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Høringsuttalelse av søknad om utsetting av genmodifisert mais Bt11

C/F/96.05.10

Under EU direktiv 2001/18

Sendt til

Miljødirektoratet

av

GenØk-Senter for biosikkerhet
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Miljødirektoratet
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7485 Trondheim
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Vedlagt er innspill fra GenØk – Senter for Biosikkerhet på offentlig høring av søknad **C/F/96.05.10**, genmodifisert mais linje Bt11, fra Syngenta Seeds SAS, under EU direktiv 2001/18. Søknaden gjelder bruksområdet dyrking.

Vennligst ta kontakt hvis det er noen spørsmål.

Med vennlig hilsen,

Idun Merete Grønsberg
Forsker II
GenØk – Senter for biosikkerhet
idun.gronsberg@genok.no

Bidragster(e):

Lilian van Hove
Forsker III
GenØK Senter for biosikkerhet

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Høringsuttalelse – genmodifisert mais Bt11, C/F/96.05.10, under EU direktiv 2001/18.

Søknad C/F/96.05.10 omhandler genmodifisert maislinje til bruksområdet dyrking.

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

Maislinjen er også resistent mot insektarter i Lepidoptera ordenen via genet *cry1Ab*.

Maislinjen er ikke godkjent for bruksområdet i Norge og EU.

Søknaden for mat, fôr og prosessering er gyldig i EU frem til 27.juli 2020.

Oppsummering

GenØk–Senter for biosikkerhet, viser til høring av søknad C/F/96.05.10 om Bt11 mais som omfatter bruksområdet dyrking.

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

- Genmodifisert mais linje Bt11 er ikke godkjent for noen bruksområder i Norge.
- Genmodifisert mais linje Bt11 er ikke godkjent for dyrking i EU.
- Mais linje Bt11 er tolerant mot sprøytemidler som inneholder glufosinat – ammonium. Dette sprøytemidlet er ikke tillatt brukt i Norge.
- Søknaden om mais linje Bt11 mangler ytterligere data og informasjon som er relevant for å kunne ytterligere vurdere kriterier rundt etisk forsvarlighet, samfunnsnytte og bærekraft.

Summary

GenØk-Centre for biosafety refers to the application C/F/96.05.10 on Bt11 maize regarding cultivation.

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

- The gene modified, maize event Bt11 is not approved for any application in Norway.
- The gene modified maize event Bt11 is not approved for cultivation in EU.
- Maize event Bt11 is tolerant to herbicides containing glufosinate ammonium. This herbicide is not allowed to use in Norway.
- The application on maize event Bt11 lacks data and information relevant for further assessment of criteria on ethically justifiability, social utility and sustainability.

Application on C/F/96.05.10

The event Bt11 maize contains genes providing herbicide tolerance (*pat*) as well as resistance to insects in the Lepidoptera family (*cry1Ab*).

Previous evaluations

GenØk-Centre for Biosafety has previously assessed maize event Bt11 as a parental event in combined stacks for application in food, feed and processing. We refer to our assessments in 2012 (1, 2), and 2014 (3).

The Norwegian Scientific Committee for Food Safety (VKM), has assessed the insect resistant and herbicide tolerant maize event Bt11 for cultivation, food, feed, import and processing in a report from 2017 (4). In this report, they go through the molecular characterization, comparative assessment, food and feed risk assessment, environmental risk assessment as well as coexistence issues. In their report, they conclude that cultivation of Bt11 is unlikely to have adverse effects on the environment and agriculture of Norway. They also conclude that the introduced proteins that is expressed in maize event Bt11 (PAT and Cry1Ab) is unlikely to have allergic or toxic effect on human or animal health.

The Norwegian Biotechnology Advisory Board (Bioteknologirådet) has assessed maize event Bt11 in a report from June 2017, where maize event 1507 also is assessed (5). In this report, they recommend that maize event Bt11 (as well as 1507) be banned in Norway due to their lack of contribution to social utility, sustainability and ethical justifiability which are major criteria in the Norwegian gene technology act (6). Highlighted issues are the ban on glufosinate-ammonium in Norway due to health and environmental risks and the lack of insects that maize event Bt11 is tolerant to. Thus, this maize event does not have a demand based on their inserted genes and expressed transgenic proteins.

The European Food Safety Authority (EFSA) published a scientific opinion on cultivation, food, feed and industrial processing of maize event Bt11 in 2005 (7). In their opinion piece, they conclude that maize event Bt11 not will have any adverse effects on the environment, and not on human or animal health.

EFSA published a per-review of the pesticide risk assessment of glufosinate ammonium in 2012 with confirmatory data submitted in addition (8) where data provided concluded with the risk associated with the use of this chemical in mammals as well as other species.

