COMMISSIE
COGEM
GENETISCHE
MODIFICATIE

Aan de staatssecretaris van
Infrastructuur en Milieu
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DATUM	27 maart 2012
KENMERK	CGM/120327-01
ONDERWERP	Advies 'additional information concerning the application for cultivation of MON89034xNK603 maize'

Geachte heer Atsma,

Naar aanleiding van een adviesvraag betreffende de aangeleverde aanvullende informatie inzake de vergunningaanvraag voor teelt, import en verwerking van de genetisch gemodificeerde maïslijn MON89034xNK603 van Monsanto Europe S.A. (EFSA/GMO/NL/2009/72), deelt de COGEM u het volgende mee:

Samenvatting

De COGEM heeft in 2009 en 2011 geadviseerd over de vergunningaanvraag voor teelt, import en verwerking van de genetisch gemodificeerde maïslijn MON89034xNK603. Deze maïslijn brengt de *cp4 epsps*, *cp4 epsps L214P*, *cry1A.105* en *cry2Ab2* genen tot expressie en is hierdoor tolerant voor glyfosaat bevattende herbiciden en resistent tegen bepaalde insecten uit de orde van de vlinderachtigen.

In haar eerdere adviezen concludeerde de COGEM dat er onvoldoende gegevens waren om eventuele effecten van de maïslijn op niet-doelwitorganismen te kunnen beoordelen. De aanvrager heeft inmiddels aanvullende informatie geleverd waardoor enkele, maar niet alle openstaande vragen naar tevredenheid zijn beantwoord.

Bij de laboratoriumexperimenten met niet-doelwitorganismen zijn alleen de effecten van de afzonderlijke Cry eiwitten geanalyseerd. Effecten waarbij de eiwitten gelijktijdig worden toegediend zijn niet onderzocht. Verder heeft de COGEM vragen over de verwachte blootstelling van het niet-doelwitorganisme *Orius insidiosus* aan het door MON89034xNK603 geproduceerde cry1A.105 eiwit, en is de COGEM van mening dat meer gegevens nodig zijn over de berekening van het eventuele effect van MON89034xNK603 op niet-doelwitvlinderachtigen. Het verslag van een in Spanje uitgevoerde veldproef bevat onduidelijkheden en tegenstrijdigheden die door de aanvrager opgehelderd moeten worden.

De COGEM vindt beantwoording van de openstaande vragen noodzakelijk om het eventuele effect van de teelt van MON89034xNK603 op niet-doelwitorganismen te kunnen beoordelen. Ook is de COGEM nog in afwachting van een op grond van haar eerdere opmerkingen aangepast 'general surveillance' plan. Concluderend is de COGEM van mening dat er op dit moment onvoldoende informatie aanwezig is om tot een definitief oordeel te kunnen komen.

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

Hoogachtend,

Prof. dr. ir. Bastiaan C.J. Zoeteman
Voorzitter COGEM

c.c.
Drs. H.P. de Wijs
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Additional information concerning the application for cultivation of MON89034xNK603 maize

COGEM advice CGM/120327-01

This advice concerns the application for cultivation, import and processing of genetically modified MON89034xNK603 maize. This maize line expresses the cp4 epsps, cp4 epsps L214P, cry1A.105 *and* cry2Ab2 *genes conferring tolerance to glyphosate containing herbicides and resistance to certain lepidopteran insects.*

In its previous opinions concerning this application, COGEM concluded that insufficient data were provided to draw conclusions on the effect of MON89034xNK603 on non-target organisms. (NTOs). COGEM was of the opinion that additional data from laboratory experiments and field trials had to be provided. The applicant recently provided additional information on the studies that assess the effect of MON89034xNK603 on NTOs. Although several of COGEMs questions are answered by this information, other questions were not sufficiently addressed.

