

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 40-3-2.¹ 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 1996.²

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.¹

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 40-3-2.³

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.⁴ 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