



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Biotechnology

Brussels,
SANTE/E1/KK/as_sante.ddg2.e.1(2016)109647

Dear Petitioner,

Subject: On-line petition on the authorisation of the GM maize

Thank you for your e-mail regarding the recent authorisations of maize NK603 x T25 and maize MON 87427 which was sent to Commissioner Andriukaitis. The Commissioner has asked me to reply on his behalf.

Let me highlight that the EU legislation provides for a well-defined regulatory framework on GMOs and particularly Directive 2001/18/EC¹ and Regulation (EC) No 1829/2003². According to this framework, which is recognised as being among the strictest worldwide, any GMO, before being placed on the EU market, has to undergo a case-by-case safety assessment of the highest possible standard by the European Food Safety Authority (EFSA) demonstrating its safety for human and animal health and the environment.

Each draft Decision is processed by the Commission in accordance with a procedure³ adopted by the European Parliament and the Council. The European Parliament has a right of scrutiny on these authorisation Decisions through motions for Resolution, such as the one adopted by the European Parliament on the draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xT25. No motion for Resolution was presented or adopted on the draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427.

Regarding the genetically modified maize NK603xT25, EFSA performed a comprehensive risk assessment of the product and published in July 2015 a favourable opinion concluding that it is as safe as its non-GM comparator and other non-GM maize varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application.

¹ 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

² 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

³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.02.2011, p.13

The draft Decision on genetically modified maize NK603xT25 was voted on 19 October 2015 in the Standing Committee composed of the representatives of Member States, which could not reach an opinion against or in favour. In accordance with the rules set in Regulation (EU) 182/2011, the Commission proposed the draft Decision to the Appeal committee, composed of the representatives of Member States, on 10 November 2015, where no opinion against or in favour was obtained either and the decision was adopted by the Commission.

Allow me to explain that the right to scrutiny is limited to the question on whether the draft implementing act exceeds the implementing powers provided for in Regulation (EU) 182/2011. The European Parliament draft motion for the Resolution was scrutinised and addressed by the Commission in the Environment, Public Health and Food Safety Committee on 1 December 2015 where it was explained that the GM maize NK603 x T25 has been found safe by EFSA and the draft Decision for its authorisation has been processed in line with the applicable procedures, justifying that the Commission has not exceeded its implementing powers.

As a consequence, the Commission continued to proceed with the draft Decision of authorisation and adopted it on 4 December 2015, in line with the legal framework.

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

Yours sincerely,



Dorothee André
Head of Unit