The provided information does not substantiate the claim that the data obtained from laboratory experiments on target organisms can be extrapolated to exposure to NTOs. In addition, COGEM asks the applicant to determine the 'maximum expected environmental concentration' for the NTO Orius insidiosus *using information of the maize line of concern i.e. MON89034xNK603, and to take into account the potential exposure of* O. insidiosus *to Cry1A.105 via exposure routes, such as prey or plant tissues other than pollen. Furthermore, COGEM asks the applicant to examine the effect of MON89034xNK604 on non-target lepidopteran species. The report on the Spanish field trial appears to contain inconsistencies and obscurities, which have to be addressed by the applicant.*

A revised general surveillance plan, as requested, has not been submitted yet.

In conclusion, COGEM is of the opinion that the above mentioned questions need to be addressed to allow conclusions on the effect of cultivation of MON89034xNK603 on NTOs.

Introduction

The scope of the present notification (EFSA/GMO/NL/2009/72) by Monsanto Company, as represented by Monsanto Europe S.A., concerns the cultivation of maize line MON89034xNK603. MON89034xNK603 was produced by crossing the two parental maize lines MON89034 and NK603 using traditional breeding methods. The maize line contains the *cry1A.105* and *cry2Ab2* genes, which confer resistance to certain lepidopteran pests. In addition, this line contains the *cp4 epsps* and *cp4 epsps L214P* genes, which confer tolerance to glyphosate containing herbicides. COGEM was asked to evaluate the safety of commercial cultivation of this maize line in the European Union with respect to human health and the environment.

Previous COGEM advices

In October 2009, COGEM issued a positive opinion on the import and processing for use in feed and food of genetically modified maize line MON89034xNK603.[1] COGEM concluded that import and processing of MON89034xNK603 poses a negligible risk to the environment. Three years earlier, in July 2006, COGEM advised positively on the cultivation of maize line NK603.[2] COGEM was of the opinion that cultivation of maize line NK603 poses a negligible risk to human health and the environment.

In December 2009, COGEM examined the application for cultivation of MON89034xNK603 maize and concluded that the provided data were insufficient to draw conclusions on the effect of MON89034xNK603 on non-target organisms (NTOs).[3] In April 2011, the applicant provided additional information on the experiments that had been carried out and added the results of a Spanish field trial that assessed the effect of MON89034xNK603 on NTOs to the dossier. COGEM studied the information provided and concluded that not all its previous questions had been answered. Based on the information provided some additional questions arose.[4]

Recently, the applicant provided further information on the questions raised by COGEM. The Dutch Ministry of Infrastructure and the Environment asks COGEM whether the information answers its previous questions and removes its objections. The additional information on the outstanding questions will be discussed below.

Outstanding questions

In its previous opinions, COGEM concluded that additional data from laboratory experiments and field trials had to be supplied to allow a reliable environmental risk analysis on cultivation of MON89034xNK603 maize.[4] In response to COGEM's questions the applicant has provided additional information and clarifications. The additional information and its assessment by COGEM will be discussed point by point.

Validity of administrating the Cry proteins separately to NTOs in laboratory studies

In its previous advices COGEM noted that none of the laboratory or greenhouse studies were carried out with plant material of MON89034xNK603. Instead, the applicant provided studies on the effect of MON89034 plant material on Collembola (*Folsomia candida*), soil microorganisms and northern bobwhite quail (*Colinus virginianus*), and the effect of purified Cry1A.105 and Cry2Ab2 proteins on earthworms (*Eisenia fetida*), ladybird beetles (*Coleomegilla maculata* and *Hippodamia convergens*), an anthocorid bug (minute pirate bug: *Orius insidiosus*), honey bee *(Apis mellifera*) and parasitic wasp *(Ichneumon promissorius*).

In order to make an accurate risk assessment, COGEM prefers the use of plant material of the GM crop of concern i.e. MON89034xNK603. Moreover, laboratory experiments should be carried out with the two proteins in combination, if the absence of interaction between the two proteins is not sufficiently demonstrated.

