



Vår ref:2017/H_142
Deres ref: 2017/8570

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



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Vedlagt er innspill fra GenØk – Senter for Biosikkerhet på offentlig høring av søknad **EFSA/GMO/DE/2017/142**, genmodifisert mais linje MZIR098, fra Syngenta Crop Protection NV/SA under EU forordning 1829/2003. Søknaden gjelder bruksområdene mat, fôr, import og prosessering.

Vennligst ta kontakt hvis det er noen spørsmål.

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Høringsuttalelse – genmodifisert mais MZIR098, EFSA/GMO/DE/2017/142, under EU forordning 1829/2003.

Søknad EFSA/GMO/DE/2017/142 omhandler genmodifisert maislinje til bruksområdene mat, fôr, import og prosessering.

Den genmodifiserte maisen har toleranse mot herbicider som inneholder glufosinat ammonium via det innsatte genet *pat-08*.

Maislinjen er også resistent mot insekter i *Diabrotica virgifera virgifera* familien via det innsatte genet *eCry3.1Ab* og *mcry3A* som koder for kimært protein Cry1Ab og modifisert protein Cry3A.

Maislinjen MZIR098 er ikke godkjent for noen av bruksområdene i Norge eller EU.

Oppsummering

GenØk-Senter for biosikkerhet, viser til høring av søknad EFSA/GMO/DE/2017/142 om MZIR098 mais som omfatter bruksområdet import og prosessering og til bruk i fôr og mat eller inneholdende ingredienser produsert fra denne maisen.

Vi har gjennomgått de dokumenter som vi har fått tilgjengelig, og nevner spesielt følgende punkter vedrørende søknaden:

- Genmodifisert mais linje MZIR098 er ikke godkjent i Norge eller EU for noen av de omsøkte bruksområdene.
- MZIR098 er tolerant mot sprøytemidler som inneholder glufosinat - ammonium som har ulike grader av helse-og-miljø fare ved bruk.
- Glufosinat ammonium er ikke tillatt brukt i Norge.
- Søknaden om mais linje MZIR098 mangler data og informasjon som er relevant for å kunne vurdere kriterier rundt etisk forsvarlighet, samfunnsnytte og bærekraft.

Summary

GenØk-Centre for biosafety refers to the application EFSA/GMO/DE/2017/142 on MZIR098 maize for import, processing, food and feed or ingredients thereof.

We have assessed the documents available, and highlights in particular the following points for the current application:

- The gene modified maize event MZIR098 is not approved for any application in Norway or the EU.
- The maize event MZIR098 is tolerant to herbicides containing gluphosinate ammonium that has distinct health and environmental dangers upon use.
- It is not allowed to use gluphosinate ammonium in Norway.
- The application on maize event MZIR098 lacks data and information relevant for assessment of criteria on ethically justifiability, social utility and sustainability.



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Application on EFSA/GMO/DE/2017/142

The maize event MZIR098 contains genes providing herbicide tolerance (*pat-08*) as well as resistance to certain insects (*mcry3A* and *eCry3.1Ab*).

This maize event has not been evaluated in Norway or EU before.

Previous evaluations

Food Standards Australia New Zealand (FSANZ) have evaluated the application on MZIR098 from Syngenta (1, 2) for food purposes. They concluded that no public health and safety concerns had been identified from the documents received from the applicant. The food from MZIR098 is considered to be as safe for human consumption as from conventional maize.

Social utility and sustainability issues on the maize event MZIR098, EFSA/GMO/DE/2017/142

In accordance with article 1, the purpose of the Norwegian Gene Technology Act (NGTA) (3), GMOs have to be “ethically and social justifiable and in accordance with the principle of sustainable development”. These issues are further elaborated within different sections of the act, and in the Consequence regulation under the act. In the Consequence regulation § 17, it is stated that as far as possible, the consequences of the application shall clarify the GMOs positive and negative effects on sustainable development, any ethical aspects that can be highlighted through usage of the applied GMO, and the possible societal advantages or disadvantages using the applied GMO. The guideline in annex 4 to the regulation, elaborate further on relevant and important focus points for consideration when evaluating these possible consequences.

