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KENMERK CGM/160929-01

ONDERWERP Aanvraag voor de hernieuwing van de toelating van gg-maïs MON810 voor teelt: beoordeling van COGEM advies op basis van EFSA opinies

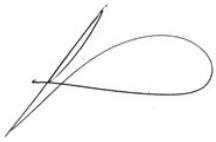
Geachte mevrouw Dijksma,

Naar aanleiding van een adviesvraag in verband met de aanstaande stemming over de teelt van genetisch gemodificeerde (gg-) maïs MON810 (EFSA-GMO-RX-MON810) in het regelgevend comité onder Richtlijn 2001/18/EC deelt de COGEM u het volgende mee.

Samenvatting:
De COGEM is gevraagd om te adviseren over de genetisch gemodificeerde (gg-)maïslijn MON810. Deze maislijn brengt het *cry1Ab* gen tot expressie en is daardoor resistent voor bepaalde plaaginsecten uit de orde van de Lepidoptera (vlinderachtigen). MON810 mag sinds 1998 in Europa geteeld worden. Vergunningen voor markttoelatingen van gg-gewassen worden verleend voor een periode van tien jaar. De vergunning voor teelt van MON810 is echter nog niet hernieuwd.
De COGEM heeft in 2008 positief geadviseerd over de aanvraag voor hernieuwing van de toelating voor teelt van MON810. Zij concludeerde dat de risico's voor mens en milieu bij de teelt van maïslijn MON810 verwaarloosbaar klein zijn.
De Europese Commissie heeft recent een conceptbesluit opgesteld voor de hernieuwing van de toelating van MON810 voor teelt en dit ter stemming voorgelegd aan de lidstaten. Omdat het laatste COGEM advies over de teelt van MON810 dateert uit 2008 en er sindsdien verschillende EFSA opinies zijn verschenen, is de COGEM met het oog op de aanstaande stemming gevraagd of deze EFSA opinies haar eerdere conclusie doen veranderen.
De COGEM is van mening dat de EFSA opinies geen informatie bevatten die de eerdere conclusie van de COGEM weerleggen. De COGEM plaatst wel enkele kanttekeningen bij de aanbevelingen van de EFSA met betrekking tot kortschildkevers en zogenaamde niet-doelwit vlinderachtigen (Lepidoptera).

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,



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Application for cultivation of genetically modified maize MON810: assessment of COGEM advice in view of EFSA opinions

COGEM advice CGM/160929-01

Summary

- COGEM has been asked to advise on cultivation of genetically modified maize MON810;
- MON 810 expresses the *cry1Ab* gene which confers resistance to certain lepidopteran pests;
- MON810 was granted an authorisation for cultivation in Europe in 1998;
- In Europe, market authorisations are granted for a period of ten years. Therefore, an application for renewal of the authorisation was filed in 2007;
- In 2008, COGEM issued a positive advice on the application for renewal and concluded that cultivation of MON810 poses a negligible risk to the environment;
- Several EFSA opinions have been published since COGEM's advice;
- The European Commission recently submitted its draft decision on the renewal of the authorisation for cultivation of MON810 to the Member States. In view of the upcoming vote on MON810, COGEM has been asked whether the EFSA opinions published since 2008 contain information that would change COGEM's previous conclusions;
- COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions;
- COGEM expresses reservations with regard to EFSA's recommendations regarding rove beetles and non-target Lepidoptera.

1. Introduction

MON810 has been cultivated in Europe (e.g. Spain, Portugal, the Czech Republic, Slovakia and Romania) since 2003.[1] The authorisation for cultivation was granted in 1998,[2] and had to be renewed in 2008. In 2007 an application for renewal of the authorisation was filed (EFSA-GMO-RX-MON810), but a decision on the renewal of the authorisation has not yet been reached.

The European Commission has recently submitted its draft decision on the cultivation of genetically modified (GM) maize MON810 to the Regulatory Committee. In view of the upcoming vote on the authorisation for cultivation of MON810, the Netherlands Ministry of Infrastructure and the Environment has asked COGEM for advice.[*]

[*] Simultaneously with the draft decision on cultivation of MON810 draft decisions on cultivation of Bt11 and 1507 were submitted by the European Commission. COGEM has also been asked to assess the EFSA opinions relevant to Bt11 and 1507. The opinions on the three GM maize lines contain similar information and sometimes refer to more than one of the GM maize lines. As each maize line has specific points of attention in addition to overarching issues, separate opinions on each of the maize lines will be issued despite of the inevitable duplications in the text.

In 2008, COGEM assessed the application for renewal of the authorisation for cultivation of MON810 and the available scientific literature and concluded that cultivation of MON810 poses a negligible risk to the environment.[3] Since COGEM's advice in 2008, several opinions and technical reports on MON810 have been published by the European Food Safety Authority (EFSA). Because of the upcoming vote on cultivation of MON810, COGEM has been asked whether the opinions of EFSA give COGEM reason to change its previous conclusion.