The original pesticide risk assessment of glufosinate made by EFSA was performed in 2005 (9) where critical “areas of concern” were raised (p.42 in pesticide risk assessment), especially with a high risk to mammals a well as off crop populations of non-arthropods and other species.

A French evaluation report from 2003 (http://gmoinfo.jrc.ec.europa.eu/csnifs/C-FR-96-05-10_RiskAssessment.pdf) about placing on the market maize event Bt11 stated the following about maize event Bt11:

- There are no antibiotic resistance marker genes present in Bt11

- The promoters are “non-functional eukaryotic sequences in a prokaryotic” context and would not be functional in the case of transfer to ie bacteria.
- Cry1Ab is not toxic or allergenic.
- There is no human or animal risk related to release of Bt11, nor to the environment.
- Maize event Bt11 does not put additional risk to the human health or environment as compared to conventional maize.

Social utility and sustainability issues on the maize event Bt11, C/F/96.05.10

In Norway, an impact assessment follows the Norwegian Gene Technology Act (NGTA) (6) in addition to the EU regulatory framework for GMO assessment. In accordance with the NGTA, the development, introduction and/or use of a GMO needs to be *ethically justifiable*, demonstrate a *benefit to society* and contribute to *sustainable development*. This is further elaborated in section 10 of the Act (approval), where it is stated that: “*significant emphasis shall also be placed on whether the deliberate release represent a benefit to the community and a contribution to sustainable development*” (See section 17 and annex 4 for more detail on the regulation on impact assessment). Recent developments within European regulation on GMOs allow Member States to restrict the cultivation of GMOs on their own territory based on socio-economic impacts, environmental or agricultural policy objectives, or with the aim to avoid the unintended presence of GMOs in other products (Directive 2015/412) (10). Additionally, attention within academic and policy spheres increased in recent years on broadening the scope of the assessment of new and emerging (bio) technologies to include issues that reach beyond human and environmental health (11-17).

To assess the criteria of *ethically justifiable*, *benefit to society* and *sustainability* as in the NGTA, significant dedication is demanded as it covers a wide range of aspects that need to be investigated (e.g. Annex 4 within the NGTA, or (18)). Nevertheless, the Applicant has currently not provided any information relevant to enable an assessment of these criteria. In our assessments, we usually highlight some areas that are particularly relevant to consider and where the Applicant should provide data for in order to conduct a thorough assessment according to the NGTA. However, in line with the Norwegian Biotechnology Advisory Board in their report on June the 16th, 2017 (5), we consider the applications of maize Bt11 and maize 1507 as having so much similarity that this report is based on the same input given in our report on maize 1507. We agree with the recommendation of the Norwegian Biotechnology Advisory Board on maize Bt11 to ban the cultivation of this maize in Norway. We will shortly summarize key issues concerning maize Bt11 below.

The ban on maize event 1507 and its relevance for assessing maize event Bt11

Norwegian authorities have banned the release of maize event 1507 in Norway. After evaluation, the Norwegian Scientific Committee for Food Safety (VKM) concluded that this maize is as safe as conventional maize. However, the Norwegian Biotechnology Advisory Board (NBAB) concluded in their assessment that this maize should not be allowed in Norway as it is ethically problematic and does not contribute to sustainable development.

Maize event 1507 is developed to be resistant to glufosinate-ammonium and so is maize Bt11. This is a class of herbicide that is banned in Norway due to the risks to human health and the environment. The NBAB concluded that it seems ethically ambiguous and inconsistent to import a plant that is resistant to this herbicide, thereby allowing the use and development of a harmful herbicide in other countries, while considering the herbicide as too harmful to be used in Norway. This also troubles the fulfilment of the criteria of *sustainable development*, as this

criteria is meant to be considered in a global context. This problem has been previously identified by the NBAB (19) and GenØk has addressed it multiple times when an applicant seeks approval of a product containing maize event 1507 (e.g. 20, 21) or tolerance to glufosinate-ammonium. Although the Norwegian Environmental Agency recommended approval of maize 1507, the Ministry of Climate and Environment was oppose to this approval. In the Royal Resolution of June 2nd 2017, a final decision was made and maize 1507 is prohibited to be traded in Norway. This is the first GM crop to be prohibited in Norway based on ethical considerations only. Although maize Bt11 is not officially banned in Norway, it contains the same characteristics that maize 1507, namely resistance to glufosinate-ammonium and a particular pesticide. Therefore, the ethical basis on which maize 1507 is banned in Norway could be applied to maize Bt11. Any other recommendation than a ban for the cultivation of maize Bt11 would be inconsistent.

