

## **Technical background on the request to stop the authorisation process of genetically engineered soybeans MON87708 x MON89788, FG72 and MON87705 x MON89788 for import (16-11-2015)**

The Standing Committee on Plants, Animals and Food has three applications for import of genetically engineered soybeans that are resistant to glyphosate on its agenda for 18 November:

- MON87708 x MON89788 (resistance to glyphosate and dicamba)
- FG72 (resistance to glyphosate and isoxaflutole)
- MON87705 x MON89788 (double resistance to glyphosate and change in oil content)

**Testbiotech and GeneWatch UK request that the authorisation of these genetically engineered soybeans is stopped for the following reasons:**

### **1. Assessment of glyphosate and glyphosate formulations**

EFSA stated in its recent conclusion on the risk assessment of glyphosate (EFSA 2015a), that there are not enough data available on the application of glyphosate to genetically engineered plants resistant to the herbicide:

„In the framework of the renewal, representative uses were proposed for conventional crops only and residue trials on glyphosate tolerant GM crops were not provided.“

And this is the reason why EFSA (2015a) risk assessment on health effects is limited to conventional crops:

“Based on the representative uses, that were limited to conventional crops only, chronic or acute risks for the consumers have not been identified.”

Further, EFSA (2015a) states that more investigations are needed, for example, in regard to the carcinogenicity of the formulations that are applied commercially:

“In particular, it was considered that the genotoxic potential of formulations should be addressed; furthermore EFSA noted that other endpoints should be clarified, such as long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of formulations (EFSA, 2015b).”

In addition, EFSA (2015b) provided an assessment of POE-tallow amine additives, which are used in several formulations with glyphosate, and came to the conclusion that these are more toxic than glyphosate:

„Compared to glyphosate, a higher toxicity of the POE-tallow amine was observed on all endpoints investigated.“

However, no data were made available on the actual load of residues from spraying with these formulations (EFSA, 2015b):

“The genotoxicity, long-term toxicity and carcinogenicity, reproductive/developmental

toxicity and endocrine disrupting potential of POE-tallow amine should be further clarified. There is no information regarding the residues in plants and livestock. Therefore, the available data are insufficient to perform a risk assessment in the area of human and animal health for the co-formulant POE-tallow amine.”

It has to be expected that the genetically engineered soybeans for which authorisation for import is being sought, have been sprayed with formulations that are not allowed in the EU, but are being used in countries such as Argentina, Brazil and the US. EFSA was unable to deliver a conclusive risk assessment on the actual risks of residues from spraying with glyphosate and the various glyphosate formulations, therefore, the precautionary principle has to be applied and authorisations of these genetically engineered plants with resistance to glyphosate need to be stopped.

The stacked soybean MON87705 x MON89788 should also be taken into account in this respect. This particular stacked soybean has been engineered to have a twofold resistance to glyphosate, thus the dosage being applied to these plants might be higher than for other genetically engineered plants. (Testbiotech, 2015a).

## **2. Possible combinatorial effects with other herbicides**

It is only since MON87708 x MON89788 and FG72 were introduced into markets that herbicides such as isoxaflutole and dicamba can be applied directly to soybeans in combination with glyphosate.

Spraying with isoxaflutole and dicamba results in residues from spraying that are assumed to impact human health. There are several similar endpoints to those found for glyphosate. For example, the residues from the usage of isoxaflutole are considered to be probably carcinogenic (Testbiotech, 2015b). Consequently, the effects on health from the combinatorial effects of these residues are likely to be more severe than can be expected from the assessment of the single components.

EFSA did not assess the combinatorial effects (synergistic or additive) resulting from the residues of these herbicides together with those of glyphosate and relevant additives. The EFSA GMO panel did not request any feeding trials with the whole food and feed (see Table 1). The EU Commission believes that further detailed risk assessment is unnecessary since risk assessment was conducted on the active ingredients of each single herbicide. However, as a publication from Kleter et al. (2011) shows, this assumption is not correct. Using herbicides to spray genetically engineered herbicide-resistant plants can lead to patterns of residues and exposure that are not taken into account in regular pesticide registration:

- “1. GM herbicide-resistant crops can change the way that herbicides can be used on these crops, for example:
  - (a) post-emergent over-the-top applications (i.e. on the crop itself) instead of directed sprays, avoiding herbicide contact with the crop; or
  - (b) pre-emergent and pre-harvest applications made to the conventional crop and not, or in different quantities, to the GM crop.
2. The residue profile of the applied pesticide may have been altered on the basis of the nature of the modification.
3. The overall pattern of pesticides applied to the particular crop may have been altered, leading to different exposure to pesticide residues overall.”

