shipments of the GE products were unloaded; iii) the processing plants where the GE products were transferred to; iv) the amount of the GE products used on farms for feed; and v) transport routes of the GE products. Environmental monitoring should be run in regions where viable material of the GE products, such as kernels, are transported, stored, packaged, processed or used for food/feed. In case of losses and spread of viable material (such as kernels) all receiving environments need to be monitored. Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing GE products during or after the production process, and during or after human or animal consumption, should be part of the monitoring procedure.

Methods for tracking and tracing the specific maize in comparison to other GE maize with similar gene constructs have to be made available.