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Mr Ladislav Miko
Acting Director-General
Directorate General for Health and Food Safety
European Commission
200, rue de la Loi
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Belgium

Subject: Request for scientific advice from EFSA on new scientific information in relation to the risk assessment of genetically modified organisms

Ref. Letter received on 26 February 2015 Incoming N° 106815

Dear Mr Miko,

In response to your letter dated 24 February 2015 (with reference Ares (2015)779557; received on 26 February 2015), EFSA assessed the scientific content of the Bortolotto et al. (2014) publication[1] (see Annex for further details).

EFSA concludes that the publication by Bortolotto et al. (2014) reveals no new scientific information that would invalidate the previous risk assessment conclusions and risk management recommendations made on soybean MON87701×MON89788 or any other GM soybean previously assessed by its Panel on Genetically Modified Organisms. Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on all GM soybean events assessed so far, including soybean MON87701×MON89788, remain valid and applicable.

Yours sincerely,

Bernhard Url

Encl: Annex

cc: Ms Waigmann, Ms Paoletti, Mr Devos, Mr Fernando Álvarez – EFSA

[1] Bortolotto OC, Silva GV, de Freitas Bueno A, Pomari AF, Martinelli S, Head GP, Carvalho RA, Barbosa GC (2014) Development and reproduction of *Spodoptera eridania* (Lepidoptera: Noctuidae) and its egg parasitoid *Telenomus remus* (Hymenoptera: Platygastridae) on the genetically modified soybean (Bt) MON87701×MON89788. Bulletin of Entomological Research, 4(6): 724-730 (see also corrigendum published online on 8 January 2015)

ANNEX

1. BACKGROUND

Upon request of the European Commission, EFSA assessed the Bortolotto et al. (2014) publication and its corrigendum published online on 8 January 2015.

2. ASSESSMENT

The EFSA assessment below is structured into two parts. In the first part of the assessment, the findings on soybean MON87701×MON89788 reported by Bortolotto et al. (2014) and the scientific quality of the study are assessed. In the second part, the relevance of the scientific publication for the risk assessment of soybean MON87701×MON89788 and any other genetically modified (GM) soybean events for which the EFSA GMO Panel already issued a scientific opinion is considered.

Soybean MON87701×MON89788 expresses the *cry1Ac* gene, which confers resistance to specific lepidopteran insects, and the CP4 *epsps* gene, conferring tolerance to the herbicidal active ingredient glyphosate (EFSA, 2012).

2.1. Summary of the scientific publication

In their study, Bortolotto et al. (2014) assessed whether soybean MON87701×MON89788 has the potential to adversely affect the southern armyworm, *Spodoptera eridania* (Cramer) (Lepidoptera: Noctuidae), and its egg parasitoid *Telenomus remus* Nixon (Hymenoptera: Platygastridae).

S. eridania can be a secondary pest of soybean, and its geographical distribution is restricted to southern USA and Central and South America. The egg parasitoid *T. remus* is considered a potential candidate species for biological control of *Spodoptera* spp. in the frame of integrated pest management (IPM) programs (e.g., Bueno et al., 2010; Pomari et al., 2013).

The authors performed two separate bioassays under laboratory controlled environmental conditions using larvae of *S. eridania* fed leaves of soybean MON87701×MON89788 (hereafter referred to as GM) and of its non-transformed near-isoline (non-GM).

- In the first bioassay, newly emerged (≤ 24 hours-old) *S. eridania* larvae were continuously fed GM or non-GM leaves until they reached pupation. Pre-imaginal developmental time and survival, pupal weight, and sex-ratio were measured. Adults (< 24 hours-old) emerging from the respective treatments were paired, and their longevity and reproduction (fecundity and egg viability) were subsequently assessed. The results of the bioassay showed that larval duration was significantly shorter in the GM treatment (21.3 days) compared to the control (23.2 days), and that adult male longevity was approximately three days longer after larvae had been fed GM soybean leaves. No statistically significant differences between GM soybean and the control were observed for the other measurement endpoints;
- In the second bioassay, consumption of GM and non-GM leaves by *S. eridania* larvae was calculated, and did not significantly differ between the treatments.