It is up to the EU Commission to establish a framework within which to conduct sufficiently robust risk assessment to implement EU legal requirements based on the precautionary principle, and

which require the highest scientific standards. Therefore, the toxic residues from spraying and their specific combinations left behind in the genetically engineered plants need to be taken into account in risk assessment. This is a matter of urgency since more and more herbicides and combinations of herbicides are being applied in the cultivation of genetically engineered plants.

In consequence these plants should not be authorised for import because the combinatorial health impacts resulting from the consumption of soybeans that have been sprayed with a these mixtures of herbicides are likely to be much higher than those resulting from single active ingredients.

### **3. Open questions regarding the risk assessment of genetically engineered plants with changed nutritional quality**

At the end of May 2015, GeneWatch UK and Testbiotech together filed a request at the EU Commission for an internal review of the authorisation for three genetically engineered soybeans. (GeneWatch UK & Testbiotech 2015).

This request also concerns MON87705, which was used as a parental plant for the production of one of the stacked events under discussion. Even though all the deadlines have passed there has been no response from the EU Commission. The request draws attention to the fact that specific guidance should be required for the risk assessment of GM crops with significantly altered nutritional content such as MON87705, and that the authorisations should not have been granted because:

1. EFSA has initiated but not completed a process of developing guidance for the assessment of GM crops with significantly altered nutritional content. As well as being incomplete, this process has not been independent or transparent. In the absence of this guidance, approvals should not have been granted for nutritionally-altered GM crops.
2. The lack of guidance has led to inconsistent and inadequate risk assessments for all three crops, which fail to meet the requirements of the legislation.
3. Labelling and post-marking monitoring proposals are also inadequate and inconsistent.
4. In addition, the impacts of pesticide residues have not been fully considered for the two herbicide-tolerant crops and the unintended effects of RNA interference have not been adequately assessed for MON 87705.

Since no such guidance is available, the soybean MON87705, alone or as a stacked event, cannot be allowed for import.

**Table 1: Overview of data from feeding trials provided to EFSA from the companies in regard to MON87705 and MON89788 (parental plants), MON89788 x MON87705, MON89788 x MON87708 and FG72**

Event	Year of the assessment	Company	Traits	Feeding trials for 90 days	Comment
MON89788 (parental plant)	2008	Monsanto	Resistance to glyphosate	Yes	
MON87705 (parental plant)	2012	Monsanto	Resistance to glyphosate / changed oil composition	(Yes/No)	The soybeans were defatted – the changed oil composition was not part of the trials
MON87705 x MON89788	2015	Monsanto	2x Resistance to glyphosate / changed oil composition	(Yes/No)	The soybeans were defatted – the changed oil composition was not part of the trials
FG72	2015	Bayer	Resistance to glyphosate and isoxaflutole	No	Data from trials not accepted by EFSA because of lack of scientific standards.
MON87708 x MON89788	2015	Monsanto	Resistance to glyphosate and dicamba	No	

#### References:

EFSA, European Food Safety Authority (2015) Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015; 13(11):4302, 107 pp.

EFSA, European Food Safety Authority (2015b) Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine. EFSA Journal 2015;13(11):4303, 13 pp.

GeneWatch UK & Testbiotech (2015) Technical background: Complaint soybean MON 87769, MON 87705, 305423, [www.testbiotech.org/node/1284](http://www.testbiotech.org/node/1284)

Kleter, G.A., Unsworth J.B., Harris C.A. (2011) The impact of altered herbicide residues in transgenic herbicide-resistant crops on standard setting for herbicide residues. Pest Management Science, 67(10): 1193-1210.

Testbiotech Comment (2015a) Application (Reference EFSAGMO- NL-2011-100) for the herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 × MON 89788 for food and feed uses, import and processing, [www.testbiotech.org/node/1337](http://www.testbiotech.org/node/1337)

Testbiotech Comment (2015b) Application (EFSA-GMO-BE- 2011-98) for the placing on the market of herbicide-tolerant genetically modified soybean FG72 for food and feed uses, import and processing from Bayer, [www.testbiotech.org/node/1336](http://www.testbiotech.org/node/1336)