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Høringsuttalelse av søknad om utsetting av genmodifisert mais 1507

C/ES/01/01

Under EU direktiv 2001/18

Sendt til

Miljødirektoratet

av

GenØk-Senter for biosikkerhet
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Miljødirektoratet
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Vedlagt er innspill fra GenØk – Senter for Biosikkerhet på offentlig høring av søknad **C/ES/01/01**, genmodifisert mais linje 1507, fra Pioneer Hi-Bred International og Mycogen Seeds under EU direktiv 2001/18. Søknaden gjelder bruksområdet dyrking.

Vennligst ta kontakt hvis det er noen spørsmål.

Med vennlig hilsen,

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Høringsuttalelse – genmodifisert mais 1507, C/ES/01/01, under EU direktiv 2001/18.

Søknad C/ES/01/01 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 det innsatte genet *cryIF*.

Maislinjen er ikke godkjent for bruksområdet i Norge og EU.

Fornyelsessøknaden for mat, fôr og prosessering er under behandling i EU.

Levende 1507 mais ble forbudt importert til Norge for bruk i fôr og industrielle prosesser pr 2.juni 2017 (1).

Oppsummering

GenØk-Senter for biosikkerhet, viser til høring av søknad C/ES/01/01 om 1507 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 1507 er ikke godkjent for noen bruksområder i Norge.
- Genmodifisert mais linje 1507 er ikke godkjent for dyrking i EU og fornyelsessøknaden for mat og fôr er under behandling.
- Mais linje 1507 er tolerant mot sprøytemidler som inneholder glufosinat – ammonium. Dette sprøytemidlet er ikke tillatt brukt i Norge.
- Det er forbudt å importere levende 1507 til Norge (1).
- Søknaden om mais linje 1507 mangler 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/ES/01/01 on 1507 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 1507 is not approved for any application in Norway.
- The gene modified maize event 1507 is not approved for cultivation in EU and the renewal of application on food, feed and processing is under “treatment”.
- Maize event 1507 is tolerant to herbicides containing glufosinate ammonium. This herbicide is not allowed to be used in Norway.
- It is not allowed to import living maize 1507 to Norway (1).
- The application on maize event 1507 lacks data and information relevant for further assessment of criteria on ethically justifiability, social utility and sustainability.

Application on C/ES/01/01

The event 1507 maize contains genes providing herbicide tolerance (*pat*) as well as resistance to insects in the Lepidoptera family (*cry1F*).

Previous evaluations

GenØk-Centre for Biosafety has previously assessed maize event 1507 as a parental event in multistacks in several applications regarding food, feed and processing¹.

Maize event 1507 has also been assessed as a renewal of application for food, feed and processing in 2015 (2).

The Norwegian Biotechnology Advisory Board (Bioteknologirådet) has assessed maize event 1507 in a report from June 2017, where maize event Bt11 also is assessed (3). In this report, they recommend that maize event 1507 (as well as Bt11) 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 (4). 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 Norwegian Scientific Committee for Food Safety (VKM) published a report with their assessment of the insect resistant and herbicide tolerant maize event 1507 in 2017. This report includes assessment of cultivation, as well as food, feed import and processing (5). 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 maize event 1507 is unlikely to have adverse effects on the environment and agriculture of Norway. They also conclude that the introduced proteins that is expressed in this maize event (PAT and Cry1F) are unlikely to have allergic or toxic effect on human or animal health.

European Food Safety Authority (EFSA) published an opinion document on maize event 1507 in 2005 regarding import, feed, industrial processing and cultivation (6).

In this document, EFSA concludes that maize event 1507 will not have any adverse effects on human and animal health or the environment with the intended usage.

EFSA published a per-review of the pesticide risk assessment of glufosinate ammonium in 2012 with confirmatory data submitted (7). The 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 (8) where critical “areas of concern” were raised (p.42 in pesticide risk assessment), especially with a high risk to mammals as well as off crop populations of non-arthropods and other species.