1.1 Aspects of the wild-type crop

Maize (*Zea mays*) is a member of the grass family *Poaceae*. Maize is a highly domesticated crop, originating from Central America, but nowadays maize is cultivated globally. Maize is predominantly wind pollinated.[4,5] Insect pollination is limited since the female flowers do not produce nectar and therefore are not attractive to insect pollinators.[6] In Europe, no wild relatives of maize are present and so hybridisation with other species cannot occur.

In the Netherlands, the appearance of volunteers is very rare to absent.[7] Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[6,8] The kernels remain on the cob after ripening and do not shatter naturally.[6,9] In cultivation areas with warmer climatic conditions, the appearance of volunteers can occur the year following maize cultivation due to spilled cobs or kernels. However, these volunteers are usually killed by common mechanical pre-planting soil preparation practices.[6]

Maize is very sensitive to weed competition.[10] During the long process of domestication, maize has lost the ability to survive in the wild.[5] Establishment of maize plants in the wild has never been observed in the Netherlands and COGEM is not aware of any reports of feral maize populations elsewhere in Europe.

1.2 Description of MON810 maize and the introduced trait

GM maize MON810 was produced by particle bombardment. It expresses a Cry1Ab protein derived from *Bacillus thuringiensis* subsp. *kurstaki* which confers resistance to certain lepidopteran pests. A detailed description of the elements introduced in MON810 is provided in COGEM's previous advice on MON810.[3] The molecular characterisation of MON810 was more recently assessed as part of COGEM's advice on import and processing of GM maize 1507xMON810xMIR162xNK603. COGEM considered the molecular characterisation adequate.[11]

2. Assessment of the EFSA opinions

COGEM advised on the renewal of the authorisation for cultivation in 2008. In 2009, EFSA issued its opinion on the continued use of MON810 maize for food, feed and cultivation.[12] The three renewal applications, member state comments, and relevant scientific publications were used by EFSA to assess whether MON810 poses a risk to the environment. In its 2009 opinion, EFSA

concluded that *maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera."*[12]

Since 2009, several additional EFSA opinions have been published. These opinions discuss relevant scientific literature published after EFSA's initial assessment,[13,14] or refine and/or evaluate the mathematical model used by EFSA to assess potential risks to non-target Lepidoptera.[15,16,17,18] In 2011, EFSA provided further information on the management measures it considered necessary: *"In situations where „extremely sensitive" non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that risk mitigation measures are adopted to reduce exposure… Risk mitigation measures are only needed when the proportion of maize and uptake of maize Bt11 (and/or maize MON 810) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area, then risk mitigation measures are not required."*[15]

In addition to these EFSA opinions, opinions on the MON810 Post Market Environmental Monitoring (PMEM) reports were also published. PMEM reports are submitted annually by the applicant and contain amongst others information on farmer questionnaire based surveys, peer-reviewed publications and on insect resistance management (IRM).[19,20,21,22,23,24,25]

In its opinion on the PMEM report of 2014 EFSA concluded, similar to its conclusions on previously submitted PMEM reports "*The data reported in the annual 2014 PMEM report on maize MON 810 do not indicate any adverse effects on human and animal health or the environment arising from the cultivation of maize MON 810 during the 2014 growing season. The GMO Panel therefore concludes that the CSM* [†] *and GS*[‡] *of maize MON 810 as carried out by the consent holder did not provide evidence that would invalidate previous GMO Panel evaluations on the safety of maize MON 810."*[25]

2.1 Scientific publications

Since COGEM's advice in 2008, a considerable amount of scientific publications on potential effects of Cry1Ab-expressing maize on non-target organisms have been published. The opinions issued by EFSA provide a welcome and detailed overview of the available literature. For example, in the EFSA opinion on MON810 issued in 2012, 97 scientific publications were discussed. According to EFSA, *"None of these publications reported new information that would invalidate the previous conclusions on the safety of maize MON 810 made by the EFSA GMO Panel."*[13]
EFSA concluded that "*its previous risk assessment conclusions on maize MON810, as well as previous recommendations for risk mitigation measures and monitoring remain valid and applicable."*[13] Another example is provided by an EFSA opinion on the Cry1Ab-expressing maize Bt11, in which 144 scientific publications (23 studies specifically relating to Bt11) provided by the

[†] CSM: Case-Specific Monitoring

[‡] GS: General Surveillance

applicant were evaluated by EFSA. EFSA stated that "*No evidence was found that would invalidate previous EFSA GMO Panel conclusions on the environmental safety of maize Bt11."*[15]

The conclusions drawn by EFSA after assessing the available literature support COGEM's conclusion that cultivation of MON810 poses a negligible risk to the environment.

2.2 Recommendations of EFSA

COGEM agrees with EFSA's conclusion that cultivation of MON810 is unlikely to pose a risk to the environment. COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions. COGEM identified two aspects in the EFSA opinions which need to be addressed.