The applicant provided a study that examined the interaction between the Cry1A.105 and the Cry2Ab2.820 proteins.[5] The biological activity of the latter protein was shown to be equivalent to the Cry2Ab2 protein which is produced by MON89034xNK603. The interaction study was carried out with target organisms (the European corn borer *Ostrinia nubilalis* and the corn earworm *Helicoverpa zea*), and showed that it is plausible that the combined effect of the Cry1A.105 and Cry2Ab2.820 proteins consisted of an additive activity on these target organisms.

In its previous advice COGEM questioned whether the results from the interaction study using target organisms can be extrapolated to non-target organisms, and asked the applicant to substantiate the claim or to provide data on studies using NTOs.

In its response the applicant points amongst others at the specificity of the Cry1A.105 and Cry2Ab2 proteins. The applicant states that the proteins do not interfere with arthropods outside the order of Lepidoptera due to the absence of high affinity receptors on the surface of intestinal cells of NTOs. Furthermore, the applicant cites recommendations from a Scientific Advisory Panel of Experts convened by the US EPA. The panel concludes that if plant incorporated proteins proved to be safe individually, their effects would not have to be tested in combination against NTOs.[6] Also, the applicant cites studies which report that synergistic or antagonistic interactions do not occur between different proteins known to be independently active.[7] These studies were conducted with Bt microbial formulations and plant incorporated protectants.

COGEM points out that there are several indications that the Cry proteins are not as specific as apparently assumed by the applicant. Several Cry protein families demonstrate cross-order activity.[8] Proteins that belong to the Cry1A family are supposed to affect lepidopteran insects specifically, but also affect Diptera and possibly Hemiptera. Proteins belonging to the Cry2A family were active to Lepidoptera, Diptera and Hemiptera. In addition, there are indications that the Cry1Ab protein increases mortality in the coleopteran insect *Adalia bipunctata*.[9,10]

Furthermore, in one of the laboratory studies on the NTO *Orius insidiosus,* an unexpected effect on mortality was observed at the maximum dose of 240 µg Cry1A.105/g diet.[11]

The occurrence of interaction between different Cry proteins is well known. The type of effect depends on the particular Cry proteins and the tested organisms. Mixtures of CryIAa and CryIAc exhibit a synergistic effect on the Gypsy Moth, *Lymantria dispar*, while no synergistic effects were observed on the silkworm, *Bombyx mori*.[12] Also the binary Cry proteins are an example of a synergistic interaction. In the case of the binary Cry34/Cry35 proteins, the presence of both proteins is required to generate effective mortality against the Western corn rootworm (*Diabrotica virgifera vergifera*).[13,14]

Even in the absence of a synergistic effect a mixture of toxins can lead to an unexpected (higher) mortality due to the additive effect and exceeding of a mortality threshold value not reached by each compound separately.

To prove its point the applicant also refers to other laboratory studies on NTOs. One of these studies examined the effect of MON89034 plant material on quail and Collembola.[15,16] The other study examined the effect of MON89034xMON88017 pollen on honeybee larvae.[17] Both studies were carried out with other maize lines. In addition, the study that used MON89034 plant material did not investigate its effect on insects. Therefore, COGEM is of the opinion that this information is not sufficient to conclude that the absence of interaction between the Cry1A.105 and Cry2Ab2 proteins also extends to non-target insects.

In conclusion, COGEM is of the opinion that the response of the applicant to its previous question is unsatisfactory. COGEM is of the opinion that the applicant should substantiate its claim that the results from interaction studies with target organisms can be extrapolated to NTOs or has to provide data on the absence of interaction between the Cry1A.105 and Cry2Ab2 proteins using a subset of non-target insect species.

Data analysis

The data from the laboratory experiments on NTOs were analysed with different statistical methods without explanation of the selection of this method. In its previous advice, COGEM asked the applicant to provide insight in the statistical methodology, including the steps which were taken, to ensure that the data satisfy the assumptions of the selected statistical method.

In its response, the applicant provides more detailed information on the rationale behind the selected statistical methods. The applicant also indicates that the data met the assumptions (e.g homogeneity of variance, normality) that allow the use of certain statistical methods. COGEM is of the opinion that its questions with regard to the statistical methodology are sufficiently answered.

