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**DATUM** 29 september 2016  
**KENMERK** CGM/160929-02  
**ONDERWERP** Aanvraag voor toelating van gg-mais Bt11 voor teelt: beoordeling van COGEM advies op basis van EFSA opinies

Geachte mevrouw Dijkma,

Naar aanleiding van een adviesvraag in verband met de aanstaande stemming over de teelt van genetisch gemodificeerde (gg-) mais Bt11 (C/F/96/05.10) 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 Bt11. Deze maïslijn brengt de genen *cry1Ab* en *pat* tot expressie en is daardoor resistent voor bepaalde plaaginsecten uit de orde van de Lepidoptera (vlinderachtigen) en tolerant voor glufosinaat-ammonium bevattende herbiciden.

De Europese Commissie heeft recent een conceptbesluit opgesteld voor de toelating van Bt11 voor teelt en dit ter stemming voorgelegd aan de lidstaten. De COGEM heeft eerder positief geadviseerd over de teelt van Bt11 en geconcludeerd dat de risico's voor mens en milieu bij de teelt van maïslijn Bt11 verwaarloosbaar klein zijn. Omdat dit COGEM advies in 2005 is uitgebracht 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 door EFSA geadviseerde maatregelen om de blootstelling van zogenaamde niet-doelwit vlinderachtigen (Lepidoptera) te verminderen.



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

Hoogachtend,

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke.

Prof. dr. ing. Sybe Schaap  
Voorzitter COGEM

c.c.           Drs. H.P. de Wijs, Hoofd Bureau ggo  
                  Mr. J.K.B.H. Kwisthout, Ministerie van IenM

# Application for cultivation of genetically modified maize Bt11: assessment of COGEM advice in view of EFSA opinions

## COGEM advice CGM/160929-02

### *Summary*

- COGEM has been asked to advise on cultivation of genetically modified maize Bt11;
- Bt11 expresses the *cry1Ab* and *pat* genes which confer resistance to certain lepidopteran pests and tolerance to glufosinate-ammonium containing herbicides;
- In 2005, COGEM issued a positive advice on the cultivation of maize Bt11 and concluded that cultivation of Bt11 poses a negligible risk to the environment;
- Several EFSA opinions have been published since the advice of COGEM in 2005;
- The European Commission recently submitted its draft decision on the authorisation for cultivation of Bt11 to the Member States. In view of the upcoming vote on Bt11, COGEM has been asked whether the EFSA opinions contain information that would change its conclusions of 2005;
- 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 the mitigation measures recommended by EFSA to reduce exposure of non-target Lepidoptera.

### **1. Introduction**

The European Commission has recently submitted its draft decision on the authorisation for cultivation of genetically modified (GM) maize Bt11 (C/F/96/05.10) to the Regulatory Committee. In 2005, COGEM advised positively on cultivation of this GM maize line.<sup>1</sup> Since COGEM's advice, several opinions and technical reports on maize Bt11 have been published by EFSA. In view of the upcoming vote, COGEM has been asked by the Netherlands Ministry of Infrastructure and the Environment whether these EFSA opinions give COGEM reason to change its previous conclusion.<sup>i</sup>

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<sup>i</sup> Simultaneously with the draft decision on cultivation of Bt11, draft decisions on cultivation of MON810 and 1507 were submitted by the European Commission. COGEM has also been asked to assess the EFSA opinions relevant to MON810 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.

### ***1.1 Aspects of 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.<sup>2,3</sup> Insect pollination is limited since the female flowers do not produce nectar and therefore are not attractive to insect pollinators.<sup>4</sup> 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.<sup>5</sup> Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.<sup>4,6</sup> The kernels remain on the cob after ripening and do not shatter naturally.<sup>4,7</sup> 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.<sup>4</sup>

Maize is very sensitive to weed competition.<sup>8</sup> During the long process of domestication, maize has lost the ability to survive in the wild.<sup>3</sup> 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 maize Bt11 and the introduced traits***

Maize line Bt11 contains the *cry1Ab* gene derived from *Bacillus thuringiensis* subsp. *kurstaki*, and the *pat* gene derived from *Streptomyces viridochromogenes*. Both genes are constitutively expressed. As a result maize Bt11 is resistant to certain lepidopteran insect pests and tolerant to glufosinate-ammonium containing herbicides. A detailed description of the elements introduced in maize Bt11 is provided in COGEM's previous advice on the renewal of the authorization for import and processing of maize line Bt11.<sup>9</sup>

### ***1.3 Previous COGEM advice***

In 1999, 2003 and 2004, COGEM advised negatively on cultivation of maize Bt11, because of insufficient information regarding potential effects on non-target organisms and persistence of the Cry1Ab protein in soil.<sup>10,11,12</sup> Apart from the Netherlands, several other Member States raised questions on the application.