Risk mitigation measures

EFSA recommends risk mitigation measures to reduce exposure of non-target Lepidoptera. This recommendation follows from the results of a modelling exercise performed to assess potential risks for non-target Lepidoptera. The Cry1Ab protein expressed by MON810 is toxic to certain lepidopteran pest insects. Non-target Lepidoptera could be exposed to the Cry1Ab protein if they ingest MON810 maize pollen which is deposited on their host plants. Lethal and sublethal effects of Cry1Ab-expressing maize pollen (e.g. MON810 or Bt11 pollen) or the Cry1Ab protein on non-target lepidopteran species have been reported under laboratory conditions.[12,26] Whether non-target Lepidoptera are affected under field conditions depends amongst others on the actual exposure to MON810 pollen.

Due to a limited number of field studies, the low abundance of non-target Lepidoptera in maize fields and the difference in biology among lepidopteran species (i.e. timing of larval development and host plants), it proved difficult to assess whether cultivation of MON810 poses a risk to European non-target Lepidoptera. EFSA therefore built a mathematical model to assess whether MON810 poses a risk to European non-target Lepidoptera.[12,15]

Based on mortality estimates obtained using this mathematical model EFSA considered risk mitigation measures (i.e. non-Bt-maize border rows) necessary if Bt11 and/or MON810 cultivation exceeded 7.5% of the "regional Utilized Agricultural Area". In addition, EFSA recommended that Bt11 and/or MON810 maize is not cultivated within 20 meter of protected habitats, in order to minimise exposure and risk to lepidopteran species of conservation concern and unknown sensitivity to the Cry1Ab protein.[15]

In the modelling exercise the percentage mortality is calculated for hypothetical and actual non-target lepidopteran species in various theoretical situations. In some of these theoretical situations, the calculated percentage exceeds the thresholds set by EFSA.

The mortality percentages estimated by the modelling exercises identify a risk to non-target Lepidoptera in, or in close proximity to MON810 maize fields. However, to signify a risk to populations of non-target Lepidoptera, the bulk of the host plants, and thus the major part of the population of non-target Lepidoptera, have to be present in, or in close proximity to MON810 and/or B11 maize fields. Although such a situation could occur in theory, in reality host plants and

thus non-target Lepidoptera populations that are present in the immediate surroundings of maize fields are also present in other environments. COGEM is of the opinion that the effect observed in the modelling exercise represents a theoretical situation, which is not representative of the actual situation in the field. It is extremely unlikely that MON810 would pose a risk to populations of non-target Lepidoptera in a realistic situation. COGEM is therefore of the opinion that there are insufficient grounds for the mitigation measures recommended by EFSA and considers both the non-Bt maize border rows in areas with a high adoption rate of Cry1Ab-expressing maize (MON810 and Bt11) as well as the 20 meter separation distance to protected areas disproportionate.

COGEM notes that the recommended mitigation measures for 1507 maize differ from the mitigation measures recommended for Cry1Ab-expressing maize (MON810 and Bt11), i.e. 30 meter instead of 20 meter separation distance to protected areas and a high adoption rate of 5% instead of 7.5%.[15,27] COGEM points out that these different recommendations will create confusion in practice.

Screening of literature

In its opinion on the PMEM report of 2012, EFSA recommended the applicant to follow-up on possible adverse effects on rove beetles (*Staphylinidae*).[22] This recommendation has been repeated in subsequent EFSA opinions on MON810 PMEM reports. [23,24,25]

The recommendation follows from a scientific publication identified by EFSA and describing the results of Spanish field trials conducted to monitor potential effects of MON810 on non-target organisms.[22] A significant lower number of rove beetles (*Staphylinidae*) was observed in one of the two studied regions.[28] The observed differences were discussed. Similar results had been reported in two other publications on field trials,[29,30] but in a laboratory experiment no effect was observed when the predatory rove beetle *Atheta coriaria* was exposed to the Cry1Ab protein expressed by MON810.[31]

According to the authors of the publication, rove beetles are a heterogeneous group of species with very different feeding habits (predators, parasitoids, mycetophagous and herbivores), which makes it difficult to identify the cause of the observed difference.[28] In another publication, the authors mention that Staphylinids are not suited for use as a “representative” taxon to detect changes caused by GM varieties in field trials, because their abundance is highly variable between years and plots.[33]

In response to the recommendation of EFSA, additional publications were analysed by the applicant in the 2013 PMEM report.[32,33,34] The applicant concluded that the observed differences in rove beetle abundance were unlikely to be attributed to the Cry1Ab protein.

As previously noted by COGEM, field trials are not well equipped to study effects on non-target organisms if these non-target organisms are present in low numbers and/or their abundance is highly variable.[35] Although differences in the number of rove beetles were observed in some of the field trial locations, they were not observed consistently. As also mentioned by EFSA, the abundance/distribution of rove beetles is highly variable over time and space.[24,33]

On the basis of the laboratory results and the variable results from field trials, COGEM is of the opinion that the observed difference most likely results from the variable distribution of rove beetles and is no cause for concern. Since screening of available literature to identify potential adverse effects of MON810 is already part of the normal general surveillance activities, COGEM does not object to EFSA's recommendation to follow-up possible adverse effect of MON810 on rove beetles by screening the available literature.

3. Conclusion

COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions that cultivation of MON810 maize poses a negligible risk to the environment.

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