Maize DP910521

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

Comments:

1 augustus 2024

We – The European GMO-Free Citizens and the Ekopark Foundation in Lelystad (the Netherlands) – do not wish to eat this genetically modified maize as oil and other ingredients.

We want to eat unsprayed food that has not been genetically manipulated. This is also better for the environment and for our health and that of animals.

Nor do we want genetically modified maize as animal feed. If you were to approve it (which we would regret), we would want every product and every end product , to be labelled as a GMO, even if GMOs can no longer be detected in an end product.

See all our comments on GM maize of an earlier date.

Rectificatie

1 augustus 2024

Betreft; Commentaren op Carnation IFD-25958-3 en Carnation IFD-26407-2 op 24-6-24.

Er is een fout in onze bezwaren geslopen.

De goede data betreffende de vorige toelating zijn:

6. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (Dianthus caryophyllus L., line 25958) genetically modified for flower colour SANTE/10174/2015 Draft Decision concerning the placing on the market, in accordance with Directive 2001/18/EC, of a carnation (Dianthus caryophyllus L., line 25958) genetically modified for flower colour, was presented to the Committee.

Vote taken: no opinion

Reasons for the negative vote or abstention: − No agreed national position − Negative public opinion − Political reasons − Risk assessment deemed not sufficient − Human-aided propagation cannot be excluded − Potential spread of pollen and cross-pollination cannot be

excluded − Social utility of this GMO is unclear In the light of Article 4(6) of the Rules of procedure of the Appeal Committee, the Chair informed the members of the Committee that the file would be submitted to the Commission for adoption.

7. Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (Dianthus caryophyllus L., line 26407) genetically modified for flower colour SANTE/10175/2015 Draft Decision concerning the placing on the market, in accordance with Directive 2001/18/EC, of a carnation (Dianthus caryophyllus L., line 26407) genetically modified for flower colour, was presented to the Committee.

Vote taken: no opinion

Reasons for the negative vote or abstention: − No agreed national position − Negative public opinion − Political reasons − Risk assessment deemed not sufficient − Human-aided propagation cannot be excluded − Potential spread of pollen and cross-pollination cannot be excluded − Social utility of this GMO is unclear In the light of Article 4(6) of the Rules of procedure of the Appeal Committee, the Chair informed the members of the Committee that the file would be submitted to the Commission for adoption.

https://food.ec.europa.eu/system/files/2017-03/app-comm_gmffer_20150331_sum.pdf

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Maize DP910521

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

Comments:

Vervolg op ons commentaar op 1 augustus 2024

2 augustus

Doorgestuurd;

"GM Bt Corn Fails Against Target Pest in US

GM Bt corn is failing in the US and yields are no better than non-GM corn, according to a report in the US's mainstream agricultural press written by North Carolina State University professor and extension specialist, Dominic Reisig. Given the problem of pest resistance, the lack of a yield advantage....., . (Read more link below, originally published by GM Watch)".

Concerns About Corn Earworm in Field Corn

Documented corn earworm resistance to all hybrids with Cry toxins since 2016

PUBLISHED ON July 14, 2024

https://www.morningagclips.com/concerns-about-corn-earworm-in-field-corn/

Link: https://gmwatch.org/en/106-news/latest-news/20442

https://entomology.ces.ncsu.edu/2016/07/earwormsbollworms-in-bt-corn/

Maize DP910521

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

Comments:

7-8-24

Vervolg op onze eerdere bezwaren.

De planten produceren insecticiden en zijn resistent tegen een herbicide. Bij deze maïsplanten (DP910521) werd de CRISPR/Cas-genschaar gebruikt om extra genen in het genoom te introduceren.

We lezen, (fragment)

:

3.3.1 “Transformation process and vector constructs

Maize DP910521 was developed by site-specific integration (SSI) using two sequential transformation steps:

1. Microprojectile co-bombardment and a CRISPR-Cas9-mediated targeted insertion process to allow the insertion of a ‘landing pad’ sequence, at a specific location of the maize genome (inbred PH184C line), using four plasmids (PHP71012, PHP70594, PHP21139 and PHP21875)”

Assessment of genetically modified maize DP910521 (application GMFF-2021-2473) - - 2024 - EFSA Journal - Wiley Online Library

We waarschuwen echter

:

“Yet more problems with CRISPR – with consequences for food safety.”

