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

1. GMO compass (2008). GMO compass database product description. Internet: www.gmo-compass.org. (d.d. 26 maart 2008)
2. COGEM (1995). Import and processing of glyphosate tolerant soybean 40-3-2 (CGM/950626-16)
3. COGEM (2006). Cultivation of glyphosate tolerant soybean 40-3-2 (CGM/061128-01)
4. COGEM (2000). Advies naar aanleiding van aanvullende informatie Monsanto Europe N.V. Sojalijn GTS 40-3-2 (CGM/000712-03)
5. OECD (2000). Consensus document on the biology of *Glycine max* (L.) Merr. (Soybean)
6. OECD (1993). Traditional crop breeding practices: An historical review to serve as baseline for assessing the role of modern biotechnology