Within application EFSA/GMO/DE/2017/42 (maize event MZIR-098), no direct documentations regarding ethics, societal considerations or sustainability has been highlighted by the applicant. An evaluation of these social scientific issues will therefore be based on general literature and previous discussions regarding similar GMO cases, e.g. maize line 1507.

As an important part of the Norwegian official policy in regard of the EEA agreement and applications of GMOs, it is important to present the applicant to the significance of the NGTA in order to elaborate on the specific issues that are relevant in a Norwegian context.

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).

Impacts in producer countries

In line with the Norwegian Governments decision regarding the maize event 1507 (4), comparable ethical difficulties in accepting the maize event MZIR098 are present. In the case of application EFSA/GMO/DE/2017/42, glufosinate-ammonium will be used in other countries and thereby exposing their farmers, citizens and environment for the danger of the herbicide. The possibility of harming farmers, citizens and the environment in other countries is a strong ethical argument in order to evaluate the application for marketing in Norway and in comparison with maize event 1507. Based on the evaluation of toxicity, maize event MZIR098 is not in consistency with the principle of sustainable development as required by the NGTA.

Assessing alternatives

To find alternative conventional maize lines within the world commodity market is not difficult, We can therefore not see how this maize would provide a greater benefit for the Norwegian society. In addition, there are also ethical and societal considerations if exposing Norwegian consumers and livestock to possible residues of glufosinate-ammonium within the imported maize event MZIR098, which potentially would require a high degree of residue level testing and control by relevant authorities, if approved.

Environmental risk issues in a Norwegian context

The level of maize production is still very low in Norway and only some varieties can grow in the southern part due to climate conditions.

There are also no wild populations of maize in Norway.

These limitations lead to minimal possibilities for establishment of maize outside agricultural practices. Loss of gene modified maize seed through storage or transport would therefore not involve great risk for spread into the wild or spread of transgenes to wild relatives.

Molecular characterization, expressed proteins and herbicide use - special issues to consider in the present application

Molecular characterization

The gene modified maize event MZIR098 from Syngenta has been modified by *Agrobacterium tumefaciens* mediated transformation with the binary plasmid vector pSYN17629 to tolerate the herbicide glufosinate ammonium through the expression of the enzyme PAT, encoded by the transgene *pat-08* from the common soil bacterium *Streptomyces viridochromogenes*. Maize event MZIR098 are also protected against certain coleopteran pests through expression of the modified mCry3A (based on sequence from Cry3Aa2 gene from *Bacillus thuringiensis* ssp.*tenebionis*) and eCry3.1Ab (encoded by a chimeric gene with selected sequences from mCry3Aa2 and Cry1Ab genes from *Bacillus thuringiensis* ssp. *Kurstaki*.)

From chapter 1.2, (p.18-50) in dossier.

The modified mCry3A protein has enhanced activity against Western corn rootworm and other related coleopteran pests of maize.

The engineered protein eCry3.1Ab is a chimera of mCry3A and Cry1Ab that is also active against *D. virgifera virgifera* and other related pests of maize. The portion of Cry1Ab included in eCry3.1Ab has not preserved the activity of Cry1Ab against lepidopterans.

PAT-08 was derived from the soil bacterium *Streptomyces viridochromogenes* PAT acetylates glufosinate-ammonium, conferring tolerance to glufosinate-ammonium in herbicide products. PAT was used as a selectable marker in the development of MZIR098.

All the proteins (eCry3.1Ab and mCry3A and PAT) produced in MZIR098 maize are identical to those produced in:

- Maize 5307 (EFSA/GMO/DE/2011/95)
- MIR604 (EFSA/GMO/UK/2005/11)
- Bt11 (EFSA/GMO/RX/Bt11) renewal

The applicant claims that no safety concerns or unintended effects was identified during the molecular characterization of MZIR098 maize, and that no issues could be identified regarding the potential for producing new toxins or allergens.

Sequence information

The applicant is using southern blot to determine the size and copy number of all detectable inserts. The positive control used is plasmid DNA. Southern blot probes are able to prove the presence of parts of the inserted gene and in this application the size of the probes range in size from approximately 2000 bp up to 12000 bp. The typical manual approach is to choose a probe of at least 300 bp in length, to ensure efficient labelling in the random priming reaction (5), and in practice probes of 100-1000 bp are generally employed (6).

