EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Biotechnology

Brussels,
SANTE/E1/MM/as sante.ddg2.e.1(2015)4023741

Dear Mr Scholze,

Subject: On-line petition Stoppt die Gift-Soja! Stop the toxic soybeans!

Thank you for your e-mail regarding soybean MON 87708 × MON 89788 which was sent to Commissioner Andriukaitis. The Commissioner has 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 1829/2003[1], Directive 2001/18/EC[2] and Implementing Regulation (EU) No 503/2013[3]. 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 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 found it to be as safe as its 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 application.

The risk assessment was reviewed by EFSA in 2013, following the receipt of new comments submitted by an NGO, questioning the safety of this GMO. However, EFSA did not identify new evidence justifying a change of its favourable opinion.

Mr Andreas Scholze

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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.

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 the human and animal health and the environment. It is worth noting that the risk assessment of the effects on the human health of plant protection products residues is not regulated by the GMO legislation but is subject of a specific EU Regulation (Regulation (EC) No 396/2005[4] 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, imported products must therefore comply with the MRLs set out in Regulation (EC) No 396/2005.

There is an MRL set for glyphosate and this active substance is currently under a review by EFSA for 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.

As to the active substance dicamba, please note that in 2013, following EFSA's assessment[5], 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.

It is important to highlight that the MRLs set for the residues of plant protection products in food take into account cumulative effects of regular consumption of food containing such residues and the safety of all consumer groups is covered. EFSA assesses the safety for consumers based on the toxicity of the pesticide, the maximum levels expected in food and the different diets of Europeans.

I hope that you will find this information useful and reassuring.

Yours sincerely,

Dorothée André
Head of Unit

4 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.

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