

Aan de minister van
Volkshuisvesting, Ruimtelijke
Ordening en Milieubeheer
Mevrouw dr. J.M. Cramer
Postbus 30945
2500 GX Den Haag

DATUM 21 mei 2008
KENMERK CGM/080521-01
ONDERWERP Advies hernieuwing vergunning import en verwerking van soja 40-3-2
(EFSA/GMO/RX/40-3-2)

Geachte mevrouw Cramer,

Naar aanleiding van de adviesvraag over het dossier EFSA/GMO/RX/40-3-2, betreffende de hernieuwing van de vergunning voor de import en verwerking van de genetisch gemodificeerde sojalin 40-3-2, door Monsanto Company, adviseert de COGEM als volgt:

Samenvatting:

De COGEM is gevraagd te adviseren over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde sojalin 40-3-2. Door de aanwezigheid van het *cp4 epsps* gen, is deze sojalin tolerant voor herbiciden met als werkzame stof glyfosaat. De COGEM heeft reeds positief geadviseerd over import en verwerking in 1996 en 2000. Bovendien heeft zij positief geadviseerd over de teelt van sojalin 40-3-2.

Voor de herziening van de vergunning, heeft de aanvrager geüpdate informatie aangeleverd. Hierbij ontbreekt echter een monitoringplan omdat de aanvrager dit niet relevant acht. Een monitoringplan bestaat uit twee delen. Voor import en verwerking is een zogenaamd 'case-specific monitoring plan' niet noodzakelijk. Echter, het aanleveren van een 'general surveillance plan' is wettelijk vereist. Een dergelijk plan moet zorg dragen dat eventuele schadelijke effecten die bij de beoordeling van het gewas niet werden voorzien, getraceerd kunnen worden.

De COGEM is van mening dat een 'general surveillance plan' belangrijk is om onvoorziene effecten te kunnen detecteren. Hoewel de COGEM van mening is dat de risico's van import en teelt van dit gewas in Nederland verwaarloosbaar klein zijn, acht zij de aanwezigheid van een dergelijk plan noodzakelijk. Bovendien is de COGEM van mening dat een vergunningaanvraag dient te voldoen aan de wettelijke eisen. Het verbaast de COGEM dat de European Food Safety Authority dit dossier als volledig heeft beschouwd.

Totdat een 'general surveillance plan' is ontvangen, kan de COGEM niet positief oordelen over de herziening van de vergunning voor import en verwerking van genetisch gemodificeerde soja 40-3-2

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 large loop on the left and a long horizontal stroke extending to the right.

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

Voorzitter COGEM

c.c. Dr. I. van der Leij

Drs. H.P. de Wijs

Renewal application import and processing of soybean line 40-3-2

COGEM advice CGM/080521-01

Summary

The notification by Monsanto Company concerns the renewal of the authorization for import and processing of the genetically modified soybean line 40-3-2. Previously, COGEM advised positively on import and processing and on cultivation of this soybean line.

To renew the authorization for import and processing of 40-3-2, the applicant has supplied updated information on the soybean line. However, an environmental monitoring plan is not provided because in the opinion of the applicant it is not relevant in this case. A monitoring plan consists of two parts. Within the scope of import and processing the case-specific monitoring plan is not required. Nevertheless, the general surveillance plan is legally required. General surveillance has been introduced to be able to observe unexpected effects of genetically modified crops on the environment. This refers to potentially adverse effects that were not anticipated on assessing the genetically modified organism.

COGEM regards a general surveillance plan important to detect unexpected effects. Although COGEM is of the opinion that import and cultivation of soybean 40-3-2 poses negligible risks for the environment in the Netherlands, COGEM considers a general surveillance plan necessary. Furthermore, in the opinion of COGEM the application does not fulfill legal requirements. COGEM is surprised that this application has passed the completeness check of the European Food Safety Authority.

Until a general surveillance plan is received, COGEM cannot advise positively on the renewal of the application for import and processing of soybean 40-3-2.

Introduction

The present application by Monsanto Company, file EFSA/GMO/RX/40-3-2, concerns the renewal of the authorization for import and processing of soybean line 40-3-2 for use in feed and food. The line is tolerant to glyphosate-containing herbicides due to the presence of the *cp4 epsps* gene.

Since 1996, Soybean 40-3-2 is approved for processing and food and feed use in the European Union (1).

Previous COGEM advices

In 1995 and 2000 respectively, COGEM advised positively on import and processing of soybean line 40-3-2 (2,4). Furthermore, in 2006, COGEM has issued a positive advice on

cultivation of this line (3). COGEM based these advices on the following considerations. COGEM is of the opinion that the Dutch climate prohibits survival and establishment of soybean. Furthermore, modern soybean cultivars do not possess any of the characteristics commonly associated with problematic weeds and there is no reason to assume that presence and expression of the introduced gene increase the potential of soybean to establish feral populations. Cultivated soybean seeds rarely displays dormancy (5) and seeds of cultivated soybean survive poorly in soil (6). Soybean volunteers are rare and do not effectively compete with other cultivated plants or primary colonizers (5). In addition, volunteers are easily controlled mechanically or chemically (5). Establishment of feral soybean populations has never been observed in European countries.

In addition, wild relatives of soybean are not present in Europe and therefore introgression of the inserted genes into wild relatives cannot occur. Furthermore, in previous advised COGEM considered the molecular analysis of soybean 40-3-2 adequate.

Renewal of the authorization

To renew the authorization for import and processing of soybean 40-3-2, the applicant has supplied, amongst others, updated information that has become available since the original authorization. However, the dossier does not contain an environmental monitoring plan because in the opinion of the applicant it is not relevant in this case. This view is based on his opinion that 1) 40-3-2 has a history of safe use in the European Union since 1996 and 2) reports of adverse effects on human and animal health and the environment are lacking.

A monitoring plan consists of two parts. A case-specific plan should be set up to verify the hypotheses made in the risk assessment. Within the scope of import and processing a case-specific plan is not required. However, a general surveillance plan is legally required. General surveillance has been introduced to be able to observe unexpected effects of genetically modified crops on the environment. This refers to potentially adverse effects that were not anticipated on assessing the genetically modified organism.

Although COGEM is of the opinion that import and cultivation of soybean 40-3-2 poses negligible risks in the Netherlands, COGEM considers a general surveillance plan necessary. Furthermore, in COGEMs opinion an application should meet legal requirements. COGEM is surprised that this application has passed the completeness check of the European Food Safety Authority.

Until a general surveillance plan is received, COGEM cannot advise positively on the renewal of the application for import and processing of soybean 40-3-2.

References

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2. COGEM (1995). Import and processing of glyphosate tolerant soybean 40-3-2 (CGM/950626-16)
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