



Deputy Director-General for Food Safety

Brussels,
SANTE/E3/MM/aj/ ddg2.e.3 (2016)879824

Dear Petitioner,

Subject: Stop the marketing authorization of genetically modified soybeans with a mixture of toxic residues

Thank you for your emails to Mr Jean-Claude Juncker, President of the European Commission, who asked me to reply on his behalf.

I would like to highlight that the EU legislation provides for what is considered to be the world's strictest legislative framework on GMOs and particularly by Regulation (EC) No 1829/2003¹, Directive 2001/18/EC² and Implementing Regulation (EU) No 503/2013³. Based on this framework, any GMO undergoes a specific risk assessment of the highest possible standard before being placed on the EU market in order to protect human and animal health and the environment.

On this basis, the European Food Safety Authority (EFSA) has issued a favourable scientific opinion on soybean MON 87708 × MON 89788, tolerant to glyphosate and dicamba-based herbicides, and on soybean FG72, tolerant to isoxaflutole herbicides, and found them to be as safe as their conventional counterpart and other non-genetically modified soybean varieties with respect to potential adverse effects on human and animal health and the environment in the context of the scope of the applications.

Please note that both, EFSA's Guidance on risk assessment of food and feed from genetically modified plants⁴ and the Implementing Regulation (EU) No 503/2013, require that the comparative assessment should include data from plants sprayed with the intended herbicides and data from unsprayed plants to assess potential unintended effects. Thus, a potential combined effect of the newly expressed proteins and the herbicide treatment is considered in the GMO risk assessment of herbicide-tolerant crops.

Let me also stress that in the EU, the risk assessment of GMOs for food and feed uses is focused on the potential impact of the introduced gene on human and animal health and the

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003.

² Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001.

³ Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006, OJ L 157, 08.06.2013.

⁴ EFSA (2011a) Guidance for risk assessment of food and feed from GM plants. EFSA Journal 9(5):1-37 [2150], <http://www.efsa.europa.eu/en/efsajournal/doc/2150.pdf>

environment. It is worth noting that the risk assessment of the effects on the human health of plant protection products (PPP) is subject of a specific EU Regulation (Regulation (EC) No 396/2005⁵ on maximum residue levels of pesticides in or on food and feed of plant and animal origin), which provides for the risk assessment of pesticide residues in food and feed and sets maximum residue levels (MRL) applicable to all food and feed placed on the market, including GMOs.

With regard to your concerns about the traces of chemical residues in GM soybean MON 87708 × MON89788, let me stress that imported products must comply with the MRLs set out in Regulation (EC) No 396/2005.

There is an MRL set for glyphosate and this active substance has been reviewed by EFSA in relation to the renewal of the marketing approval as active substance in plant protection products. A large body of research work is available, both as studies submitted by the applicant in its dossier for the renewal of the approval and as scientific peer-reviewed open literature. The Commission has asked EFSA to take all relevant data into account when issuing its opinion. On 12 November 2015, EFSA published its Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA concluded that glyphosate does not have a genotoxic potential.

In compliance with its legal obligations, the Commission presented a draft review report and a draft Regulation as regards the possible renewal of the substance to the Standing Committee on Plants, Animals, Food and Feed. Discussions within the Committee are ongoing.

As to the active substance dicamba, please note that in 2013, following EFSA's assessment⁶, the Commission has set a specific import tolerance of 0.4 mg/kg for the metabolite of dicamba, which is formed in the dicamba-tolerant MON 87708 soybean.

Regarding the herbicide-tolerant soybean FG72, please note that there is an MRL set for the pesticide isoxaflutole as well.

The pesticides legislation requires cumulative and synergistic effects of pesticide residues to be considered in the MRL setting, but only when the methods for assessment are available. This is not yet the case and the legislation recognizes that further work in this respect is needed. The Commission is working with the Member States, EFSA and other scientists to develop a methodology to take into account cumulative and synergistic effects of pesticides residues. Since the development of such a methodology for cumulative risk assessment is very complex, the finalisation of the full methodology will still need some time, both at risk assessment as well as at risk management level. However, this issue is not specific to GM crops but pertains to all uses of PPPs, as in conventional agriculture it may be necessary to treat a crop with PPPs containing different active substances, either due to pest pressure from different organisms and/or due to issues of resistance management.

Yours sincerely,



Ladislav Miko

⁵ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.3.2005.

⁶ Reasoned opinion on the modification of the MRL for dicamba in genetically modified soybean, EFSA Journal 2013; 11(10):3440.