The European Food Safety Authority (EFSA) issued its opinion on this application in 2005.<sup>13</sup> In this opinion, the application, additional information provided by the applicant, comments of the Member States and available scientific literature were taken into account. EFSA concluded that "*Bt11 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use.*"<sup>13</sup>

COGEM was asked to advise on this opinion. The information in the EFSA opinion sufficiently answered the questions previously raised by COGEM. In accordance thereof, COGEM concluded that cultivation of Bt11 poses a negligible risk to the environment, and advised positively on the application.<sup>1</sup>

In 2012, COGEM advised positively on import and processing of maize lines Bt11xMIR162x1507xGA21 and Bt11x59122xMIR604x1507xGA21.<sup>14,15</sup> In the applications, the bioinformatic analyses on purpose of the molecular characterisation of the parental lines were updated. These analyses did not reveal any new concerns, and COGEM concluded that the molecular characterisation of Bt11 was adequate.

## **2. Assessment of the EFSA opinions**

In the COGEM advice of 2005, COGEM concluded that cultivation of Bt11 poses a negligible risk to the environment.<sup>1</sup> Since 2005, several additional EFSA opinions have been published. These opinions provide additional clarifications on the conclusion of EFSA,<sup>16</sup> discuss relevant scientific literature published after EFSA's initial assessment<sup>19,17,18</sup> or concern the use of a mathematical model to assess potential risks of the cultivation of Bt11 maize to non-target Lepidoptera.<sup>19,20,21,22</sup>

In 2011, EFSA evaluated several publications which were published after its initial opinion. According to EFSA *"No evidence was found that would invalidate previous EFSA GMO Panel conclusions on the environmental safety of maize Bt11."*<sup>19</sup> Nevertheless, based on results obtained with the mathematical model EFSA concludes that *"there is a risk to certain „extremely sensitive" non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize Bt11 (and/or maize MON 810) pollen deposited on their host-plants."*... *"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."*<sup>19</sup>

### **2.1 Scientific publications**

Since COGEM's advice in 2005, 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 Bt11 issued in 2011, it was mentioned that 144 scientific publications (23 studies specifically relating to Bt11) provided by the 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."*<sup>19</sup> Another example is provided by an EFSA opinion on the Cry1Ab-expressing maize MON810, in which 97 scientific publications were discussed. EFSA concluded that *"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."*<sup>23</sup>

The conclusions drawn by EFSA after assessing the available literature support COGEM's conclusion that cultivation of Bt11 poses a negligible risk to the environment.

## **2.2 Risk mitigation measures**

COGEM agrees with EFSA's conclusion that cultivation of Bt11 is unlikely to raise additional safety concerns for the environment compared to conventional maize. COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions. COGEM identified one aspect in the EFSA opinions which needs to be addressed.

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 Bt11 is toxic to certain lepidopteran pest insects. Non-target Lepidoptera could be exposed to the Cry1Ab protein if they ingest Bt11 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.<sup>19,24,25</sup> Whether non-target Lepidoptera are affected under field conditions depends amongst others on the actual exposure to Bt11 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 Bt11 poses a risk to European non-target Lepidoptera. EFSA therefore used a mathematical model to assess potential risks of Bt11 cultivation to European non-target Lepidoptera.<sup>19</sup>

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.<sup>19</sup>

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 Bt11 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 Bt11 and/or MON810 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 Bt11 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 (Bt11 and MON810) 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%.<sup>19,26</sup> COGEM points out that these different recommendations will create confusion in practice.

### 3. Conclusion

COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions that cultivation of Bt11 maize poses a negligible risk to the environment.

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