



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO/E1/KK/oz/sanco.ddg2.e.1(2013)3650485

Dear Mr Lannoye,

Subject: Open letter against GM animals in the EU

Thank you for your letter of 25 October 2013 to which you attached the concerns of Belgian citizens regarding the use of GM animals in EU farming.

Let me inform you that the existing EU legislation on GMOs is also applicable to the deliberate release of GM animals into the environment and for food/feed derived from GM animals. However, as of today, no application related to GM animals has been submitted in the EU. Let me reassure you that if an application related to the marketing or deliberate release of a GM animal and/or derived food and feed would have to be submitted in the EU, not only food, feed and environmental safety aspects but also animal health and welfare would be considered under Regulation (EC) No 1829/2003 or Directive 2001/18/EC.

In order to prepare for possible future evolution in this field, the Commission requested the European Food Safety Authority (EFSA) to develop guidance on the above mentioned aspects. As a consequence, EFSA has published in January 2012 guidance on the scientific requirements for the risk assessment of food and feed derived from GM animals and relevant animal health and welfare aspects of GM animals. Guidance on the scientific requirements for the environmental risk assessment of GM animals was published in May 2013.

In the food sector, the AquaAdvantage salmon produced by AquaBounty is the most advanced application that the Commission is aware of. It has received favourable opinions from the US Food and Drug Administration (FDA) following a food safety and environmental risk assessment in the United States in 2010. However, in 2012 the FDA reopened the environmental risk assessment as the 2010 opinion was considered insufficient. The new opinion on the environmental assessment has not yet been finalised.

As regards possible presence on the EU market of non-authorised GM products, the current EU legislation requires that Member States and operators perform controls of the implementation of Regulation (EC) No 1829/2003 or Directive 2001/18/EC. Additionally, the Food and Veterinary Office of the Commission's Health and Consumers DG (FVO) through its audits, inspections and related activities check compliance with the requirements of GMO legislation within the European Union and compliance with EU import requirements in third countries exporting to the EU. Where

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necessary, the Commission could adopt emergency measures targeting the countries/products where it has been identified that the control system is not sufficient to avoid the introduction of non-authorised GM animal as or in products in the EU.

I would also like to reassure you that I am aware of the concerns of consumers in the EU regarding the ethical issues related to the genetic modification of farm animals. I am currently considering sending a new request to the European Group on Ethics in Science and New Technologies to provide an opinion on the ethical implication of using GM animals for food production in particular. This would update the previous opinion adopted by this group in 1996 http://ec.europa.eu/bepa/european-group-ethics/docs/opinion7_en.pdf.

Concerning the ongoing discussions with the United States on the Transatlantic Trade and Investment Partnership (TTIP), as clearly stated by President Barroso, the Commission excludes negotiating changes of basic regulations, like those related to GMOs, which are there to protect human life and health, animal health and welfare, and/or environment and consumer interests.

I hope that I have been able to reassure you that European Commission takes the issues relating to genetically modified animals very seriously.

Paola Testori Coggi