In their corrigendum, Bortolotto et al. (2014) attributed the observed differences in larval development and male longevity of *S. eridania* to differences in the genetic background of the soybean materials used.

Bortolotto et al. (2014) also investigated the effects of soybean MON87701×MON89788 on the egg parasitoid *T. remus*. Parasitoid females (≤ 24 hours-old) were offered eggs of *S. eridania* laid by females that were reared either on GM or non-GM soybean plants as larvae. After 24 hours, the parasitised egg masses were transferred to glass tubes and kept in climatic chambers under environmentally controlled conditions until adult emergence. Longevity and reproduction of parental *T. remus* females, and pre-imaginal developmental time and sex-ratio of their offspring were measured. No adverse host-mediated effects were observed on the parasitoid, suggesting that *T. remus* is not adversely effected by soybean MON87701×MON89788 and consequently its use in managing *S. eridania* outbreaks in soybean fields is not compromised.

EFSA considers that the study, including bioassays, by Bortolotto et al. (2014) is well conducted, and that overall the conclusions drawn by the authors are supported by the data. A limitation, however, is that the authors did not provide sufficient information on the genetic background of the non-GM soybean line used as a comparator in the control treatment (e.g., through a breeding tree). EFSA is therefore not in position to assess whether the non-GM soybean line used as a comparator has a genetic background comparable to that of the line of soybean MON87701×MON89788, and thus whether it is an appropriate conventional counterpart. Owing to the lack of information on the comparator, it is challenging to determine the exact cause of the reported findings. Therefore, scientific uncertainty remains on the cause of the observed differences in *S. eridania* development and longevity which could be due to unintended effects associated with the genetic modification process, due to the intended traits, or due to differences in the genetic background of the soybean materials used. Yet, the observed differences in larval development and male longevity of *S. eridania* are small and favourable to pest development, suggesting that *S. eridania* populations may increase in soybean MON87701×MON89788 fields (Bernardi et al., 2014). Since no adverse effects were observed for *T. remus*, this egg parasitoid could still be used to prevent *S. eridania* outbreaks on soybean MON87701×MON89788 in the frame of IPM programs.

2.2. Relevance of the scientific publication for the risk assessment of GM soybeans

In line with the mandate provided by the European Commission, EFSA assessed the relevance of the findings reported by Bortolotto et al. (2014) for the risk assessment of soybean MON87701×MON89788 and any other GM soybean event for which the EFSA GMO Panel already issued a scientific opinion.

During its evaluation of the Bortolotto et al. (2014) publication, EFSA noted that the findings reported by the authors are mostly relevant for the environmental risk assessment of GM soybean events. Therefore, the EFSA assessment below focuses on the relevance for the environmental risk assessment of GM soybean events, including soybean MON87701×MON89788, for which the EFSA GMO Panel issued a scientific opinion (Table 1).

Table 1. Overview of previously risk assessed GM soybean applications by the EFSA GMO Panel

GM plant application	Event	Scope	Reference
EFSA-GMO-NL-2011-93	MON87708	Import/processing	EFSA (2013a)
EFSA-GMO-BE-2010-79	MON87701	Import/processing	EFSA (2011b)
EFSA-GMO-NL-2010-78	MON87705	Import/processing	EFSA (2012c)
EFSA-GMO-UK-2009-76	MON87769	Import/processing	EFSA (2014a)
EFSA-GMO-NL-2009-73	MON87701×MON89788	Import/processing	EFSA (2012a)
EFSA-GMO-NL-2009-64	BPS-CV127-9	Import/processing	EFSA (2014b)
EFSA-GMO-NL-2008-52	A5547-127	Import/processing	EFSA (2011a)
EFSA-GMO-NL-2007-45	305423	Import/processing	EFSA (2013b)
EFSA-GMO-UK-2007-43	356043	Import/processing	EFSA (2011c)
EFSA-GMO-NL-2006-36	MON89788	Import/processing	EFSA (2008)
EFSA-GMO-NL-2005-24	40-3-2	Cultivation	EFSA (2012b)
EFSA-GMO-NL-2005-18	A2704-12	Import/processing	EFSA (2007)
EFSA-GMO-RX-40-3-2 (8.1b_20.1b)	40-3-2	Import/processing	EFSA (2010)
EFSA-GMO-RX-40-3-2 (8.1a and 20.1a)	40-3-2	Import/processing	

