Import and processing of the genetically modified dicamba and glyphosate tolerant soybean line MON87708 x MON89788

COGEM advice CGM/131210-02

Summary

The present notification (EFSA/GMO/NL/2012/108) concerns import and processing for use in feed and food of the genetically modified soybean line MON87708 × MON89788. Cultivation is not part of this notification.

Soybean line MON87708 × MON89788 line expresses a dicamba mono-oxygenase and a variant of the 5-enolpyruvylshikimate-3-phosphate synthase enzyme conferring tolerance to dicamba and glyphosate containing herbicides, respectively.

MON87708 × MON89788 was produced by means of conventional breeding of the two genetically modified parental soybean lines. Previously, COGEM issued a positive advice on the import and processing of both parental lines.

In Europe, there are no wild relatives of soybean and therefore, hybridisation with other species is not possible. Soybean does not possess any of the attributes commonly associated with problematic weeds such as seed shattering, dormancy and cold resistance. Establishment of feral soybean populations has never been observed in Europe. In addition, soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants, weeds or primary colonisers.

COGEM considers the appended general surveillance (GS) plan sufficient for import of MON87708 × MON89788. *However, the GS plan could be improved on a number of points.*

In view of the above, COGEM is of the opinion that incidental spillage of MON87708 × MON89788 poses a negligible risk to the environment. Since 2008, COGEM abstains from giving advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organisations.

COGEM considers the environmental risks associated with import and processing of soybean line MON87708 × MON89788 to be negligible.

Introduction

The scope of the present notification (EFSA/GMO/NL/2012/108) filed by Monsanto Europe S.A., concerns import and processing of soybean line MON87708 × MON89788. This line is tolerant to dicamba and glyphosate containing herbicides.

Parental line MON89788 has an EU approval for import, food and feed since 2008.[1] In Japan, Canada and the United States MON89788 has been approved for use in food and feed, and for environmental release.[2]

In October 2013, EFSA released a positive scientific opinion on market admission of the parental line MON87708 for food and feed uses, import and processing. The EFSA GMO Panel concluded that MON87708 is as safe as its conventional counterpart with respect to potential

effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant.[3,4] In Canada and the United States MON87708 has been approved for use in food and feed, and for environmental release.[5]

Previous COGEM advice

In 2007 COGEM issued a negative advice on import and processing of parental soybean line MON89788 because its molecular characterization did not meet the criteria laid down by COGEM.[6,7] Furthermore, COGEM questioned the general surveillance (GS) plan. After the applicant provided additional information on the molecular characterization and the GS plan, COGEM advised positively.[8] In 2010 and 2011, COGEM also advised positively on import and processing of the hybrid line MON87701 x MON89788, and the parental line MON87708, respectively.[9.10]

Aspects of the crop

Soybean (*Glycine max*) is a member of the genus *Glycine* and belongs to the *Fabaceae* (*Leguminosae*) family. Soybean is grown from equatorial to temperate zones. The optimum temperature for soybean growth is between 25°C and 30°C. Soybean seeds will germinate when the soil temperature reaches 10°C and under favourable conditions a seedling will emerge in a 5-7 day period. Soybean is sensitive to frost and therefore does not survive freezing conditions.[11,12]

In the Netherlands, frost is common. On average 58 days in a year have minimum temperatures below 0°C.[13,14] In summer the days are long whereas soybean is a quantitative short-day plant. The Dutch climate is therefore not optimal for cultivation of soybean. However, field trials with a number of soybean varieties have shown that cultivation of soybean under temperate climatic conditions is possible.[15,16] Further improvement of these varieties may eventually result in soybean varieties suited for commercial cultivation in the Netherlands. Due to the characteristics of soybean, COGEM is of the opinion that this development does not affect the environmental risk assessment of MON87708 x MON89788.

The soybean plant is not weedy in character.[11] Like for all domesticated crops, soybean has been selected for minimal seed scattering to reduce yield losses during harvesting. Soybean seeds rarely display dormancy and poorly survive in soil.[17] Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants or primary colonisers.[11] In addition, volunteers are easily controlled mechanically or chemically.[11] COGEM is not aware of any reports of feral soybean populations in Europe.

