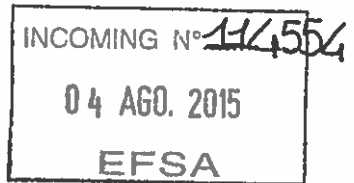


EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for the Food Chain



Brussels,
SANTE/E1/SP/oz sanco.ddg2.e.l(2015) 3491271

Dear Mr Url,

Subject: New sequencing information of events MIR604 and GA21 maize

In accordance with Articles 9 and 21 of Regulation (EC) 1829/2003 on GM food and feed, authorisation-holders of GM food and feed shall inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food or feed. The Commission shall make the information available to EFSA and the Member States without delay.

On 23 July 2015, Syngenta sent to the Commission new sequencing information relating to events MIR604 and GA21 maize on the basis of Articles 9 and 21 of Regulation (EC) 1829/2003.

I would be grateful if EFSA could analyse the data and the performed analysis provided by Syngenta and indicate whether, on the basis of these elements, the favourable conclusions of the adopted opinions of the following GMOs have to be adapted: MIR604 maize, GA21 maize, Bt11xGA21 maize, MIR604xGA21 maize, Bt11xMIR604 maize and Bt11xMIR604xGA21 maize.

I would be grateful to receive an answer by end of September 2015.

Yours sincerely,

Ludislav Miko

Mr Michael Flüh
Acting Director
DG Health and Food Safety
for the DDG absent

Mr Bernhard Url
Executive Director
European Food Safety Authority
Via Carlo Magno 1A
I-43126 Parma

Enclosure: Letter from Syngenta dated 20/07/2015
CD rom with MIR604 sequencing and GA21 sequencing information

Email Copy: Ms E. Waigmann, Ms C. Paoletti (EFSA)
Ms D. André, Ms S. Pelsser, Ms K. Kantorska, Ms M. Mirazchiyska (DG
SANTE)

European Commission - DG SANTE
 Directorate E - Safety of the Food Chain
 E1 Biotechnology
 Dorothee André
 Rue Belliard 232 03/100
 B-1049 Brussels

20 July 2015

Dear Mrs André

Subject: Communication relating to sequencing information of Events MIR604 and GA21 maize

We would like to bring to your attention a sequencing update relating to the maize single events MIR604 and GA21 which are approved for import and use in the EU as single events or in stacked products under the Regulation EC (No) 1829/2003. The list of products is shown in Table 1 and the update is described in more detail in Annexes 1 and 2 to this letter.

The sequencing update describes discrepancies in the original reporting of MIR604 and GA21 maize events, rather than a change in the sequence during the breeding process. The results of our detailed analyses confirm that these reporting discrepancies do not have implications for the human and animal health or the environmental risk assessments previously performed and support the conclusion that products containing MIR604 and GA21 maize remain as safe as conventional maize.

Articles 9 and 21 of Regulation (EC) No 1829/2003 request the authorization-holder to inform the Commission of any new information which might influence the evaluation of the safety in use of food and feed respectively. However since this is a reporting discrepancy which does not have implications for previous risk assessments, we are providing this update relating to the single maize events MIR604 and GA21 to allow for accuracy and consistency moving forward.

The update is also being sent to EFSA as part of their ongoing assessment relating to cultivation and import dossiers containing these events.

Table 1: List of MIR604 and GA21 approved products and products pending Commission Decision in the EU

Event name	Application number	Commission Decision
GA21 import	EFSA-GMO-UK-2005-19 EFSA-GMO-RX-GA21	Commission Decision 2008/280 of 28 March 2008
MIR604 Import	EFSA-GMO-UK-2005-11	Commission Decision 2009/866 of 30 November 2009
Bt11 x GA21 Import	EFSA-GMO-UK-2007-49	Commission Decision 2010/426 of 28 July 2010
MIR604 x GA21 Import	EFSA-GMO-UK-2007-48	Commission Decision 2011/892/EU of 22 December 2011
Bt11 x MIR604 Import	EFSA-GMO-UK-2007-50	Commission Decision 2011/893/EU of 22 December 2011
Bt11 x MIR604 x GA21 Import	EFSA-GMO-UK-2008-56	Commission Decision 2011/894/EU of 22 December 2011
GA21 Cultivation	EFSA-GMO-UK-2008-60	Pending Commission Decision

If you require further information, please do not hesitate to contact me.

For the purposes of correspondence please address your response to



Yours sincerely



Enclosed (provided at CD-ROM):

Annex 1: MIR604 Sequencing information

Annex 2: GA21 Sequencing information