



direct +32 (0)2
Fax direct +32 (0)2
e-mail: @monsanto.com

Monsanto Europe S.A./N.V.
Avenue de Tervuren 270-272
Tervurenlaan 270-272
B – 1150 Brussels
Belgium

European Commission (DG SANTE)

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

Brussels, 30 October 2015

Subject: *Response to the letter of the European Commission communicating the demand of Germany to restrict the geographical scope of maize MON 810 (Ref. SANTE/E1/MK/as sante.ddg2.e.1(2015) 4509544)*

Dear ,

We formally received your letter dated 1 October 2015, communicating the demand from Germany under Article 26c of Directive 2001/18/EC to have its whole territory excluded from cultivation of maize MON 810, on 2 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 Germany's demand and the associated consequences. We request that you and the Federal Ministry of Food and Agriculture in Germany 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. Germany'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. While Germany in its letter refers to the necessity to maintain biodiversity, natural and landscape features or specific ecosystem functions and services to justify its demand, more than a decade of experience with MON 810 cultivation in the EU and globally demonstrates no confirmed adverse effects related to the event in these regards. This has been described in the EFSA scientific opinion² on the MON 810 renewal application, which states that "*The EFSA Panel agrees with the assessment that the likelihood of unintended environmental effects due to the establishment and spread of maize MON810 will be no different from that of conventional maize varieties*". We regret to conclude that Germany 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 Germany runs counter to a founding principle of the EU, the single market in goods and services which encourages investment. Regrettably, Germany's demand sends a negative signal to innovative industries wishing to invest in the

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>

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 sustainable and economic manner.

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 Germany'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 feeds³ or a threshold for the adventitious presence of MON 810 in conventional maize seed. It should be noted that any adventitious presence of GM seeds would not have negative effects on the cultivation of conventional or organic maize; and cultivation of MON 810, conventional and organic maize should not be considered as incompatible as appropriate coexistence measures can easily be implemented⁴. Control efforts and costs are therefore not expected to increase if MON 810 is cultivated in country.

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 research⁵), we are disappointed with Germany'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,

Monsanto Co.

cc. [REDACTED] (DG SANTE)
[REDACTED] (Monsanto)

³ 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>

⁴ Messéan A, Angevin F, Gomez-Barbero M, Menrad K, Rodriguez Cerezo E (2006) New case studies on the coexistence of GM and non-GM crops in European Agriculture. Technical Report Series of the Joint Research Center of the European Commission. Institute for prospective technological studies, Sevilla

⁵ https://ec.europa.eu/jrc/sites/default/files/jrc_080624_newsrelease_bt_maize_en.pdf

UPS Internet Shipping: Etiket bekijken/printen

- Zorg ervoor dat er geen andere verzend- of traceeretiquetten op uw pakket aanwezig zijn.** Kies de knop Afdrukken in het afdrukvenster dat verschijnt. Opmerking: Als uw browser deze functie niet ondersteunt, kunt u het etiket afdrukken met behulp van de optie Afdrukken in het menu Bestand.
- Vouw het afgedrukte etiket op de onderste volle lijn.** Plaats het etiket in een UPS Shipping pouch. Als u geen hoesje hebt, plakt u het gevouwen etiket met doorzichtig plakband over het gehele etiket.
- Afhalen en Afgeven:**
Klanten met dagelijkse afhaalservice: Zorg dat uw zendingen op de normale manier gereed liggen voor de chauffeur.
Om een afhaling te plannen of een UPS-locatie te vinden, selecteert u Afhaling plannen of Een locatie zoeken in de zijnavigatie van de tab Verzenden.

UPS Access Point™

LIBRAIRIE GEORGES HENRI
AVENUE GEORGES HENRI, 260
WOLUWE-SAINT-LAMBERT 1200

UPS Access Point™

FLEURISTE L'ART OSE
AVENUE PREKELINDEN, 81-83
WOLUWE SAINT LAMBERT 1200

UPS Access Point™

MAGASIN OPTIQUE BEOO
AVENUE DE L'ARMEE, 136
ETTERBEEK 1040

HIER VOUWEN

<p>PAK 1 OF 1</p> <p>SHP #: 0328 V3V3 JNT SHP WT: 0.5 KG SHP DWT: 0.5 KG DATE: 30 OCT 2015</p> <p>RECEPTION SERVICES (5TH FLOOR) TERVURENLAAN 270-270 1150 BRUSSEL</p> <p>SHIP TO:</p> <p>EUROPEAN COMMISSION - DG SANTÉ UNIT E1 BIOTECHNOLOGY AND PLANT HEALTH AVENUE DU BOURGET, 1 1140 EVERE</p>	<p>BEL 344 9-00</p> 	<p>UPS EXPRESS 1</p> <p>TRACKING #: 1Z 032 8V3 66 9604 3427</p>		<p>EDI</p> <p>BILLING: P/P</p> <p>Referentienr. 1:</p> <p>UIS 17.6.02 WNT100 69.0A 10/2015</p> 
---	--	--	--	---