The use of long probes to detect recombinant DNA can lead to false negative results. The strength of the interaction between probe and target is based on the number of bonds that form between the single strand of DNA that is the probe and the matching recombinant DNA that is the target. A long probe that binds perfectly to a short insertion will not be strongly bound and may be washed off depending on the stringency of the wash. The best probe is one that approximates the size of the target sequence and does not exceed approximately 500 nucleotides in length (7, 8).

Other relevant issues:

- No backbone sequences were detected
- The deletions found from maize genomic sequence during integration of MZIR098 insert were investigated and found to have no effect of the functionality of the insert (p. 32 dossier).

Bioinformatic analysis of maize event MZIR098

Analysis of insert, junction and flanking DNA sequences

Summary

The region spanning the MZIR098 event and 1000 bp of flanking sequences in the MZIR098 maize were amplified and sequenced. The sequences were compared to MZIR098 insert in pSYN17629 and to the DNA sequences obtained from non-transformed maize (NP2222). Comparative sequence analysis showed that the MZIR098 was intact in the transformed maize and no rearrangement or base pair changes occurred because of the transformation event. BlastN and BlastX search of relevant databases also showed that no known maize endogenous gene was disrupted. However, 10 bp of non-coding sequences were truncated from the left and right borders compared to the T-DNA in the pSYN17629 and 24 bp was deleted from the genomic DNA at the locus of insertion (Dossier pp 30-35, Appendix 1.2.2-1.2.7).

Comment

The conclusion made by the applicant is supported by the data presented. References were presented to show that the 10 bp truncation in the left and right border sequences have no effect on the function of the T-DNA insert but none was provided to show that the 24 bp deletion in the genomic DNA at the insertion site also have no effect on the function the T-DNA. The applicant should provide a reference or explain why the deletion has no effect on the function of the T-DNA. Figure 1.2.5 is just a cartoon. The applicant should present a genetic map of the genomic insertion site.

In silico evaluation of ORFs within insert and junction sites for potential allergenicity and toxicity

Summary

The six in-frame translation of DNA sequences at the junction between the maize genomic DNA and the T-DNA insert and the whole T-DNA insert were assessed for similarity to known

protein allergens and toxins in relevant up-to-date databases (NCBI Entrez Protein Database version 2017, Comprehensive Allergen Resource Database version 2017 and Syngenta toxin database). No significant matches to known allergens and toxins were found for ORFs in the junctions and within the eCry3.1AB and mCry3A proteins but the PAT has significant match with proteins belonging to GNAT toxin-antitoxin (TA) system (Dossier pp35-37, 98-99, Appendix 1.2.9-1.2.10a).

Comment

The conclusion are supported by the data provided and we agree to the conclusion made by the applicant. However, the method employed relies on similarity matches to annotated known or putative proteins and annotation is based on already characterized proteins rather than functional characterization of the query protein (9). We suggest that the homology search method should be corroborated with alternative *in silico* prediction methods like the machine learning approaches (10). With respect to the significant match of the PAT protein to the GNAT domain of the TA system, the applicant stated “*Therefore PAT is unlikely to act on the same substrates as the TA system components, and un-intended acetylation reactions catalyzed by PAT are unlikely to occur*” (Dossier p98, third paragraph). The applicant should demonstrate this experimentally, albeit as a worst-case scenario.

In silico evaluation of the expressed proteins for potential adjuvanticity

The potential adjuvanticity effect of the expressed proteins (eCry3.1AB, mCry3A and PAT) either singly or in combination was not reported in the dossier. No similarity searches with putative or know adjuvants were conducted. The applicant wrote “*There is no evidence indicating that PAT, eCry3.1AB and mCry3A may cause adjuvant effect as components of MZIR098 maize for food and feed*” (Dossier P116, second paragraph). The applicant should provide *in silico* and experimental data to support the conclusion made.

Comments relevant for the assessment of the current application

PAT protein

Accordingly, the PAT protein has been used as a selection marker for maize event MZIR098 during transformation.

However, as the gene encoding this protein, *pat-08*, has not been removed, glufosinate-ammonium can potentially be used during cultivation as an option.