Soybean is predominantly a self-pollinating species. The cross-pollination rate of soybean is an average of 1 to 3%.[11,18,19,20,21] The dispersal of pollen is limited because the anthers mature in the bud and directly pollinate the stigma of the same flower. In Europe, hybridisation with other species is not possible since there are no wild relatives of soybean.[11]

Molecular characterization

Soybean line MON87708 × MON89788 was produced by conventional crossbreeding of the genetically modified parental soybean lines MON87708 and MON89788. Previously COGEM

evaluated the molecular characterization in the notifications concerning import and processing of the genetically modified parental lines and concluded that the molecular characterization of the individual parental lines is adequate.[8,10]

The applicant confirmed by Southern blot analysis that the hybrid line contained both the parental transgenic inserts of MON87708 and MON89788 and that no rearrangements of these inserts occurred. COGEM is of the opinion that the molecular characterization of MON87708 x MON89788 is sufficient and meets the criteria laid down by COGEM.[7]

Properties of the introduced genes

Soybean line MON87708 × MON89788 expresses a dicamba mono-oxygenase enzyme (DMO) derived from the bacterium *Stenotrophomonas maltophilia*, and a variant of the 5-enolpyruvylshikimate-3-phosphate synthase enzyme (CP4 EPSPS), derived from the bacterium *Agrobacterium* sp. strain CP4.

DMO demethylates dicamba, rendering it inactive. As a result MON87708 is tolerant to treatment with dicamba containing herbicides. EPSPS is an enzyme involved in the biosynthesis of aromatic amino acids. Glyphosate inhibits EPSPS, resulting in a lack of amino acids essential for growth and development of plants. In contrast to EPSPS, the CP4 EPSPS enzyme of *B. thuringiensis* is not inhibited by glyphosate and therefore, MON89788 is tolerant to glyphosate containing herbicides.[22]

Environmental risk assessment

The current notification concerns import and processing of soybean line MON87708 × MON89788. In case of spillage, soybean seed may be released into the environment. Soybean seeds rarely display dormancy, poorly survive in soil and do not survive freezing winter conditions. The Dutch climatic conditions are not optimal for growth of soybean. In the summer, days are long, whereas soybean is a quantitative short-day plant that needs short days for induction of flowering.

Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants, weeds or primary colonisers.[11] In addition, volunteers are easily controlled mechanically or chemically.[11] There are no indications that soybean line MON87708 × MON89788 has an increased potential to survive or establish feral populations in case of incidental spillage.

Since 2008 COGEM abstains from advice on the potential risks of incidental consumption in case a food/feed assessment is already carried out by other organisations.[23] This application is submitted under Regulation (EC) 1829/2003, therefore a food/feed assessment is carried out by EFSA and national organisations involved in the assessment of food safety. In the Netherlands a food and/or feed assessment for Regulation (EC) 1829/2003 notifications is carried out by RIKILT. Regarding the risks for food and feed, the outcome of the assessment by other organisations (EFSA, RIKILT) was not known at the moment of the completion of this advice.

General surveillance plan

General surveillance (GS) has been introduced to be able to observe unexpected adverse effects of genetically modified (GM) crops on the environment. The setting or population in which these effects might occur is either not, or hardly predictable. The GS plan is required for every notification for market authorisation. The current GS plan states that unanticipated adverse effects will be monitored by the authorisation holder and operators involved in the handling and use of viable soybean MON87708 × MON89788.

In 2010, COGEM published a report on the principles that, according to COGEM, should be followed for GS.[24] COGEM considers the submitted GS plan sufficient for import of MON87708 × MON89788 however, the plan can be improved on the following points.

In the present GS plan, the authorization holder states that the operators have agreed to provide information relevant to the monitoring of MON87708 × MON89788 to the authorisation holder. COGEM argues that the GS plan could include a guarantee that operators will monitor for unanticipated effects. The GS plan further states that if the authorisation holder identifies an unexpected adverse effect caused by the GM plant, he will inform the European Commission immediately. COGEM is of the opinion that Member States should also be directly informed of these effects by the authorisation holder, to ensure that appropriate measures for protection of humans and the environment can be implemented immediately.

In the EFSA guidance document, EFSA states that the applicant should make raw data and analysis of monitoring data available to the Competent Authorities and the European Commission.[25] COGEM agrees with this request and points out that in the GS plan of soybean MON87708 × MON89788 the applicant should make a statement on this point.[26]

Advice

COGEM has been asked to advise on import and processing for use in food and feed of soybean line MON87708 × MON89788. This line expresses a *dmo* and *cp4 epsps* gene conferring tolerance to dicamba and glyphosate containing herbicides, respectively.

Although field trials have indicated that it might be possible to develop soybean varieties for cultivation in the Netherlands, the Dutch climate is not optimal for soybean growth. Soybean volunteers are rare throughout the world and do not effectively compete with other cultivated plants or primary colonisers. Modern soybean cultivars do not possess any of the characteristics commonly associated with problematic weeds. There is no reason to assume that expression of the introduced suppression cassette will increase the potential of soybean to establish feral populations. In addition, establishment of feral soybean populations in Europe has never been observed.

