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European Commission (DG SANTE)

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Unit E1 Biotechnology and Plant Health
Rue Belliard 232 03/100
B-1049 Brussels

Brussels, 3 November 2015

Subject: *Response to the letter of the European Commission communicating the demand of Italy to restrict the geographical scope of maize MON 810 (Ref. SANTE/E1/MK/as sante.ddg2.e.1(2015) 4540180)*

Dear [redacted],

We formally received your letter dated 2 October 2015, communicating the demand from Italy under Article 26c of Directive 2001/18/EC to have its whole territory excluded from cultivation of maize MON 810, on 5 October 2015. With this letter, referring to Article 26c (2) and Article 26c (3) of Directive 2001/18/EC, we would like to express our disappointment with Italy's demand and the associated consequences. We request that you and Italy consider the grounds for our disappointment, as well as the additional comments and requests as detailed below.

Multiple regulatory agencies around the world¹, including the European Food Safety Authority (EFSA)² have concluded that MON 810 is unlikely to have adverse effects on humans, animals or the environment. This conclusion has been confirmed by the experiences during almost 20 years of widespread commercial cultivation globally, including 11 years in the EU. Italy's request to prohibit MON 810 cultivation on its territory contradicts and undermines the scientific consensus on the safety of MON 810 and its long history of safe use. We regret to conclude that Italy is deviating from a science-based approach and has elected to prohibit MON 810 cultivation on arbitrary political grounds. We consider this decision to be disproportionate and discriminatory.

Directive (EU) 2015/412 and thus the demand of Italy runs counter to a founding principle of the EU, the single market in goods and services which encourages investment. Regrettably, Italy's demand sends a negative signal to innovative industries wishing to invest in the European Union. Arbitrary political decisions to reject the cultivation of GM crops also deny European farmers the right to choose to use safe, innovative agricultural technologies to enhance productivity in a

¹ Center for Environmental Risk Assessment (CERA) ; <http://cera-gmc.org/GmCropDatabaseEvent/MON810>

² EFSA, 2009. Scientific Opinion on the Applications for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified maize MON 810; (2) feed consisting of and/or containing maize MON 810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON 810, all under Regulation (EC) No 1829/2003 from Monsanto; <http://www.efsa.europa.eu/en/efsajournal/pub/1149.htm>

sustainable and economic manner. More specifically, the demand to have its whole territory excluded from cultivation of maize MON 810 illustrates Italy's political choice of denying farmers in several regions of the country (e.g. the Po Valley) access to a technology that presents important economical, human and animal health and environmental advantages as presented in numerous peer reviewed articles^{3, 4, 5}.

Directive (EU) 2015/412 requires that Member State measures should not affect the free circulation of authorized GMOs and should not prevent or restrict the use of MON 810 seeds in other Member States. Furthermore, we consider that it is Italy's responsibility to cooperate with neighbouring Member States that do allow MON 810 cultivation to agree on appropriate "coexistence measures" at the borders. Finally, restrictions on the cultivation of MON 810 varieties in the absence of legally established tolerance levels for adventitious presence in conventional seed might impact the commercialization of conventional maize varieties in the EU. Adventitious presence of GM seeds occurs naturally as a result of counter season seed multiplication of both conventional and GM seeds in countries which have adopted GM technologies. In the absence of EU-standardized rules on adventitious presence in seeds, further disruptions in the free movement of conventional maize seeds may be expected to result from individual Member State restrictions on the cultivation of MON 810 seeds. We therefore encourage the European Commission and Member States to develop appropriate solutions, such as the establishment of a definition of "technical zero" following the approach established for feeds⁶ or a threshold for the adventitious presence of MON 810 in conventional maize seed.

In view of the safety of MON 810 cultivation for humans, animals and the environment and considering the benefits experienced by European farmers who have cultivated MON 810 varieties (documented in independent, EU funded research⁷), we are disappointed with Italy's arbitrary political decision to prohibit the cultivation of MON 810 on its territory. Such decisions not only discourage investment in innovation and agriculture in the EU, they also deny European farmers' rights to choose safe, innovative products. We trust that the European Commission and Member states will take the necessary steps to avoid disruptions in the free movement of authorized GMOs and conventional maize seeds resulting from individual Member State restrictions on the cultivation of MON 810 seeds by establishing clear EU-standardized and/or national solutions for the adventitious presence of MON 810 in conventional maize seed.

Yours sincerely,

[REDACTED]
[REDACTED]
Monsanto Co.

cc. [REDACTED] (DG SANTE)

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³ Folcher et al., 2009. Biocontrol of *Ostrinia nubilalis* and *Sesamia nongrioides* by Bt maize in South Western France: search of biological indicators by a model-based approach for managing mycotoxin risks. IOBC/WPRS Bulletin. Vol. 45, 487-490.

⁴ Papst et al., 2005. Mycotoxins produced by *Fusarium* spp. in isogenic Bt vs. non Bt maize hybrids under European corn borer pressure. Agron. J. 97, 219-224.

⁵ Meissle et al., 2010. Pests, pesticide use and alternative options in European maize production: current status and future prospects. Journal of Applied Entomology. Vol. 134, 357-375.

⁶ Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired; <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0619>

⁷ https://ec.europa.eu/jrc/sites/default/files/jrc_080624_newsrelease_bt_maize_en.pdf

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