CaMV promoter in maize event MZIR098

A version of the 35S Cauliflower mosaic virus (CaMV) promoter, called 35S-04 is present in the transgenic maize event MZIR098. This promoter drives the constitutive expression of the transgene *pat-08*.

The 35S promoter have been used in many plant transformation vectors due to its strong positive selection and constitutive overexpression as a plant promoter (11). It is commonly used to drive transgene expression in many of the genetically engineered (GE) crop plants that have been commercialized so far (12-14). Safety questions related to the use of the Cauliflower Mosaic Virus 35S promoter (P35S) in GM plants has been discussed in an article from Podevin and Du Jardin (15). In this article, the authors state that some P35S variants contain open

reading frames (ORFs) that when expressed could lead to “unintended phenotypic changes”. Gene VI encodes the multifunctional P6 protein that can be divided into four domains (16). Functions of P6 include nuclear targeting (17), viral particle binding and assembly (18), si- and ds-RNA interference and interference suppression (19) and transcriptional transactivation (20, 21). The main debate when it comes to the use of this promoter is that it may not only be active in plants, but may confer activity with respect to gene expression in lower and higher vertebrates such as mammals and fish. Today there are reports that conclude that the 35S CaMV promoter is active in several eukaryotic cell lines after transfection (12, 14), as well as that the promoter is able to drive expression of a transgene in fish as demonstrated recently by Seternes et al (13). The potential risk when it comes to GM food/feed that contains the CaMV promoter may be unlikely but cannot be excluded.

Adjuvancy effects

The potential adjuvancy of Cry proteins has previously been addressed by the GMO Panel of the Norwegian Scientific Committee for Food Safety (22). Scientific studies have shown that the Cry1Ac protein is highly immunogenic and has systemic and mucosal adjuvant effects (23). In the evaluation of another GM maize, MIR604 x GA21, the panel found that it was difficult to evaluate if kernels from this stack would cause more allergenic reactions than kernels from unmodified maize. The Panel continues:

“As the different Cry proteins are closely related, and in view of the experimental studies in mice, the GMO Panel finds that the likelihood of an increase in allergenic activity due to Cry1Ab and mCry3A proteins in food and feed from maize Bt11 x MIR604 x GA21 cannot be excluded. Thus, the Panel's view is that as long as the putative adjuvant effect of Cry1Ab and mCry3A with reasonable certainty cannot be excluded, the applicant must comment upon the mouse studies showing humoral antibody response of Cry1A proteins and relate this to a possible adjuvant effect of the Cry1Ab and mCry3A proteins expressed. Furthermore, although Cry1Ab and mCry3A proteins are rapidly degraded in gastric fluid after oral uptake, there is also the possibility that the protein can enter the respiratory tract after exposure to e.g. mill dust. Finally, rapid degradation is no absolute guarantee against allergenicity or adjuvanticity” (24).

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.”

We also agree with these concerns and highlight them for the maize event MZIR098.

Protein expression and characterization of the newly expressed protein(s)

Maize tissues (leaf, root, kernel, pollen and whole plant) from four different locations in the US and at four different growth stages were analyzed using enzyme-linked immune-sorbent assay (ELISA) to get a life cycle expression profile of MZIR098 maize.

Non-trangenic, near-isogenic hybrid maize were used as a control.

Both glufosinate-ammonium treated and untreated samples were analyzed.

Cry proteins mCry3A and eCry3.1Ab

Levels

Levels of eCry3.1Ab, mCry3A and PAT were quantifiable in most tissues except pollen, where eCry3A and PAT levels were below LOD.

All detected protein levels were as expected.

Susceptibility and resistance development

Although efficient against northern corn rootworms (25), the susceptibility against these two BT toxins vary. The toxin eCry3.1Ab is more toxic to these rootworms than mCry3A.

Cross-resistance has been detected between Cry3Bb1 and both mCry3A and eCry3.1Ab (26). Thus, although these proteins have been modified to increase the toxicity against target organisms (rootworms), detection of resistance and cross resistance is an important issue for consideration for further use of these (26-29).

Especially for eCry3.1Ab, resistance development have been developed in larvae already after four generations of selection in a study by Frank et al in 2013 (28).

It has also been a concern that resistance to one or more toxins present in a plant may diminish the overall ability of the product to delay resistance development (30). This has been discussed for so called “pyramided” products (several similar genes).

