



**EUROPEAN COMMISSION**  
 HEALTH AND CONSUMERS DIRECTORATE-GENERAL  
 Safety of the Food Chain  
**Biotechnology**

Brussels,  
 SANCO/E1/[REDACTED] sanco.ddg2.e.1(2014)933921

Dear [REDACTED],

**Subject: WTO ruling on genetically modified seed and food/proposal for a reversal of burden of proof.**

Thank you for your email of 9 February 2014 to President Barroso regarding international trade of GMOs and the need for a reversal of proof as regards demonstration of safety of these GMOs on health and the environment. The President has asked that I, as the head of the unit responsible for GMOs, respond on his behalf.

I would like to confirm you that the European system for authorisation of GMOs is precisely built upon the principle of “reversal of proof” you are calling for. Indeed the EU legislation provides for a well-defined regulatory framework on GMOs and particularly Directive 2001/18/EC<sup>1</sup> and Regulation (EC) No 1829/2003<sup>2</sup>, which is recognised as being among the strictest worldwide. According to this framework a GMO can be placed on the EU market for food and feed use or for cultivation only after having been through a thorough risk assessment, performed by the applicant and evaluated by the Member States and the European Food Safety Authority (EFSA). This risk assessment has to demonstrate that the GMO is safe for human and animal health and for the environment.

In practice, this means that the applicant holds the responsibility to prove the safety of the GMO by compiling a precisely defined set of data/studies on all possible areas of environmental risks, including potential for plant-to-plant gene transfer to compatible relatives, or the environmental impacts due to interaction with target organisms and non-target organisms. Applicants also has the obligation to propose a post-market environmental monitoring plan within the application. Member States and EFSA are responsible for assessing the submitted application and may require supplementary information or clarifications from applicants. When adopting their opinion, Member

<sup>1</sup> 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

<sup>2</sup> 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

States and EFSA may also propose management measures which will be scrutinised by risk managers when proposing an authorisation decision.

I would also like to stress that the EU legislation on GMOs<sup>3</sup> foresees the possibility for Member States to adopt co-existence measures in order to avoid the unintended presence of GMOs in other products, and to prevent potential economic loss and impacts due to traces of GM crops in non-GM crops, such as conventional and organic crops. The European Coexistence Bureau (ECoB)<sup>4</sup>, which is hosted by the Commission, has been developing together with Member States best practices for co-existence, e.g. between insect resistant GM maize and conventional and organic maize<sup>5</sup>, and the Commission published in July 2010 a recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops.

The European Commission is committed to promote and defend its strict authorisation system for GMOs towards its international trading partners, and in international organisations such as the World Trade Organisation. For instance, in the context of the ongoing negotiations with the United States on the Transatlantic Trade and Investment Partnership (TTIP), the European Commission has made clear that basic laws, like those relating to GMOs or which are there to protect human life and health, animal health and welfare, or environment and consumer interests, will not be part of the negotiations.

I hope that I have been able to address your concerns.

Yours sincerely,

A grey rectangular box redacting the signature of the official.

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<sup>3</sup> Article 26a of Directive 2001/18/EC on the deliberate release of GMOs into the environment (OJ L 106, 17.4.2001)

<sup>4</sup> <http://ecob.jrc.ec.europa.eu/>

<sup>5</sup> <http://ecob.jrc.ec.europa.eu/documents.html>