COGEM is of the opinion that the risk of spread of soybean MON87708 × MON89788 within the Netherlands due to incidental spillage of this soybean is negligible. Wild relatives of soybean are not present in Europe and therefore introgression of the introduced genes into closely related species cannot occur. COGEM considers the current GS plan sufficient for import and processing of soybean line MON87708 × MON89788. However, the GS plan could be improved on a number of points.

Based on the aspects discussed, COGEM is of the opinion that import and processing of soybean line MON87708 × MON89788 poses a negligible risk to the environment. 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. Commission Decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2008/933/EC). Official Journal of the European Union Documentno. C(2008) 7517
2. Center for Environmental Risk Assessment – GM Crop Database. http://cera-gmc.org/index.php?action=gm_crop_database&mode=ShowProd&data=MON89788 (website visit november 2013)
3. EFSA Panel on GMO (2013). Scientific Opinion on application EFSA-GMO-NL-2011-93 for the placing on the market of the herbicide-tolerant genetically modified soybean MON87708 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2013; 11(10): 3355
4. EFSA (2013). Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-NL-2011-93) for the placing on the market of the herbicide-tolerant genetically modified soybean MON87708 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto Europe S.A.. EFSA supporting publication 2013: EN-491
5. International Service for the Acquisition of Agri-biotech Applications. http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=253. (website visit november 2013)
6. COGEM (2007). Import and processing of glyphosate tolerant soybean MON89788 (EFSA/GMO/NL/2006/36). Advice CGM/070807-01
7. COGEM (2008). Heroverweging criteria voor de moleculaire karakterisering bij markttoelatingen van gg-gewassen. Signalering CGM/081219-01
8. COGEM (2008). Molecular characterization of soybean MON89788 (EFSA/GMO/NL/2006/36). Advice CGM/080827-01
9. COGEM (2010). Import and processing of genetically modified soybean MON87701xMON89788. Advice CGM/100202-01
10. COGEM (2011). Import of genetically modified soybean MON87708 with a new herbicide tolerance trait. Advice CGM/110801-02
11. OECD (2000). Consensus document on the biology of *Glycine max* (L.) Merr. (Soybean)
12. Bramlage WJ *et al*. (1978). Chilling stress to soybeans during imbibition. Plant Physiol 61:525-529
13. Koninklijk Nederlands Meteorologisch Instituut (KNMI), maand- en seizoensoverzichten, jaaroverzichten-archief. http://www.knmi.nl/klimatologie/maand_en_seizoensoverzichten/jaar/jaar12.html (website visit november 2013)

14. Compendium voor de leefomgeving, meteorologische gegevens 1990-2010. http://www.compendiumvoordeleefomgeving.nl/indicatoren/nl0004-Meteorologische-gegevens-in--Nederland.html?i=9-54 (website visit november 2013)
15. Paauw JGM (2006). Rassenonderzoek sojabonen op lössgrond 2004-2006. Projectrapport Praktijkonderzoek Plant en Omgeving b.v.
16. Biobred: www.biobred.eu/ (website visit november 2013)
17. OECD (1993). Traditional crop breeding practices: An historical review to serve as baseline for assessing the role of modern biotechnology
18. Ray JD *et al.* (2003). Soybean natural cross-pollination rates under field conditions. Environ Biosafety Res 2(2): 133-138
19. Ahrent DK & Caviness CE (1994). Natural cross-pollination of twelve soybean cultivars in Arkansas. Crop Science Society of America. 34(2): 376-378
20. Carlson JB & Lersten NR (1987). Reproductive morphology. In: Soybeans improvement, production, and uses. Second edition. Ed Willcox JR. American Society of Agronomy, Madison, Wisconsin
21. Chang YC & Kiang YT (1987). Geometric position of genotypes, honeybee foraging patterns and out-crossing in soybean. Bot Bull Acad Sinica28: 1-11
22. Funke T *et al.* (2006). Molecular basis for the herbicide resistance of Roundup Ready crops. Proc. Natl. Acad. Sci. USA. 103: 13010-13015
23. COGEM (2008). Toelichting advies GA21. Letter CGM/080117-02
24. COGEM (2010). General Surveillance. Topic report CGM/100226-01
25. EFSA Panel on Genetically Modified Organisms (2011). Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 9:2316
26. COGEM (2011). Comments on the European Food Safety Authority draft version of the revised 'Guidance on the post-market environmental monitoring (PMEM). Advice CGM/110520-01