Safety evaluation and non-target effects of Cry proteins mCry3A and eCry3.1Ab

The Bt protein mCry3A has been evaluated by EFSA in, among others, the scientific opinion made on maize event Bt11 x MIR604 (31). Here, no data, neither toxicology of allergenic, yielded evidence that mCry3A was hazardous for human health/raises safety concerns.

The other Bt protein, eCry3.1Ab was evaluated by EFSA in 2015 (32) where they found that it was unlikely that this protein would have adverse effects on the environment with the use in question (food and feed, import and processing).

Non-target effects of mCry3A and eCry3.1Ab together were evaluated by the applicant and the risk for effects were not detected to be higher than for these two proteins alone (p.107 dossier).

As a comment, the protein eCry3.1Ab is the result of a variable-region exchange from Cry proteins Cry1Ab with Cry3A. The resulting protein has a high bioactivity against target insects in the *Diabrotica virgifera virgifera* family (33). This exchange has resulted in a protein that also exerts different modes of action /has different binding sites than their “parental” proteins. However, laboratory effects data show that it is unlikely that there is an increased risk for non-target organisms upon cultivation with expressed eCry3.1Ab protein (34).

Toxicity and allergenicity

Testing of the newly expressed proteins were performed on test substance batches (proteins) from *E. coli*.

Toxicity

Chapter 1.4 in technical dossier.

For the assessment of toxicity of PAT, mCry3A and eCry3.1Ab, several factors were evaluated by the applicant:

- Molecular and biochemical characterization
- Bioinformatics
- Stability under processing
- Resistance to proteolytic enzymes
- History of safe use
- Toxicity studies
- Protein interactions

Several ORFs were also detected for all three proteins. But, no homology to known toxins were detected with the analytic tools used that had any food/feed safety concern.

Acute oral toxicity study performed on microbially produced mCry3A (p.104, dossier). No data appeared that rose concern regarding health of safety.

The history of safe use for the protein PAT was found by the applicant NOT to require a repeated dose 28-day oral toxicity study.

Potential for toxicity from the combined expression of PAT, mCry3A and eCry3.1Ab.

Due to low levels of expression and that each have distinct and well defined mode of action, the applicant find it unlikely that the proteins would interact and produce unintended effects that can harm humans or animals.

No interaction data is provided here that supports this statement.

However, a 90 day feeding study was performed in rodents according to implementation of EC regulation 503/2013 (35). Data from this study did not reveal any safety concerns.

Allergenicity

Chapter 1.5 in technical dossier.

Allergenicity tests were performed by the applicant according to the following:

- *In silico* analysis (junction-to-insert, insert)
- Specific serum screening
- Pepsin resistance, digestibility testing
- Other tests

For amino acid sequence homology studies, see page: 12. No sequences were detected that were potentially allergenic or toxic in the bioinformatics analysis performed.

The serum screening were not considered as necessary, although some Cry proteins have been thought of as potential adjuvants (see section on adjuvants, p. 13).

The other allergenicity tests did not reveal any concerns related to human or animal health.

Summary:

- Maize event MZIR098 contains genes encoding two cry proteins and one PAT protein.
- Large probes (over 1000 bp) are used during Southern blot to verify presence of inserts.
- A CaMV promoter is used for continuous expression in the maize event.
- Maize event MZIR098 contains Cry proteins, that have been and still are evaluated as potential adjuvants.
- Allergenicity and toxicity safety studies are performed mainly on microbially produced PAT, mCry3A and eCry3.1Ab proteins.
- No sequence data, or performed analysis of the microbially produced proteins reveal any allergenic or toxic potential of the inserted genes or encoded proteins.
- PAT is used as a selection marker but not removed afterwards. Glufosinate ammonium can therefore potentially be used as a herbicide during cultivation.
- Cross-resistance between distinct Cry proteins, whereof two are expressed in this maize event, have already been detected.

