

# Import and processing of the genetically modified soybean MON87705xMON87708xMON89788 with an altered fatty acid profile

## COGEM advice CGM/160419-01

- This application (EFSA/GMO/NL/2015/126) concerns import and processing for use in feed and food of genetically modified (GM) soybean MON87705xMON87708xMON89788;
- This GM soybean MON87705xMON87708xMON89788 was produced by conventional crossbreeding of MON87705, MON87708 and MON89788;
- COGEM advised positively on import and processing of all three parental lines;
- The GM soybean contains the expression cassettes for *cp4 epsps* and *dmo* conferring tolerance to glyphosate and dicamba containing herbicides;
- MON87705xMON87708xMON89788 contains a suppressor cassette for *fatb* and *fad2* resulting in a modified fatty acid composition;
- The molecular characterization of MON87705xMON87708xMON89788 is updated and meets the criteria of COGEM;
- The chance that a feral soybean population will establish in the Netherlands is negligible;
- Soybean cannot hybridise with other species in the Netherlands;
- Import and processing of soybean MON87705xMON87708xMON89788 poses a negligible risk to the environment in the Netherlands;
- COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is carried out by other organisations.

### 1. Introduction

The present application (EFSA/GMO/NL/2015/126) filed by Monsanto Europe S.A., concerns import and processing of genetically modified (GM) soybean line MON87705xMON87708xMON89788. It contains a *FAD2-1A/ FATB1-A* suppression cassette resulting in an altered fatty acid profile of the soybean seeds. Additionally, the line expresses the *dmo* gene and two copies of the *cp4 epsps* gene, conferring tolerance to dicamba and glyphosate containing herbicides. Soybean line MON87705xMON87708xMON89788 was produced by conventional crossbreeding of GM soybean lines MON87705, MON87708 and MON89788.

EFSA issued positive opinions on import, food and feed uses and processing of all three parental lines.<sup>1,2,3</sup> Also positive opinions were issued for import, food and feed uses of the soybean lines MON87705xMON89788 and MON87708xMON89788.<sup>4,5</sup> In 2008 MON89788 was authorised for food and feed uses in Europe.<sup>6</sup> In Canada and the United States MON89788 was authorised for use in food and feed, and for environmental release since 2007.<sup>6</sup>

## Previous COGEM advice

COGEM advised positively on import and processing of parental lines MON87705, MON87708 and MON89788.<sup>7,8,9</sup> COGEM also advised positively on the import and processing of the soybean lines MON87705xMON89788, MON87708xMON89788 and MON87769x MON89788.<sup>10,11,12</sup>

## 2. Environmental risk assessment

### 2.1 Aspects of the wild-type crop

Soybean (*Glycine max*) belongs to the *Leguminosae (Fabaceae)* family and is cultivated from equatorial to temperate zones. The optimum temperature for soybean growth is between 25°C and 30°C. Soybean is sensitive to frost and therefore does not survive freezing conditions.<sup>13,14,15</sup> In the Netherlands, frost is common. On average 58 days a year have minimum temperatures below 0°C.<sup>16,17</sup> Although the Dutch climate is not optimal for cultivation of soybean, soybean is cultivated on a small scale.<sup>18</sup>

The soybean plant is not weedy in character.<sup>14,15</sup> To reduce yield losses during harvesting, soybean has been selected for minimal seed scattering. Soybean seeds rarely display dormancy, poorly survive in soil and do not form a persistent soil seed bank.<sup>14,19</sup> Soybean volunteers are rarely observed throughout the world and do not effectively compete with other cultivated plants or primary colonisers.<sup>14,15</sup> In addition, volunteers are easily controlled mechanically or chemically.<sup>15</sup> To the best of COGEM's knowledge there are no reports of feral soybean populations in Europe. Soybean volunteers are uncommon in the Netherlands and have never led to wild populations.

Soybean is predominantly a self-pollinating species. The anthers mature in the bud and directly pollinate the stigma of the same flower.<sup>14,15</sup> The cross-pollination rate of soybean is low and on average between 1 to 3%.<sup>14,15,20,21,22,23,24</sup> Pollen disperses only over short distances. In Europe, hybridisation with other species is not possible because there are no wild relatives of soybean.<sup>14,15</sup>

**Conclusion:** In the Netherlands feral soybean populations do not occur and hybridisation of soybean with other species is not possible.