Protein concentrations

In its previous advice, COGEM asked the applicant for more detailed information on the establishment of the maximum doses that were used in the laboratory experiment. In its present answer, the applicant provides more information on the calculation of the maximum dose and the margin of exposure. COGEM notes that in the case of pollen the applicant used the fresh weight expression levels, whereas dry weight expression levels were used in the case of leaf material. COGEM wonders why the applicant treats these tissue types differently. In addition, COGEM noted that the applicant used the expression levels of the parental maize line MON89034 in the calculations. As the expression levels may vary between different maize lines COGEM is of the opinion that the expression levels of MON89034xNK603 should have been used. However, because in this particular case the expression levels in the two maize lines are very similar, COGEM finds the presented data acceptable.

Laboratory study exposing* Orius insidiosus *to Cry1A.105

In the laboratory study on the effect of Cry1A.105 on *O. insidiosus* a significant effect on mortality was observed at 240 µg Cry1A.105/g diet. No significant differences on survival

were detected with concentrations of ≤ 120 µg Cry1A.105 /g diet. In its previous advice COGEM asked the applicant to discuss the significance of the observed effect.

In its response the applicant clarified the calculation of the dose that was used in the laboratory study on the effect of Cry1A.105 on *O. insidiosus*. This dose is based on the expression level of Cry1A.105 in MON89034xNK603 pollen. According to the applicant pollen is the major route by which *O. insidiosus* may be exposed to the Cry protein. The applicant calculated the 'maximum expected environmental concentration' (MEEC) to which *O. insidiosus* could be exposed and stated that the 'no observed effect concentration' exceeds the MEEC fourteen times. COGEM points out that *O. insidiosus* feeds on insects as well as plant tissues such as pollen[18,19]. The expression of Cry proteins in MON89034xNK603 pollen is low when compared to the expression in other plant tissues, and Cry proteins may accumulate in prey species. As a result, the exposure of *O. insidiosus* under field conditions may be higher than would be expected based on the expression level of Cry1A.105 in MON89034xNK603 pollen.

In conclusion, COGEM asks to take into account the potential exposure of *O. insidiosus* to Cry1A.105 via other exposure routes, such as additional plant tissues and prey.

Field trials

In the original application three studies referred to field trials with maize line MON89034xNK603. In two of them the effect of MON89034xNK603 on target organisms was studied. Only in the study that referred to the Argentinean field trials (three sites) that were carried out in 2005/2006, the abundance of NTOs (*Chrysopa* spp. *Coccinellidae*, *Doru* spp., *O. insidiosus, Trichogramma* spp.) was investigated.

In its previous answer to COGEM's questions the applicant included the results from a European field trial. This field trial was carried out in Spain (one site) during two years and examined the effect of MON89034xNK603 on several NTOs using pitfall traps, sticky traps and visual counts.[20] Predators, parasitoids, detrivores and herbivores were represented in the taxa collected.

The applicant concluded that in the Spanish field trial no biologically meaningful differences were observed between MON89034xNK603 and the conventional control hybrid. In its previous advice, COGEM asked the applicant to provide further information on the 'maintenance pesticides' that were applied because the application of pesticides could obscure effects on NTOs. In its answer, the applicant states that only herbicides and no insecticides were applied.

COGEM considers the information provided sufficient to conclude that the application of these 'maintenance pesticides' will not have interfered with the observation of effects on NTOs.

COGEM points out that the report on the Spanish field study appears to contain flaws and inconsistencies, in particular with regard to the data on *Coccinellidae*. The sticky trap data show that significant lower numbers were present in MON89034xNK603 as in the control. In

contradiction to these data, the 'visual observations' show that higher numbers were present in MON89034xNK603. No explanation is given for these differences.