GM soybean events for import/processing (low exposure conditions)

The EFSA GMO Panel has issued scientific opinions on several GM plant applications covering the import/processing for food/feed uses of GM soybean events (Table 1). Although the experiments reported in Bortolotto et al (2014) have been performed with and are directly relevant for soybean MON87701×MON89788, considerations on their potential environmental consequences can be extended to cover all GM soybean applications for import/processing.

Since the scope of the GM plant applications mentioned in Table 1 excludes cultivation in the European Union, the environmental risk assessment focused on low exposure scenarios (Roberts et al., 2014). Under low exposure conditions, the environmental risk assessment is mainly concerned with: (1) the accidental release into the environment of viable GM soybean seeds (e.g., during transport and/or processing); and (2) the exposure of bacteria to recombinant DNA in the gastrointestinal tract of animals fed GM material and those present in environments exposed to faecal material (manure and faeces).

The findings reported by Bortolotto et al. (2014) only bear relevance to the first route of exposure outlined above, as GM soybean plants may potentially adversely affect non-target parasitoids and the pest control services they contribute to. However, the accidental release of viable seed of GM soybean during import/transportation in the European Union will not result in the establishment of feral soybean populations, as soybean does not contain weedy characteristics. Soybean does not establish temporary or persistent feral populations. The level of exposure of non-target organisms to occasional feral soybean plants (if any) is at most extremely low. Therefore, potential interactions with non-target organisms are not considered to be relevant issues under import conditions.

Overall, no plausible pathway to harm for non-target organisms, including parasitoids, could be identified by EFSA and its GMO Panel in the context of GM soybean applications for import/processing.

GM soybean events for cultivation (high exposure conditions)

At present, none of the GM plant applications submitted to EFSA cover the cultivation of soybean MON87701×MON89788 in the European Union. Therefore, the findings reported by Bortolotto et al. (2014) have no direct relevance.

For the previous EFSA GMO Panel assessment of the cultivation of soybean 40-3-2 (application EFSA-GMO-NL-2005-24; see Table 1), the data gathered by Bortolotto et al. (2014) also have no impact, for the following reasons:

- No adverse effects were reported on *S. eridania* and *T. remus*;
- Should unintended effects associated with the genetic modification process be the cause for the observed differences in larval development and male longevity of *S. eridania*, they are event-specific, and therefore cannot be extrapolated from one transformation event to another;
- Soybean 40-3-2 only expresses the CP4 EPSPS protein, and there are no indications that the expression of the CP4 EPSPS protein in glyphosate-tolerant plants causes direct adverse effects on non-target organisms (reviewed by McLean, 2011).

However, if GM plant applications for the cultivation of soybean MON87701×MON89788 or GM soybean events with similar traits would be submitted to EFSA in the future, then the relevance of the data reported by Bortolotto et al. (2014) would be considered further under high exposure conditions, like any other relevant scientific publication[2]. Considerations in this context would include that Bortolotto et al. (2014) reported no adverse effects on the pest *S. eridania* and the egg parasitoid *T. remus* in their study and that *S. eridania* and *T. remus* are not present in the European fauna (Fauna Europaea; Meissle et al., 2012; Romeis et al., 2014).

3. Overall conclusion

The publication by Bortolotto et al. (2014) reveals no new scientific information that would invalidate the previous risk assessment conclusions and risk management recommendations made on soybean MON87701×MON89788 (EFSA, 2012) or any other GM soybean previously assessed by the EFSA GMO Panel (see Table 1 for an overview). Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on all GM soybean events assessed so far, including soybean MON87701×MON89788, remain valid and applicable.

4. References

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[2] The EFSA GMO Panel continuously screens and reviews the scientific literature, so as to ensure that most recent and relevant data are considered in its risk assessments in a pro-active manner

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