Published: 22 February 2020

Fragment;

Study; https://www.science.org/doi/10.1126/sciadv.aax2941

“The lead authors of the study, Boris Skryabin and Timofey Rozhdestvensky, told The Scientist magazine that their findings could have relevance for gene editing across all kingdoms of life, from plants to human cells. They warned that duplications could lead to dangerous frameshift mutations, resulting in misshapen proteins.”

https://gmwatch.org/en/106-news/latest-news/19323

Yet more problems with CRISPR – with consequences for food safety (gmwatch.org)

Glufosinaat is niet onschuldig

opmerkingen van de CA van Hongarije.

Citaat: “Glufosinaat is giftig voor het microbioom, de residuen en metabolieten van dit herbicide interfereren met verschillende metabolische processen in de darmen van de organismen die het consumeren, of het nu mensen of dieren zijn.”

https://www.gentechvrij.nl/2022/06/27/nieuw-commentaar/

Geen toelating voor dit gentech mais!

Maize DP910521

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

Comments:

Introduction

The GMO Panel assessed the herbicide tolerant maize, DP910521, which produces an insecticide and the selectable PMI marker gene (EFSA, 2024a). This event was developed to confer resistance to glufosinate and produce the Cry1B.34 toxin, which is a synthetic fusion of three different Cry-proteins originally derived from soil bacteria. The toxin is meant to be active against lepidoptera, such as fall armyworm (Spodoptera frugiperda), without it being clearly restricted to specific target species. The genetic intervention involved a multistep process using CRISPR/Cas to introduce a 'landing pad' at the target site, where the gene constructs for the production of new proteins (new traits) are subsequently inserted.

1. Systematic literature review

There appears to be no peer reviewed study on the mode of action of the newly expressed insecticidal toxin. Nor was a publication provided on the risks of unintended effects associated with the specific genetic engineering processes used to produce DP910521.

2. Molecular characterisation

This was a two-step process:

Step 1 (not related to the trait):

Insertion of a 'landing pad' sequence at a specific site in the maize genome that was achieved with microprojectile bombardment and CRISPR/Cas9- mediated insertion (homology-directed repair, HDR)

This first step included four plasmids: one plasmid to introduce the gene scissors (CRISPR/Cas), and one with sequences for the 'landing pad'. The 'landing pad' uses the flippase (FLP) recombinase and FLP recognition targets (FRT) to insert a gene in the target site. The other two plasmids were introduced to produce proteins to improve regeneration (the WUS2 and the ODP2 protein). The DNA sequence for the 'landing pad' is meant to be integrated permanently; the other three plasmids are meant to be expressed only transiently.

It is important to acknowledge that unless adequate gene sequencing methodology is applied, specific unintended genetic changes and associated risks may remain undetected. In this context, it is not sufficient to simply assume that the types of unintended genetic changes may be no different to conventional breeding (EFSA 2024b). It is essential in this respect to take the site of the genetic change into account, and to consider whether there are, e.g. inversions, insertions or deletions that are otherwise either unlikely or less likely to occur (Koller & Cieslak, 2023).

Step 2 (related to the trait):

The 'landing pad' and the flippase (FLP) recombinase were used in combination with the FLP recognition targets (FRT) to insert the gene constructs needed to establish the desired traits. Microprojectile co-bombardment of a selected line containing the landing pad at the target location was used to insert the intended expression cassettes into the maize genome. This process used four plasmids

The gene cassettes are intended to express three new proteins:

• The phosphomannose isomerase (PMI) gene from E. coli to facilitate the detection of the successfully engineered plants (marker gene)

• a maize-optimised version of the PAT coding sequence of the phosphinothricin acetyltransferase gene (mo-pat) from Streptomyces viridochromogenes

• the coding sequence of the insecticidal protein Cry1B.34, in combination with several enhancers / promotors (enhancer from the Mirabilis Mosaic Virus (MMV), the promoter region of the lamium distortion-associated virus (LLDAV). The chimeric coding gene sequence of the cry1B.34 gene, consists of sequences of a cry1B-class gene, the cry1Ca1 gene and the cry9Db1 gene.