The differences in numbers of *Coccinellidae* between MON89034xNK603 and the controls fluctuate markedly over the years. The applicant refers to this variance to state that observed differences between MON89034xNK603 and the control are non-significant. This assumption of the applicant lacks foundation, since it is not clear whether the observed difference is really the exception, or that it is the other way around.

The report specifies both the total number of *Coccinellidae* adults and *Stethorus* spp. It also states that in some occasions the total number of *Coccellinidae* consisted nearly entirely of *Stethorus* spp. Surprisingly, both in the text and in Table 7 the mean number of *Stethorus* appears to exceed the mean number of *Coccinellidae*. Upon recalculation the given mean numbers of *Coccinellidae* seem to be correct, but the recalculated mean numbers of *Stethorus* significantly differ from the values in the report.

The applicant should address the abovementioned points, discuss and explain the observed differences and offer substantiation for its claims and assumptions.

Pollinators/nectar feeders and butterflies

In addition to predators, parasitoids and herbivores which were collected in the Spanish field trial, COGEM also considers pollinators/nectar feeders and protected/endangered butterflies as relevant ecological groups. The latter two groups were not studied in the Spanish field trial. The applicant declares that they are not sufficiently present in the field and not representative of a commercial maize field.

Pollinator/nectar feeders were not observed in the field trial, but the effect of the Cry1A.105 and Cry2Ab2 proteins which are produced by MON89034xNK603 was examined in laboratory experiments on honey bees. Based on the results from these experiments, COGEM is of the opinion that there is no indication that the Cry1A.105 or the Cry2Ab2 proteins have an adverse effect on honey bees when administered separately. However, in MON89034xNK603 both proteins are present.

As previously mentioned, COGEM still has some questions regarding the study that examined the presence of an interaction between the two proteins. Therefore, COGEM will await the response of the applicant on this issue before finalising its opinion on the effect of MON89034xNK603 on honey bees.

Butterflies were not observed in the field trial and no laboratory experiments were carried out to examine the effect of MON89034xNK603 on non-target lepidopteran species. In the technical dossier a theoretical exposure analysis was performed on non-target lepidopteran species to MON89034xNK603 pollen. In its previous advice, COGEM declared that it strongly prefers the use of experimental data to examine the effect of MON89034xNK603 on non-target lepidopteran species over a theoretical exposure analysis. COGEM pointed out that

in the latter case flaws can be introduced by the use of assumptions, estimations and extrapolations.

In its response the applicant repeats the previously presented exposure analysis using the expression levels of the Cry1A.105 and Cry2Ab2 proteins in the maize line of concern (MON89034xNK603). In addition, the applicant refers to studies that examined the effect of another maize line, i.e. MON89034xMON88017 on two non-target lepidopteran species.

COGEM is of the opinion that data on other maize lines are not sufficient to conclude that MON89034xNK603 will not cause adverse effects on non-target lepidopteran insects.

COGEM notes that reported LC50 values vary widely, depending amongst others on the way of administration, design of the experiments, and origin and history of the insects tested. In some instances the reported LC50 values varied more than 10-fold.[8] In order to make a theoretical exposure assessment based upon the LC50 value of the target organism, it is a prerequisite that this LC50 is the lowest value reported to avoid underestimation of the possible effect. Therefore, the applicant should provide an overview of LC50 values reported and a justification for the chosen value.

General surveillance

General surveillance has been introduced to be able to observe unexpected adverse effects of genetically modified crops on the environment. The setting or population in which these effects might occur is either not, or hardly predictable. The central tool for general surveillance in case of cultivation of MON89034xNK603 maize is an annual farmer questionnaire which is addressed to a subset of farmers that cultivate MON89034xNK603 maize. In COGEM's view the questionnaire should not only contain questions about the performance of MON89034xNK603 maize on the field, but should also contain questions about unexpected effects of the MON89034xNK603 maize on the whole of the farmer's premises. COGEM is also of the opinion that the part of the farm questionnaire dealing with animals is too general. Birds, deer and insects are assigned to one category "wildlife". Information about the occurrence of wildlife should be obtained by different questions for specific groups of organisms (e.g. mammals, (predatory) birds, and insects). In addition, the farmer should be asked whether unusual numbers of other animals were observed and whether dead animals were found. The questions in the farm questionnaire refer to the "usual situation", but the usual situation is not well defined. It would be better to rephrase the questions to acquire data that can be used to detect negative or positive trends in populations of organisms relevant to the monitoring scheme.