### 2.2 Description of the introduced genes and traits

MON87705xMON87708xMON89788 soybean was produced by conventional crossbreeding of the GM soybean lines MON87705, MON87708 and MON89788. In its previous opinions issued in 2010, 2011 and 2008, COGEM evaluated the molecular characterization of all parental lines and considered them adequate.<sup>7,8,9</sup> The bioinformatics analyses of soybean MON87705xMON87708xMON89788 were updated using recent databases. COGEM is of the opinion that the molecular characterization is performed correctly.

Inserted expression cassettes	Encoded protein/elements	Trait
<i>dmo</i>	Dicamba mono-oxygenase enzyme (DMO) from <i>Stenotrophomonas maltophilia</i> <sup>8</sup>	Tolerance to dicamba containing herbicides
Codon optimized <i>cp4 epsps</i>	Variant of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) enzyme originating from <i>Agrobacterium tumefaciens</i> strain CP4 <sup>9</sup>	Tolerance to glyphosate containing herbicides
FAD2-1A/FATB1-A suppression cassette	Endogenous FATB1-A and FAD2-1A sense and antisense gene segments generating an inverted repeat <sup>7</sup>	Altering fatty acid profile in soybean seeds by suppression of the endogenous <i>FATB</i> and <i>FAD2</i> RNA levels
For a detailed description of the introduced genes and traits see references.		

#### *Altered fatty acid composition*

MON87705xMON87708xMON89788 contains a *FAD2-1A/FATB1-A* suppression cassette. *FATB1-A* and *FAD2-1A* are thioesterases and desaturases respectively, and both are involved in fatty acid metabolism. Changing the expression of these proteins leads to an altered fatty acid profile of the soybean seeds. An altered fatty acid composition can influence the seed predation rate. However, predation is only one of the factors involved in seed survival and not a determining factor in survival of soybean in Northwest Europe. The seed will germinate when the soil temperature reaches 10°C and will emerge in a 5-7 day period under favourable conditions.<sup>15</sup> Soybean can under certain environmental conditions grow as a volunteer in the year following cultivation. However, soybean is not frost tolerant, and does not survive freezing winter conditions.<sup>14,15,25</sup> Volunteers do not compete well with other cultivated or wild plants and can be controlled mechanically or chemically.<sup>14,15</sup>

**Conclusion:** The molecular characterization of soybean MON88705xMON88708xMON89788 is adequate. There are no indications that expression of the introduced sequences will increase the potential of soybean MON88705xMON88708xMON89788 to establish feral populations.

### **2.3 Food/ feed assessment**

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 applications is carried out by RIKILT. COGEM abstains from giving advice on the potential risks of incidental consumption since a food/feed assessment is already carried out by other organisations.<sup>26</sup> The

outcome of the assessment by other organisations (EFSA, RIKILT) was not known when this advice was completed.

### 3. General Surveillance

COGEM has published several recommendations for further improvement of the general surveillance (GS) plan,<sup>27,28</sup> but considers the current GS plan adequate for import and processing of soybean MON87705xMON87708xMON89788.

### 4. Overall conclusion

Import and processing of soybean MON87705xMON87708xMON89788 poses a negligible risk to the environment in the Netherlands. COGEM abstains from giving advice on potential risks of incidental consumption since a food/feed assessment is already carried out by other organizations.

### 5. References

1. European Food Safety Authority (EFSA) (2012). Scientific Opinion on application (EFSA-GMO-NL-2010-78) for the placing on the market of soybean MON 87705 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal 10: 1-34
2. European Food Safety Authority (EFSA) (2013). Scientific opinion on application EFSA-GMO-NL-2011-93 for the placing on the market of the herbicide-tolerant genetically modified soybean MON 87708 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal 3355: 1-30
3. European Food Safety Authority (EFSA) (2008). Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2006-36) for the placing on the market of glyphosate-tolerant soybean MON89788 for food and feed uses, import and processing under Regulation (EC) 1829/2003 from Monsanto, The EFSA Journal 758: 1-23
4. European Food Safety Authority (EFSA) (2015). Scientific Opinion on an application (Reference EFSA-GMO-NL-2011-100) for the placing on the market of the herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal 13: 1-30
5. European Food Safety Authority (EFSA) (2015). Scientific opinion on application (EFSA-GMO-NL-2012-108) for the placing on the market of the herbicide-tolerant genetically modified soybean MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal 13 1-26
6. Center for Environmental Risk Assessment (CERA) (2012). GM Crop Database. [http://cera-gmc.org/index.php?action=gm\\_crop\\_database&mode=ShowProd&data=MON89788](http://cera-gmc.org/index.php?action=gm_crop_database&mode=ShowProd&data=MON89788) (visited: February 16, 2016)