In regard to risk assessment, the flippase system is used to allow targeted insertion at the 'landing pad'. However, its use can also be associated with "truncations, insertion of other plasmid fragments or rearrangement of the template DNA" (Gao et al., 2020). Unintended effects may also occur at off-target sites. Therefore, the application of suitable methods to detect off-target genetic changes are essential. All open reading frames should be carefully investigated for emergent unintended biologically active molecules.

Furthermore, as shown by Gao et al. (2020), the expression of the gene constructs (inserted into the 'landing pad') depends on the genetic background of the plants. "It is noteworthy that expression at identical sites was significantly different across different genetic backgrounds...". Therefore, gene expression should be investigated, including a broad range of different genetic backgrounds and environmental conditions.

The material used to investigate gene expression was taken from field trials across six locations in the United States and Canada during the 2020 growing season: Iowa, Illinois, Nebraska, Pennsylvania, Texas and Ontario. There was no targeted investigation into the impact of different environmental conditions (abiotic stressors) or differing genetic backgrounds. This is not acceptable as the plants are intended for cultivation in countries, such as Brazil, where other transgenic varieties with differing comparative relative maturity (CRM) and different genetic backgrounds are cultivated.

Summary of molecular analysis

EFSA should have requested that the applicant use suitable methods to detect unintended genetic changes, and to assess all the biologically active molecules occurring at novel open reading frames. Data collection on gene expression should include the highest dosage of the complementary herbicides that may be used in the countries of cultivation. Transgenic plants with differing genetic backgrounds should be grown in the field trials with a broad range of defined environmental conditions. The plant material derived from such trials should be assessed with 'Omics' techniques to investigate changes in the gene activity of the transgenes and changes in the plants' own genes.

3. Comparative assessment of plant composition and agronomic and phenotypic characteristics

Implementing Regulation 503/2013 requests:

"In the case of herbicide tolerant genetically modified plants and in order to assess whether the expected agricultural practices influence the expression of the studied endpoints, three test materials shall be compared: the genetically modified plant exposed to the intended herbicide; the conventional counterpart treated with conventional herbicide management regimes; and the genetically modified plant treated with the same conventional herbicide management regimes."

"The different sites selected for the field trials shall reflect the different meteorological and agronomic conditions under which the crop is to be grown; the choice shall be explicitly justified. The choice of non-genetically modified reference varieties shall be appropriate for the chosen sites and shall be justified explicitly."

The data presented by the applicant do not meet the requirements of Implementing Regulation 503/2013: (1) the field trials were not conducted in all relevant regions where the GE maize will be cultivated, and extreme weather conditions were not tested in a targeted way; (2) the field trials did not take all relevant agricultural management practices into account; (3) different genetic backgrounds inheriting the transgenes were not taken into account.

Data on environmental factors and stress conditions

Field trials to assess plant composition as well as agronomic and phenotypic characteristics of the GE maize were conducted in the US and Canada for one year (2010); at eight (compositional analysis) resp. eleven (agronomic performance) sites. Some extreme weather conditions were reported in a number of fields, but no targeted investigation was carried out to, for example, investigate the impact of climate change. In order to assess changes in gene expression, the plants should have been grown in various environmental conditions, and exposed to well-defined environmental stress conditions, including taking maize growing regions, such as Brazil, into account.

From the information available, we assume that the data provided do not sufficiently represent the agricultural practices and bio-regional conditions under which these plants are likely to be grown.

No experiments were requested to show the extent to which specific environmental conditions influence plant composition and agronomic characteristics. Hence, the data made available do not allow conclusions to be drawn (as requested in Implementing regulation 503/2013), or to conclude on whether the expected environmental conditions in which the plants are likely to be cultivated will influence the expression of the studied endpoints.

Data on herbicide application rates

The complementary herbicide (glufosinate) was only applied once during the field trials. It seems the dosage was chosen in accordance with the label recommendations (EFSA, 2024a). However, as Myiazaki et al. (2019) show, the herbicide applications are likely to differ across regions and in response to pressure from herbicide resistant plants.

Therefore, from the information available, we assume that the data provided do not sufficiently represent the agricultural practices, e. g. higher dosages and repeated spraying.

Consequently, the GE maize plants tested in field trials do not sufficiently represent the products intended for import. The data presented by the applicant are insufficient to conclude on the impact of the herbicide applications on gene expression, plant composition or biological characteristics of the plant, as requested in EU Regulation 503/2013.