In its previous response on our questions the applicant states that the MON89034xNK603 questionnaire will be updated when the EFSA opinion on the harmonized Farmer Questionnaire is published. The EFSA guidance on Post Market Environmental Monitoring (PMEM) has recently been published. According to the applicant the industry is presently working on a harmonized PMEM plan that takes the views of EFSA on PMEM into

consideration. Therefore, the applicant considers it premature to provide details on the PMEM plan for MON89034xNK603.

COGEM would like to assure that all its remarks are included in the general surveillance plan of MON89034xNK603. Therefore, COGEM will await the PMEM plan to determine whether all its points are included.

Conclusion

In its previous opinions on this application, COGEM concluded that the provided data were not sufficient to conclude that cultivation of MON89034xNK603 would have negligible adverse effects on NTOs. In addition, COGEM was of the opinion that the General Surveillance plan could be improved on several points.

The applicant has provided additional information on the experiments that were carried out to assess whether MON89034xNK603 affects NTOs. Although some of COGEMs questions are answered by the additional information, some questions remain:

1) COGEM previously stated that it is of the opinion that the laboratory experiments on NTOs should be carried out with the two pure proteins in combination, when the absence of interaction is not sufficiently demonstrated. In the laboratory experiments presented, the effect of the separate Cry proteins was examined in NTOs and the combined effect was studied in target organisms. The provided information does not prove that the data from laboratory experiments that were carried out with the separate Cry proteins can be extrapolated to the situation were NTOs are exposed to both the Cry1A.105 and the Cry2Ab2 proteins. In other words, that a combination effect between the two Cry proteins would lead to an altered specificity on non-target insects. COGEM is of the opinion that the applicant should substantiate its claim that the results from interaction studies with target organisms can be extrapolated to NTOs or should provide data on the absence of interaction between the Cry1A.105 and Cry2Ab2 proteins using a subset of non-target insect species.

2) COGEM previously noted that a significant effect on *O. insidiosus* mortality was observed at 240 µg Cry1A.105/g diet, but not with ≤ 120 µg Cry1A.105 /g diet and asked the applicant to discuss the significance of the observed effect. According to the applicant the 'no-observed effect concentration 'of 120 µg Cry1A.105 / g diet corresponds to fourteen times the MEEC. COGEM asks the applicant to determine the MEEC using information of the maize line of concern i.e. MON89034xNK603, and to take into account the potential exposure of *O. insidiosus* to Cry1A.105 via other exposure routes such as prey and/or different types of plant tissues.

3) The report on the field study carried out in Spain appears to contain inconsistencies and possible flaws, in particular in the data on Coccinellidae. The applicant has to address these issues.

4) COGEM previously pointed out that butterflies were not studied in the Spanish field trial or in laboratory experiments. Instead, the effect of MON89034xNK603 on non-target lepidopteran species was assessed using a theoretical exposure analysis. COGEM previously pointed out that in such an analysis flaws can be introduced by the use of assumptions,

estimations and extrapolations. One of COGEM's concerns with regard to the theoretical exposure analysis is that the LC50 value of target organisms used in the calculation is not representative for the actual LC50. As this concern is not taken away by the applicant, COGEM is the opinion that the provided data are not sufficient to conclude that non-target lepidopteran species will not be affected by cultivation of MON89034xNK603.

In conclusion, COGEM is of the opinion that the above mentioned questions need to be addressed to allow conclusions on the effect of cultivation of MON89034xNK603 NTOs. In addition, COGEM awaits a revised general surveillance plan to determine whether all points that were raised in its previous advice are included.

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