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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
E1. Biotechnology

Brussels,

8 July 2015

Dear Petitioner,

The Commission is pleased to reply to the petition entitled "Tell Juncker to keep his promise to make EU GMO decisions more democratic".

First of all, it should be stressed that the EU legislation provides for regulatory framework on Genetically Modified Organisms (GMOs)[1], 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 and up to date standard by the European Food Safety Authority (EFSA) and the Member States, in order to protect human and animal health and environment.

Legitimate concerns such as impacts of GMOs on conventional or organic products are given due consideration in the EU legislation: the Member States can adopt co-existence measures to prevent potential economic loss due to unintended presence of GM crops in conventional and organic crops. The recently adopted Directive (EU) 2015/412 related to GMO cultivation even imposes that Member States in which GMOs are cultivated put in place coexistence measures in border areas of their territory to avoid possible cross-border contamination into neighbouring Member States where GMO cultivation is prohibited.

The Commission takes note of the concerns of the petitioner as regards the outcome of the review of the GMOs legislation and the legislative proposal made by the Commission on 22 April 2015[2] to amend Regulation (EC) No 1829/2003 in order to allow Member States to restrict or ban the use of genetically modified food and feed on their territory.

In a Communication published the same day[3], the Commission explained the reasons of the chosen approach to address the perceived democratic deficit surrounding the authorisation of GMOs.

The Communication recalls, in particular, that Member States never expressed a qualified majority in favour or against a Commission's draft implementing decision authorising GMOs. This situation of systematic "no opinion" vote in the EU comitology procedure is

[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; 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

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015PC0177&from=EN

[3] http://ec.europa.eu/food/plant/docs/plant_gmo_authorisation_communication_en.pdf, and http://ec.europa.eu/food/plant/docs/plant_gmo_authorisation_communication_annex_en.pdf

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unique to the GMOs sector, and it reflects the polarised views of Member States with regard to GMOs. The Communication outlines that the reasons raised by the Member States voting against or abstaining are diverse, but most often do not relate to the way the risk assessment of the GMO has been performed or to the requirements of the decision of authorisation itself. Rather, these Member States refer to other kind of considerations reflecting their national contexts.

The Commission has concluded that the right way of addressing this perceived democratic deficit in the decision making process would be to give more room for expression of the legitimate concerns of democratically elected governments on GMOs, based on the model of the recently adopted Directive (EU) 2015/412. In making this proposal the Commission has taken into account the fact that it is necessary to preserve a harmonised authorisation system at EU level based on a single risk assessment in order to ensure the same level of safety throughout the EU. Furthermore, the Commission considered that departing from the horizontal rules of the comitology procedure, for example to prevent the Commission from adopting implementing decisions when the Appeal Committee issues a "no opinion", would not be justified. Indeed, Regulation (EC) No 182/2011 on EU comitology was adopted by the European Parliament and the Council - both being direct emanations of citizens at EU level – and it allows the fair expression of Member States' positions in accordance with the rules fixed in the Treaties. These requirements are applicable to all the implementing acts adopted by the Commission and they are not questioned outside the GMO area. Thirdly, it appeared that the individual reasons expressed by Member States during the vote on EU decision of authorisation would be better addressed under a subsidiarity approach.

In relation to other concerns raised in the petition, it should be stressed that, although the Single Market is one of the pillars of EU law, the Treaties also recognise the possibility for Member States to invoke overriding reasons of public interest to justify measures which could be considered as equivalent to quantitative restrictions of goods (Article 36 TFEU and related case-law of the Court of Justice[4]). Therefore, the rules of the Single Market do not prevent Member States from adopting "opt out" measures which are reasoned and based on compelling grounds in accordance with EU law. Furthermore, the proposal guarantees that the risk assessment and risk management of GMOs are not undermined. Indeed the justifications used by Member States when adopting a measure restricting or banning GMOs shall, in no case, conflict with the risk assessment carried out pursuant to Regulation (EC) No 1829/2003.

Finally, on 24 April 2015, the Commission adopted 17 decisions of authorisations corresponding to the genetically modified food and feed referred to in the petition. This adoption was done by application of the requirements of Regulation (EC) No 1829/2003, after that these products have received a favourable scientific assessment by the European Food Safety Authority.

In conclusion, the Commission hopes that the above has reassured you on the fact that the legislative proposal of the Commission is the right approach to address the challenges in relation to the decision making process applying to GMOs.

Signed by Ladislav MIKO

[4] See for instance, CJEU, 20.02.1979, Case 120/78 Rewe-Zentral (Cassis de Dijon) [1979] ECR 649