7. COGEM (2010). Import and processing of genetically modified glyphosate tolerant soybean MON87705 with an altered fatty acid profile. COGEM advice CGM/101013-03
8. COGEM (2011). Import of genetically modified soybean MON87708 with a new herbicide tolerance trait. COGEM advice CGM/110801-02
9. COGEM (2008). Molecular characterization of soybean MON89788. COGEM advice CGM/080827-01
10. COGEM (2013). Import and processing of the genetically modified soybean line MON87705xMON89788. COGEM advice CGM/130107-01
11. COGEM (2013). Import and processing of the genetically modified dicamba and glyphosate tolerant soybean line MON87708xMON89788. COGEM advice CGM/131210-02
12. COGEM (2014). Import and processing of the genetically modified soybean line MON87769 x MON89788. COGEM advice CGM/140716-01
13. Bramlage WJ *et al.* (1978). Chilling stress soybeans during inhibition. *Plant Physiol.* 61: 525-529
14. Andersson MS & de Vicente MC (2010). Soybean (*Glycine max* (L.) Merr.). In: Gene flow between crops and their wild relatives. Eds: Andersson MS *et al.*, The Johns Hopkins University Press, Baltimore
15. Organisation for Economic Co-operation and Development (OECD) (2000). Consensus document on the biology of *Glycine max* (L.) Merr. (Soybean)
16. Compendium voor de leefomgeving, meteorologische gegevens 1990-2010.  
[www.compendiumvoordeleefomgeving.nl/indicatoren/nl0004-Meteorologische-gegevens-in-Nederland.html?i=9-54](http://www.compendiumvoordeleefomgeving.nl/indicatoren/nl0004-Meteorologische-gegevens-in-Nederland.html?i=9-54) (visited: February 17, 2016)
17. Koninklijk Nederlands Meteorologisch Instituut (KNMI). Klimaatatlas.  
[www.klimaatatlas.nl/klimaatatlas.php?wel=temperatuur](http://www.klimaatatlas.nl/klimaatatlas.php?wel=temperatuur) (visited: February 17, 2016) [in Dutch]
18. Van Roekel A (2015). Na nederwiet nu ook nedersoja. [www.kennislink.nl/publicaties/na-nederwiet-nu-ook-nedersoja](http://www.kennislink.nl/publicaties/na-nederwiet-nu-ook-nedersoja) (visited: February 17, 2016) [in Dutch]
19. Organisation for Economic Co-operation and Development (OECD) (1993). Traditional crop breeding practices: An historical review to serve as baseline for assessing the role of modern biotechnology
20. Wang K & Li X (2013). Pollen dispersal of cultivated soybean into wild soybean under natural conditions. *Crop Science* 53: 2497-2505
21. Ahrent DK & Caviness CE (1994). Natural cross-pollination of twelve soybean cultivars in Arkansas. *Crop Science Society of America* 34: 376-378
22. Carlson JB & Lersten NR (1987). Reproductive morphology. In *Soybeans improvement, production, and uses* Second edition. Ed. Willcox JR, American Society of Agronomy, Madison
23. Ray JD *et al.* (2003). Soybean natural cross-pollination rates under field conditions. *Environ. Biosafety Res.* 2: 133-138
24. OECD (2008). Safety assessment of transgenic organisms. OECD consensus documents. Volume 1
25. Wageningen UR. Hoe teel je soja in Nederland? [www.wageningenur.nl/nl/artikel/Hoe-teel-je-soja-in-Nederland.htm](http://www.wageningenur.nl/nl/artikel/Hoe-teel-je-soja-in-Nederland.htm) (visited: April 16, 2016) [in Dutch]
26. COGEM (2008). Toelichting advies GA21. COGEM brief CGM/080117-02 [in Dutch]
27. COGEM (2010). General Surveillance. COGEM report CGM/100226-01
28. COGEM (2015). Advice on improving the general surveillance of GM crops. COGEM advice CGM/150601-02