The applicant mentioned that the use of the *pat* gene that makes the plant resistant to glufosinate-ammonium is only used as a marker gene and that this characteristic will not be utilized. However, it remains a crop that could tolerate the use of glufosinate-ammonium and even though tolerating this herbicide may not be the reason for the insertion of this this gene, it still allows for the (illegal in Norway) use of glufosinate-ammonium. Furthermore, we regard a reference to this resolution as sufficient and therefore consider a further elaboration on the evaluation of maize Bt11 according to the NGTA as superfluous.

Short summary of previous evaluations

In previous hearings of applications of import and processing of GM crops with these characteristics, we have pointed out that information was lacking to enable a fruitful evaluation of the criteria in the NGTA. These points remain relevant for the current application. Below we summarize key issues on which information is required for this assessment:

- *Co-existence*; the cultivation of GM plants in general is causing problems with regard to co-existence. It is important to obtain information about the strategies adopted to ensure co-existence with conventional and organic maize production and the applicant should provide information on this to enable an accurate evaluation of the criteria in the NGTA. As also mentioned by the NBAB in their evaluation of this application on maize 1507, a code of conduct for coexistence and system for controlling the separation of GMOs and non-GMOs should be in place. This will lead to additional costs for society and /or other parts of the production chain, but we do not know what it will cost. Information on this is needed to conduct a comprehensive evaluation.
- *Benefit to society*; A report on the perceptions among Norwegian citizens on GMOs describes how about half of the respondents expressed that they were negative for sale of GMO-products in Norwegian grocery stores in the future, and only 15 percent were positive (22). Furthermore, it should be noted that 29 % of the global maize production is GM. It is therefore not a problem for Norway to import GM free maize and therefore no need to replace current imports. The GM maize in question does also not contain any beneficial characteristics for consumers that would prioritize this maize over non-GM maize.

- *Impacts of the Bt-toxin on target and non-target organisms*; Both impacts on non-target organisms and resistance development among target pests of Bt maize have been documented. Evaluation of resistance development within the target pest population and strategies suggested to halt this development are warranted, as impacts on non-target organisms is crucial in a sustainability assessment.

Environmental risk issues in a Norwegian context

The level of maize production is 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. Cultivation of maize 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

We have commented on maize event Bt11 in other applications previously and refer to these for further elaboration on points regarding molecular characterization and protein expression (1-3).

Toxicity and allergenicity

Toxicity

PAT and Cry1Ab proteins have previously been assessed by EFSA to be safe based on the criteria of analysis of homology to other proteins known to be toxic, rapid degradation in digestion assays (*in vitro*), no sequence similarity to known toxins and no acute oral toxicity found in previous analysis of the proteins.

Allergenicity

Proteins PAT and Cry1Ab have been tested for their allergenic potential through the weight of evidence approach in several other applications.

Although both proteins are considered as non-allergenic based on the analysis done, we will mention the issue on adjuvancy connected to some of the Cry proteins (23-26). There is a lack of knowledge regarding which of the Cry proteins and to what extent, these proteins acts as adjuvants.

EFSA have a call for literature review on immunogenicity/adjuvanticity assessment of proteins, including Cry proteins, which results/review have not been published yet (<http://www.efsa.europa.eu/en/tenders/tender/170407>).

Herbicides

Herbicide use on GM plants

The use of herbicides, and in this case the herbicide glufosinate-ammonium, is one of the important issues regarding this application on cultivation.

Although the Applicant states that they not will use this herbicide during cultivation in the EU, the option is present.

By adding on a plant that have an additional option for spraying, will give a potential increase in herbicide usage over time.

In a Norwegian context, cultivation of maize event Bt11 and use of the herbicide glufosinate-ammonium is not an option as glufosinate-ammonium usage is banned.

Glufosinate-ammonium and health

Glufosinate-ammonium is harmful by inhalation, swallowing and by skin contact. Serious health risks may result from exposure over time. Observations of patients poisoned by glufosinate-ammonium have found that acute exposure causes convulsions, circulatory and respiratory problems, amnesia and damages to the central nervous system (CNS) (27, 28).

Chronic exposure in mice has been shown to cause spatial memory loss, changes to certain brain regions, and autism-like traits in offspring (29, 30).

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 (27, 28, 31, 32). EFSA has concluded on the risk of glufosinate ammonium, as especially harmful to mammals (9).

Main summary

- The current Application for maize event Bt11 is for cultivation.
- Maize event Bt11 is tolerant to the herbicide glufosinate-ammonium which is banned in Norway. This herbicide has different degrees of health and environmental damage upon use.
- Although the Applicant is not going to use the herbicide during cultivation in EU, the option is present.
- Maize event Bt11 is not approved for any applications in Norway.
- A maize event with almost the same inserted traits for herbicide tolerance and also toxicity against a certain class of insects (living maize event 1507) has recently been banned by the Norwegian authorities.
- No further information regarding sustainable development, social utility or ethical issues are present.

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