Data from different genetic backgrounds and their impact on plant composition as well as agronomic and phenotypic characteristics

As shown by Gao et al. (2020), the expression of the gene constructs inserted into the ‘landing pad’ depends on the genetic background of the plants.

Therefore, gene expression in a broad range of different genetic backgrounds should be investigated. Maize varieties with differing genetic backgrounds (different maturity groups) were only grown in the control group, but the transgenic plants all had the same genetic background. This is not acceptable as the plants are intended for cultivation in countries, e. g. Brazil, where other varieties with differing comparative relative maturity (CRM) will be grown under different environmental conditions.

Agronomic and phenotypic characteristics

According to EFSA, eleven agronomic and phenotypic endpoints were measured with nine of them being subjected to statistical analysis. The results were as follows:

• For maize DP910521, statistically significant differences were detected for early stand count, days to flowering, plant height, days to maturity and 100-kernel weight, regardless of whether it was treated or not with the intended herbicide.

We do not consider these data to be sufficient for risk assessment, as they were derived from transgenic plants with only one genetic background and one herbicide application, without taking a broad range of defined environmental stress conditions into account.

Data from compositional analysis

According to EFSA, statistical analysis was applied to a total of 72 constituents (10 in forage and 62 in grain).

• For maize DP910521 not treated with the intended herbicide, statistically significant differences with the conventional counterpart were found for 11 endpoints (four in forage and seven in grain).

• For maize DP910521 treated with the intended herbicide, statistically significant differences with the conventional counterpart were found for 15 endpoints (three in forage and 12 in grain).

We do not consider these data to be sufficient for risk assessment, as they were derived from transgenic plants with only one genetic background and one herbicide application, without taking a broader range of defined environmental stress conditions into account.

Furthermore, the material derived from the plants should have been assessed using 'Omics' techniques to investigate changes in the gene activity of the transgene and the plant genome, including investigating changes in metabolic pathways and the emergence of unintended biologically active gene products (see Benevenuto et al., 2022).

In addition, in awareness of the absence of any independent data on this maize, we strongly recommend establishing a system with independent controls to repeat the trials and double check the data on plant composition and agronomic characteristics.

Conclusion on the comparative assessment of plant composition as well as on phenotypic and agronomic characteristics

The data provided by the applicant and accepted by EFSA are insufficient to draw conclusions on how environmental stressors, herbicide applications and genetic backgrounds will impact gene expression, plant metabolism, plant composition or agronomic and phenotypic characteristics.

The plants should have been subjected to a much broader range of defined environmental conditions and stressors in order to collect reliable data on compositional analysis and agronomic characteristics. Furthermore, EFSA should have requested the applicant to submit data from field trials that reflect current agricultural practices, including all relevant complementary herbicides and several genetic backgrounds.

Based on the available data, no final conclusions can be drawn on the safety of the plants. The data neither fulfill the requirements of Implementing Regulation 503/2013 nor Regulation 1829/2003. This is also underlined in several statements made by experts from Member States (EFSA, 2024b).

4. Toxicity

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;"

Characterisation of the toxin Cry1B.34

The chimeric coding gene sequence of the cry1B.34 gene, consists of sequences of a cry1B--class gene, the cry1Ca1 gene and the cry9Db1 gene. Therefore, the toxin Cry1B.34 has to be considered to be a synthetically fused toxin that does not occur in nature. Its specificity in regard to target pest species is not well characterised. The language used by Corteva (and simply adopted by EFSA) describes it as being toxic to 'certain lepidopteran insect pests'. The dossier appears to show that the fall armyworm (Spodoptera frugiperda) is one of the target species.

The above characterisation of the toxin cannot be regarded as sufficient as the toxin is completely novel for the environment. This aspect is underlined in several statements made by experts from Member States (EFSA, 2024 b).

Combinatorial or synergistic factors impacting toxicity and allergenicity

It is known that plant constituents, such as protein inhibitors or other co-factors, can greatly enhance the toxicity of Bt toxins (MacIntosh et al., 1990; Pardo-López et al., 2009). Therefore, to determine 'no observed effect concentration' or 'no observed effect dose', it is not sufficient to use the proteins produced by the bacteria in isolation. Instead, it is necessary to take the real conditions of exposure into account, e. g. in combination with plant protein inhibitors. In addition, the residues from spraying with glufosinate should also be considered. These findings are relevant to determining chronic and subchronic toxicity, immunogenicity (allergenicity), the impact on microorganisms (intestinal microbiome or soil organisms) and the effects on non-target organisms.

