

10 JUL 2015

Ref. BU/JK/EW/CP/AL/lg (2015) – out – 14440308

Mr Ladislav Miko
Acting Director-General
DG SANTE
European Commission
200, rue de la Loi
B-1049 Brussels

Subject: Mandate on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) 1829/2003 on GM food and feed

Ref.: Your letter dated 27/03/2015 – EFSA INCOMING No 108389 (30/03/2015)

Your letter dated 22/09/2014 - EFSA INCOMING No 99280 (22/09/2014)

Dear Mr Miko,

We hereby confirm the receipt of your letter dated 27 March 2015 (Ref. Ares (2015) 1362776) providing clarifications on questions, detailed by EFSA in a letter dated 24 November 2014, regarding the Terms of Reference on the mandate on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) 1829/2003 (Low Level Presence, LLP).

The mandate was originally communicated to EFSA in your letter dated 22 September 2014 (Ref. Ares(2014)3096951) requesting EFSA, in accordance with Article 29 of Regulation (EC) No 178/2002, to advise whether or not all requirements of Annex II to Regulation (EC) 503/2013 on applications for authorisation of GM food and feed are necessary to conclude on the safety of applications covering the unintended presence of GM products in food and feed at the adventitious or technically unavoidable presence at the threshold of 0.9% or below. If no, EFSA will indicate which requirements are unnecessary and the underlying rationale.

EFSA wishes to thank you for the clarifications which are considered to address the EFSA questions.

We therefore welcome the present mandate and commit to issue an EFSA GMO Panel scientific opinion providing guidelines on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) 1829/2003 on GM food and feed.

In order to achieve this task, a GMO Panel Working Group will be created consisting of GMO Panel member(s) and, if needed, ad-hoc experts with expertise relevant in risk assessment of food and feed. Given that the present GMO panel finalises its mandate in June 2015, it is proposed to start work on the mandate with the new Panel scheduled to take on its duties in July 2015. In order to be able to take adequately into account Member State and stakeholder

comments, two consultations will be organised in a stepwise manner. Following the endorsement of a draft scientific opinion by the EFSA GMO Panel, a consultation with Member States via appropriate means will be launched in summer 2016. Comments from this consultation will be addressed and an updated draft scientific opinion, again endorsed by the EFSA GMO Panel, will be launched for public consultation (aiming at the public and including all stakeholders) via the EFSA website in the last quarter of 2016. The outcome of the consultations will be published in a technical report on the EFSA website. Due to the above steps, EFSA requests to extend the deadline for issuing an EFSA GMO Panel guidance to May 2017.

Yours sincerely,



Bernhard Url

cc: Mr Gumbel, Mr Gautrais, Mr Vanhoorde, Ms André, Ms Pelsser, Ms Mirazchiyska,
Ms Kantorska, Ms Ziane – DG SANTE
Ms Kleiner, Ms Waigmann, Ms Paoletti, Ms Lanzoni, Mr Divéki, Ms Lheureux – EFSA