¹ <http://genok.no/radgiving/horningsuttalelser/>

A Spanish report from “Ministerio de medio Ambiente, Comisión Nacional de Bioseguridad,” was published in 2003 (9) where they went through the characterization of the product to be commercialized (maize event 1507). Labelling of the product and an environmental risk assessment was made, focusing on the potential for gene transfer, potential for survival, establishment and dissemination, expression of the transgenic proteins and other relevant issues to be able to evaluate the potential for hazard for human, animals and the environment were assessed. The Spanish commission concluded that with the data available, there was no potential for adverse effects on animals, human or the environment and that the resistance development towards Cry1F protein had a “limited potential development” for the target insects.

The Norwegian Authorities have, through a Royal Resolution dated on the 2nd of June, 2017 (1) pointed the following regarding maize event 1507:

- Ministry of Climate and Environment (KLD) propose that maize event 1507 is prohibited to be traded in Norway under the Gene Technology Act (4). This applies to living maize only (dead and processed 1507 is not covered by this prohibition)
- This prohibition applies for the approved areas of use after directive 2001/18/EC (<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0018&from=EN>), feed and industrial processes.
- The Ministry base its conclusion on the following: “the use is ethically problematic” and emphasizes that based on the use of glufosinate ammonium where the maize is produced and that Norway has a ban on this herbicide, import of 1507 is evaluated as ethically problematic and not sustainable by consumer organizations in Norway. This is because the cultivation of the maize depends on the use of glufosinate ammonium, a herbicide that is banned in Norway.
- Maize event 1507 have no traits evaluated as useful for Norwegian consumers/users since it is not allowed to use the herbicide that the maize is modified to tolerate.

See also <https://www.regjeringen.no/no/aktuelt/regjeringen-sier-nei-til-genmodifiserte-planter/id2555387/>

Social utility and sustainability issues on the maize event 1507, C/ES/01/01

In Norway, an impact assessment follows the Norwegian Gene Technology Act (NGTA) (4) 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 with maize 1507 and where the Applicant should provide data for in order to conduct a thorough assessment according to the NGTA. However, as the import or processing of maize 1507 in Norway is already banned and we agree with the recommendation of the Norwegian Biotechnology Advisory Board on maize 1507 to ban the cultivation of this maize in Norway (3), we will only summarize key issues concerning maize 1507.

The ban on maize event 1507

Norwegian authorities have banned the release of Maize 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 1507 is developed to be resistant to glufosinate-ammonium. 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 Norwegian Biotechnology Advisory Board (19) and GenØk has addressed it multiple times when an

Applicant seeks approval of a product containing maize 1507 (e.g. 20, 21). Although the Norwegian Environmental Agency recommended approval of maize 1507, the Ministry of Climate and Environment decided on a ban on living maize 1507. 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.

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 *pat* gene, it still allows for the (illegal in Norway) use of glufosinate-ammonium. Furthermore, we consider approval of this application against the Royal Resolution. We regard a reference to this resolution as sufficient and therefore consider a further elaboration on the evaluation of maize according to the NGTA as superfluous.

Short summary of previous evaluations

In previous hearings of applications of import and processing of GM crops with the events maize 1507, 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.



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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 1507 in several other applications previously and refer to these for further elaboration on points regarding molecular characterization and protein expression².

Toxicity and allergenicity

Toxicity

PAT and Cry1F 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 not acute oral toxicity found in previous analysis of the proteins.

Allergenicity

Proteins PAT and Cry1F 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 related to some (not all) Cry proteins that has been reported and mentioned (23-26). This is not investigated for all Cry proteins.

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>).

² <http://genok.no/radgiving/horingsuttalelser/>

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 1507 and use of the herbicide glufosinate-ammonium is not an option as both living 1507 as well 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 (8).

Main summary

- The current Application for maize event 1507 is for cultivation.
- Maize event 1507 is tolerant to the herbicide glufosinate-ammonium which is banned in Norway. This herbicide has different degrees of health and environmental damage upon use.
- Maize event 1507 is not approved for any applications in Norway and living maize 1507 has recently been banned by the Norwegian authorities.
- Although the Applicant is not going to use the herbicide during cultivation in EU, the option is present.
- No further information regarding sustainable development, social utility or ethical issues are present.

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