In conclusion, the data is insufficient to assess the specificity of the toxin, or the toxicity of the protein in isolation and its allergenic potential.

Furthermore, whole food and feed feeding studies should be carried out only after the mode of action, the specificity, the 'no observed effect concentration' or 'no observed effect dose' of the proteins have been explored.

Cumulative effects (mixtures of GE plants in one diet) should also be considered. For example, Bt toxins or residues from spraying may contribute to synergistic effects that can be decisive for the overall toxicity of a given diet.

All in all, the toxicity assessment carried out by EFSA is not conclusive and cannot be accepted.

Effects of residues from spraying with complementary herbicide specific to GE plants

The residues from spraying were considered to be outside the remit of the GMO Panel. However, without taking the assessment of these residues into account, conclusions cannot be drawn on the safety of the imported products.

EU legal provisions, such as Regulation 1829/2003 (and 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. Therefore, potential adverse effects resulting from combinatorial exposure of various potential stressors need to be tested.

Glufosinate has been shown to impact or disturb the microbiome (Dong et al., 2020). This can have a substantial impact on long-term toxicity (mixed toxicity) of whole food and feed derived from the maize. In general, the microbiome can be seen as a common network of life, encompassing and closely interacting with plants, animals and humans. Microbial networks are thought to have co-evolved with their hosts and have developed a mutualistic relationship that benefits both the host and microorganisms. They act at the interphase and communicate between the organisms and their wider environment while at the same time being part of an organism's closer environment.

In regard to food and feed safety, EFSA (2020) considers microbiomes to be highly relevant to the health status of their hosts. Therefore, it is desirable to understand the importance of their role in risk assessment. EFSA expects that gut microbiome research (not only in the case of GE plants) will play a relevant role in regulatory science with potential implications for future risk assessments and predictive risk models. As EFSA states: "considering that the gut microbiome is a biological component directly and indirectly involved in the metabolism of food/feed components and chemicals and in the protection of the host against adverse environmental exposure, it would be useful to establish criteria on how to evaluate the potential adverse impacts of perturbators on this defensive barrier, and consequently, on human/animal health."

However, no attempts have been made to integrate the microbiome into the risk assessment of food and feed derived from the GE maize. This is in direct contradiction to Regulation 1829/2003 which requests "genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment." (Recital 9).

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.

In addition, cumulative effects (mixtures of GE plants in one diet) may play a decisive role. For example, Bt toxins, or residues from spraying with other herbicides, may contribute to synergistic effects that can be decisive for the overall toxicity of a given diet.

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

Health effects in feeding trials

The feeding trials revealed a high incidence of pathologic effects, such as mammary gland tumors in rats. These effects are explained by historic data showing a genetic disposition of the strain of rats being used. However, these predispositions may mask the relevant effects caused by the maize.

We, therefore, believe it is essential to carry out more detailed research. For this purpose, we propose hypothesis-driven experiments, focusing, in particular, on the immune system (e.g. on signs of increased inflammation), composition of the gut microbiome and combinatorial effects, which take into account combinations of other GE plants in feed as well as the residues from spraying with the complementary herbicides. EFSA may, however, recommend suitable methods that are better or at least equivalent to the whole food and feed approach in feeding studies.

The above-described in-depth research should be given priority as the toxin produced in the plants does not have any history of use.

5. Environmental risk assessment

It seems that no data were provided showing the specificity and the efficacy of the toxin. Since spillage and proliferation in the environment (for example via dung) cannot be excluded, these data are necessary before any risk assessment can be performed. The need for these data cannot be dismissed by, for example, pointing out a low likelihood of exposure (see also comments made by experts from Member States). Without data on the actual toxicity, the maize should not be introduced into the environment (and food chain) at all. In addition, no data were made available to show whether the protein can accumulate in food webs, or persist and accumulate in the environment (e. g. the soil). Again, this means there is a lack of basic information needed for environmental risk assessment.

