Application for cultivation of genetically modified maize 1507: assessment of COGEM advice in view of EFSA opinions

COGEM advice CGM/160929-03

Summary

- COGEM has been asked to advise on cultivation of genetically modified maize 1507;
- Maize 1507 expresses the *cry1F* and *pat* genes which confer resistance to certain lepidopteran pests and tolerance to glufosinate-ammonium containing herbicides;
- In 2003, COGEM issued a positive advice on the cultivation of maize 1507 and concluded that cultivation of 1507 poses a negligible risk to the environment in the Netherlands;
- Several EFSA opinions have been published since the advice of COGEM in 2003;
- The European Commission recently submitted its draft decision on the authorisation for cultivation of 1507 to the Member States. In view of the upcoming vote on 1507, COGEM has been asked whether the EFSA opinions contain information that would change its conclusions of 2003;
- 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 cultivation of genetically modified (GM) maize 1507 (C/ES/01/01) to the Regulatory Committee. In 2003, COGEM advised positively on cultivation of this GM maize line.[1] Since COGEM's advice, several opinions and technical reports on maize 1507 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.[i]

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 plants are

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

predominantly wind pollinated.[2,3] Insect pollination is limited since the female flowers do not produce nectar and therefore are not attractive to insect pollinators.[4] 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.[5] Domesticated maize requires warm conditions in order to grow and does not tolerate prolonged cold and frost.[4,6] The kernels remain on the cob after ripening and do not shatter naturally.[4,7] 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.[4]

Maize is very sensitive to weed competition.[8] During the long process of domestication, maize has lost the ability to survive in the wild.[3] 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 1507 and the introduced traits

GM maize 1507 was produced by particle bombardment. It contains the *cry1F gene* derived from *Bacillus thuringiensis* subsp. *aizawa,* and the *pat g*ene derived from *Streptomyces viridochromogenes*. Both genes are constitutively expressed. As a result maize 1507 is resistant to certain lepidopteran insect pests and tolerant to glufosinate-ammonium containing herbicides. A detailed description of the elements introduced in maize 1507 is provided in COGEM's recent advice on the renewal of the authorisation for import and processing of maize 1507.[9]

1.3 Previous COGEM advice

In 2003, COGEM advised positively on cultivation of GM maize 1507.[1] COGEM concluded that cultivation of GM maize 1507 poses a negligible risk to the environment in the Netherlands. However, COGEM emphasised that standardisation of studies on potential effects of GM crops to non-target organisms was needed. Furthermore, COGEM considered it advisable to differentiate the monitoring plan for the different regions of maize cultivation. Additionally, COGEM was of the opinion that the 'general surveillance plan' was too informal and permissive.

In 2015, COGEM advised on the renewal of the authorisation for import and processing of maize 1507.[9] In the application, the bioinformatic analyses on purpose of the molecular characterisation were updated. These analyses did not reveal any new concerns, and COGEM concluded that the molecular characterisation of 1507 was adequate.

2. Assessment of the EFSA opinions

Since the positive COGEM advice of 2003, several EFSA opinions have been published. These opinions provide additional clarifications on the conclusion of EFSA,[10] discuss relevant scientific literature published after EFSA's initial assessment[11,12,13] or concern the use of a mathematical model to assess potential risks of the cultivation of 1507 maize to non-target Lepidoptera.[12,14,15,16]

In 2005, EFSA issued its opinion on the use of GM maize 1507 for import, feed and industrial processing, and cultivation.[17] In the opinion the notification, additional information provided by the applicant, comments of the Member States and available scientific literature were taken into account. EFSA concluded that *"1507 maize will not have an adverse effect on human and animal health or the environment in the context of its proposed use."*[17]

In 2011, EFSA evaluated additional information provided by the applicant and a number of publications which were published after its initial opinion. EFSA concluded *"that, subject to appropriate management measures, maize 1507 cultivation is unlikely to raise safety concerns for the environment."*[12] Risk mitigation measures to reduce exposure of non-target Lepidoptera to maize 1507 pollen were recommended by EFSA in view of the results obtained with the mathematical model. According to EFSA *"Mitigation measures are only needed when the proportion of maize and uptake of maize 1507 are sufficiently high, regardless of the other parameters. If maize 1507 cultivation remains below 5% of the Utilized Agricultural Area, then risk mitigation measures are not required."*[12]

2.1 Scientific publications

Since COGEM's advice in 2003, a considerable amount of scientific publications on potential effects of Bt-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 1507 issued in 2012, EFSA performed a literature search to identify recent scientific publications relevant to the risk assessment and/or management of maize 1507. EFSA identified 61 relevant publications of which 25 had already been discussed in previous EFSA opinions. The remaining 36 publications were discussed in the EFSA opinion of 2012. EFSA concluded that *"None of these publications reported new information that would invalidate the previous conclusions on the safety of maize 1507 made by the EFSA GMO Panel."*

The conclusions drawn by EFSA after assessing the available literature support COGEM's conclusion that cultivation of 1507 poses a negligible risk to the environment in the Netherlands.[13]

2.2 Risk mitigation measures

COGEM agrees with EFSA that cultivation of 1507 maize is unlikely to raise safety concerns for the environment. COGEM is of the opinion that the EFSA opinions do not contain information that refutes COGEM's previous conclusions on cultivation of maize 1507. 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 Cry1F protein expressed by 1507 is toxic to certain lepidopteran pest insects. Non-target Lepidoptera could be exposed to the Cry1F protein if they ingest 1507 maize pollen which is deposited on their host plants. Lethal and sublethal effects of 1507 pollen (or the Cry1F protein) on non-target lepidopteran species have been reported under

laboratory conditions.[12,18] Whether non-target Lepidoptera are affected under field conditions depends amongst others on the actual exposure to 1507 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 1507 poses a risk to European non-target Lepidoptera. EFSA therefore used a mathematical model to assess potential risks of cultivation of maize 1507 to European non-target Lepidoptera.[12]

Based on mortality estimates obtained using this mathematical model EFSA considered risk mitigation measures (i.e. non-Bt-maize border rows) necessary if 1507 cultivation exceeded 5% of the 'Utilized Agricultural Area'.[12,13] In addition, EFSA recommended that 1507 maize is not cultivated within 30 m of protected habitats, in order to minimise exposure and risk to lepidopteran species of conservation concern.[12]

In the modelling exercise the percentage mortality is calculated for hypothetical 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 1507 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 the 1507 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 1507 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 1507 maize as well as the 30 meter separation distance to protected areas disproportionate.

COGEM notes that the recommended mitigation measures for Cry1Ab-expressing maize (MON810 and Bt11) differ from the mitigation measures recommended for 1507 maize, i.e. 20 meter instead of 30 meter separation distance to protected areas and a high adoption rate of 7.5% instead of 5%.[12,19] 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 GM maize 1507 poses a negligible risk to the environment in the Netherlands.

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