

Aan de staatssecretaris van  
Infrastructuur en Milieu  
dhr J.J. Atsma  
Postbus 30945  
2500 GX Den Haag

DATUM 13 januari 2011  
KENMERK CGM/110113-01  
ONDERWERP Advies naar aanleiding van de EFSA opinie over de hernieuwing van de vergunningen voor import en verwerking van soja 40-3-2

Geachte heer Atsma,

De COGEM is naar aanleiding van het verschijnen van de EFSA opinie over de hernieuwing van de vergunningen voor import en verwerking van de genetisch gemodificeerde sojalin 40-3-2 (EFSA/GMO/RX/40-3-2) gevraagd of haar commentaar geuit bij een eerder advies is weggenomen. De COGEM adviseert u als volgt.

#### **Samenvatting**

In 2008 heeft de COGEM geadviseerd over de hernieuwing van de vergunning voor import en verwerking van de genetisch gemodificeerde sojalin 40-3-2. Deze sojalin is sinds 1996 in de Europese Unie toegelaten voor import en verwerking. Soja 40-3-2 brengt het *cp4 epsps* gen tot expressie en is daardoor tolerant voor glyfosaat bevattende herbiciden.

In het hernieuwingsdossier was geen 'general surveillance' plan aanwezig, omdat de aanvrager van mening was dat dit voor deze aanvraag niet relevant was. De COGEM vindt de aanwezigheid van een 'general surveillance' plan noodzakelijk. Hoewel de COGEM van mening was dat de risico's van import en verwerking van soja 40-3-2 in Nederland verwaarloosbaar klein zijn, kon zij gezien het ontbreken van het 'general surveillance' plan niet positief adviseren.

Inmiddels heeft de aanvrager op verzoek van de EFSA een 'general surveillance' plan aangeleverd. Daarmee komt het eerdere bezwaar van de COGEM te vervallen. De COGEM wijst erop dat de beoordeling van de voedselveiligheid, inclusief incidentele consumptie, door een andere instantie wordt uitgevoerd.

Concluderend acht de COGEM de milieurisico's van import en verwerking van soja 40-3-2 verwaarloosbaar klein.

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. Drs. H.P. de Wijs

Dr. I. van der Leij

# **Additional advice on the renewal of the authorizations for import and processing of genetically modified soybean 40-3-2**

## **COGEM advice CGM/110113-01**

### **Introduction**

Recently, EFSA published her opinion on the application for renewal of the authorizations for the continued marketing of food, feed and/or other products containing, consisting of, or produced from genetically modified soybean 40-3-2.<sup>1</sup> Soybean line 40-3-2 is tolerant to glyphosate-containing herbicides due to the expression of the *cp4 epsps* gene and has been approved for processing and food and feed use in the European Union since 1996.<sup>2</sup>

On basis on the information in the original application, updated studies in the present application and other scientific data, EFSA concluded that soybean line 40-3-2 is as safe as its conventional counterpart and is unlikely to have any adverse effect on human and animal health and the environment.<sup>1</sup>

The Netherlands' Ministry of Infrastructure and the Environment (the former Ministry of Housing, Spatial Planning and the Environment) asked COGEM whether the EFSA opinion sufficiently answers COGEMs previous comments on the application for renewal of the authorizations of genetically modified soybean 40-3-2.

### **Previous COGEM advice**

In 2007, an application for the renewal of the authorizations for soybean 40-3-2 was filed. Although the presence of a general surveillance plan is legally required, the application did not contain a general surveillance plan. The applicant considered such a plan irrelevant because in his opinion 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.

In her advice on the renewal of the authorization of soybean 40-3-2 COGEM concluded that import of soybean 40-3-2 posed negligible risks to the Dutch environment. Since the purpose of general surveillance is the detection of unexpected effects, COGEM considered the presence of a general surveillance plan necessary. In addition, COGEM concluded that due to the absence of a general surveillance plan the application did not fulfill legal requirements. In view of the above, COGEM could not advise positively on the application for the renewal of the authorizations for the continued marketing of genetically modified soybean line 40-3-2.<sup>3</sup>

### **Advice**

As stated before, COGEM is of the opinion that import of genetically modified soybean 40-3-2 poses negligible risks to the Dutch environment.

EFSA requested the applicant to provide a general surveillance plan. A general surveillance plan was presented in response to this request.<sup>4</sup> Therefore, COGEMs objections on the renewal of the authorizations for continued marketing of genetically modified soybean 40-3-2 are lifted.

COGEM points out that a food/feed safety assessment is carried out by other organisations. Therefore, COGEM abstains from advice on the potential risks of incidental consumption.

## References

1. EFSA GMO Panel (2010). Scientific Opinion on applications (EFSA-GMO-RX-40-3-2[8-1a/20-1a], EFSA-GMO-RX-40-3-2[8-1b/20-1b]) for renewal of authorisation for the continued marketing of (1) food containing, consisting of, or produced from genetically modified soybean 40-3-2; (2) feed containing, consisting of, or produced from soybean 40-3-2; (3) other products containing or consisting of soybean 40-3-2 with the exception of cultivation, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2010; 8(12):1908 pp.1-38
2. European Commission (1996). Commission decision of 3 April 1996 concerning the placing on the market of genetically modified soya beans (*Glycine max* L.) with increased tolerance to the herbicide glyphosate, pursuant to Council Directive 90/220/EEC. Official Journal of the European Communities, L107/10 – 30/04/1996
3. COGEM (2008). Renewal application import and processing of soybean line 40-3-2. Advice CGM/080521-01
4. EFSA (2010) Annex F: Post-market environmental monitoring plan (soybean 40-3-2) - Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on the application (reference EFSA-GMO-RX-40-3-2[8-1a/20-1a]) for renewal of the authorisation of existing products produced from glyphosate tolerant genetically modified soybean 40-3-2 for food and feed uses from Monsanto. EFSA Journal 2010; 8(12):1910 pp. 1-8