Furthermore, the appearance of teosinte in Spain and France (see Testbiotech, 2016; Trtikova et al., 2017) has to be considered in more detail. Maize volunteers can be found in the EU on a regular basis, as reported by Palaudelmàs et al. (2009) in Spain or Pascher (2016) in Austria.

Testbiotech is aware of an EFSA (2022) opinion regarding the teosinte situation in France and Spain. Here, EFSA comes to the conclusion:

“The new evidence retrieved confirms that where maize and EU teosinte plants co-occur and flower synchronously, maize alleles (transgenic or not), can move into teosinte populations at rates that depend on different factors. Hence, the possible introgression of transgenes from maize MON810, Bt11, 1507 and GA21 into EU teosinte may only provide a selective advantage to GM teosinte hybrid progeny under high infestation of target pests and/or when glufosinate-ammonium- and/or glyphosate-based herbicides are applied. However, this fitness advantage will not allow GM teosinte hybrid progeny to overcome other biological and abiotic factors limiting their persistence and invasiveness. Therefore, EFSA considers that the growth habits of EU teosinte plants and teosinte hybrid progeny are such that the

acquisition of insect resistance and/or herbicide tolerance is unlikely to change their relative persistence and invasive characteristics under EU conditions."

This opinion is not sufficiently backed by the science: the characteristics of potential hybrids and next generations need to be investigated and cannot be predicted simply from the data of the original event. It is well known that there can be next generation effects and interference from the genetic background that cannot be predicted from the assessment of the original event (Bauer-Panskus et al., 2020). Furthermore, as mentioned, gene expression at the 'landing pad' can depend on the genetic background of the transgenic plants (Gao et al., 2020). This issue is relevant for gene flow from maize to teosinte, and from teosinte to maize.

In addition, new evidence has become available since EFSA prepared its opinion, (Arias-Martin et al., 2019, 2022, 2024) which was also assessed by EFSA (2024, c). The new EFSA assessment shows that the environmental risk assessment of DP910521 needs to be revised. EFSA (2024c) states that "the evidence indicates that the hybridisation potential between maize MON 810 and teosinte found in Spain can be greater than assumed previously", that the hybrid offspring "may be more vigorous (e.g. taller, thicker stem, more leaves) than teosinte" and "that teosinte/maize hybrids express the Cry1Ab protein at similar levels than maize MON 810." EFSA (2024 c) has further requested data to assess the invasiveness and hybridisation potential between maize MON 810 and teosinte in field conditions.

Testbiotech warns that viable kernels from the transgenic maize should not be imported if this data is not available. It cannot be excluded, that plants grown from the kernels (intentionally or unintentionally) may quite easily result in the emergence of super weeds, thus posing a pose serious risk to food security in Europe.

Whatever the case, without detailed consideration of the hazards associated with potential gene flow from maize to teosinte, and from teosinte to maize, no conclusion can be drawn on the environmental risks of maize DP10521.

Consequently, the EFSA environmental risk assessment is not acceptable.

6. Others

As far as monitoring and methods to identify the specific event are concerned, Implementing Regulation 503/2013 requests that:

The method(s) shall be specific to the transformation event (hereafter referred to as 'event-specific') and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised transformation events and conventional counterparts. This testing shall include closely related transformation events.

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 whether any (adverse) effects on health could 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 was transferred to; iv) the amount of the GE products used on farms for feed; 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.

In addition, this maize highlights some general problems. These are:

(1) Due to current EFSA practices, it is not possible to access the original data from the companies within the period of consultation. Therefore, the opinion has to provide all the necessary data to allow other experts to conclude on whether the provisions of GMO regulation (esp. 503/2013) are fulfilled. We are making this comment after our recent experience in requesting access to documents, which in many instances, took months to achieve. The Commission should advise EFSA to improve transparency. Currently, only a summary of the application is published on the EFSA website.

(2) A Testbiotech report (Testbiotech, 2021) shows how the European Food Safety Authority (EFSA), which is responsible for risk assessment of GE plants, intentionally puts crucial issues aside. This careless approach exemplifies an overall decrease in general food safety standards that has been ongoing since the introduction of GE plants. The number of events authorised for import has, at the same time, steadily increased. In light of these findings, the Commission should try to avoid simply 'rubber stamping' all applications for the import of GE plants, and thus reduce the overall number of products entering the market, while ensuring that these products undergo much more thorough risk assessment.

References

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