Herbicides

Herbicide use on GM plants – main issues

Herbicide tolerant (HT) plants are sprayed with one or more herbicide(s), which will kill weeds without harming the plant with inserted transgene(s). The use of HT GM plants may cause negative effects on ecosystem as well as animal/human health. Of particular concern are: 1) increased use of, and exposure to, toxic herbicides; 2) accelerated resistance evolution in weeds; 3) accumulation of herbicides in the plants and in plant products; 4) combinatorial effects of co-exposure to several herbicides at the same time (plants with pyramided HT genes/traits); and 5) points 1-4 indicate that the agricultural practice of growing HT GM plants, have an increasing challenge related to fulfill the criteria for a sustainable agriculture.

Total use of herbicides and environmental effects

Increased use of HT GM plants are connected to increased use of the herbicide they are tolerant to. From 1995 to 2014 the global agricultural use of glyphosate, the mostly used agricultural herbicide, rose 14.6 fold, from 51 million kg to 747 million kg and HT GM crops with glyphosate resistance are seemingly the major driver for this change. Moreover, by 2016, about 56 % of the global use of glyphosate was related to the use of HT GM crops (36). Increased use of herbicides on HT GM crops has the potential to affect ecosystem, animal and human health. Non-target biodiversity will be exposed both directly and indirectly, in terrestrial, soil and aquatic ecosystems. The issue on environmental pollution is of concern (37).

Increased use and resistance evolution in weeds

Specific for the HT GM plants is that herbicides potentially can be sprayed in higher doses than before, and repeatedly during the growth season of the plants. The increased use is of high concern in relation to the evolution of resistance in weeds.

Six species of weeds are shown to be resistant to glufosinate ammonium and 50 % of these were discovered after 2015 (38).

Accumulating herbicide residues and health effects

The issue of accumulation of herbicides in the HT plants, including their metabolites, are not regularly tested as part of the risk assessment of HT plants. It is also important to emphasize that feeding studies to test HT GM plant material have very limited relevance when the GM plant test material has not been sprayed with the relevant herbicide (39). Studies performed in *D. magna* with another herbicide, glyphosate, have shown that this is relevant and that residues of, in this case, glyphosate negatively affect the feed quality of HT GM soybeans (40-42).

About the glufosinate ammonium chemical

GM plants that contain the *pat* gene from *Streptomyces viridochromogenes* becomes tolerant to herbicides containing glufosinate-ammonium. Glufosinate ammonium is a class of herbicides that are banned in Norway and in EU (except a limited use on apples) due to both acute and chronic effects on mammals including humans. Although this trait is used for selection during

the transformation process, the gene is not removed, and glufosinate ammonium can thus be used as a herbicide on the plants, if needed.

Glufosinate ammonium is harmful with serious health risks to mammals including humans

Glufosinate ammonium is harmful by inhalation, swallowing and by skin contact. Serious health risks may result from exposure over time. Effects on humans and mammals include potential damage to brain, reproduction including effects on embryos, and negative effects on biodiversity in environments where glufosinate ammonium is used (43-46). EFSA has concluded on the risk of glufosinate ammonium, as especially harmful to mammals (47).

Combinatorial effects of herbicides and Bt-toxins

Stacked GM plant have the combination of two or more genes of interest in one single plant. Some of these have “gene pyramiding” of several Bt-toxins and/or herbicide tolerance traits. Today there is a clear trend towards combining two or more transgenic traits present in single events through conventional breeding.

Stacked events are in general more complex than the single events as there are more genes involved. There has been an increased interest in the possible combinatorial and/or synergistic effects of stacked traits (7, 48, 49). Stacking may critically influence the bioactivity and hence the potential for unintended effects. Therefore, robust data are necessary to identify whether the combined presence of transgenes and multiple co-technology herbicides may influence the quality of the plant or harm the environment.

The maize hybrid MZIR098 is tolerant to glufosinate ammonium in addition to insect resistance through two Bt-toxins. Co-exposure of these two Bt-toxins and spraying with glufosinate ammonium may trigger combinatorial effects in non-target organism in the environment. However, this represents a major knowledge gap in the scientific literature.

Main summary

Maize event MZIR098 is tolerant to herbicides containing glufosinate ammonium. This herbicide is harmful to health and environment upon use and is banned in Norway.

The issue on accumulation of the herbicides and its potential metabolites should be considered for GM plants to be used for food and feed purposes.

The applicant has not provided data that are relevant for a proper assessment of social utility, sustainable development or ethical justifiability according to the NGTA.

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