



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, 27 October 2015

Subject: Response to the letter of the European Commission communicating the demand of Northern Ireland, Scotland and Wales (United Kingdom) to restrict the geographical scope of maize MON 810 (Ref. SANTE/E1/MK/as sante.ddg2.e.1(2015) 4489087)

Dear ,

We formally received your letter dated 30 September 2015, communicating the demand from Northern Ireland, Scotland and Wales (United Kingdom) under Article 26c of Directive 2001/18/EC to have their whole territory excluded from cultivation of maize MON 810, on 1 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 Northern Ireland, Scotland and Wales' demands and the associated consequences. We request that you, the United Kingdom and Northern Ireland, Scotland and Wales 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. Northern Ireland, Scotland and Wales' requests to prohibit MON 810 cultivation on their territory contradict and undermine the scientific consensus on the safety of MON 810 and its long history of safe use. We regret to conclude that Northern Ireland, Scotland and Wales are 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.

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>

Directive (EU) 2015/412 and thus the demands of Northern Ireland, Scotland and Wales run counter to a founding principle of the EU, the single market in goods and services which encourages investment. Regrettably, the Northern Ireland, Scotland and Wales' demands send 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 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 Northern Ireland, Scotland and Wales' 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.

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 research⁴), we are disappointed with Northern Ireland, Scotland and Wales' arbitrary political decisions to prohibit the cultivation of MON 810 on their 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 https://ec.europa.eu/jrc/sites/default/files/jrc_080624_newsrelease_bt_maize_en.pdf

Extremely Urgent
Très urgent

• The UPS EXPRESS ENVELOPE is to be used for document shipments only.
L'utiliser pour l'expédition de documents uniquement.
• Cash and negotiable items are prohibited.
Les envois d'espèces ou d'articles négociables ne sont pas autorisés.



Commercial Invoices/Shipping Documentation

Shippers crossing customs borders are required to have supporting documentation for customs clearance.
original and two copies of the invoice with:
and address details for you and your consignee
description and value of goods

0.0 KG ENV 1 OF 1	
RECEPTION SERVICES (5TH FLOOR) TERVURENLAAN 270-270 1150 BRUSSEL	SHP#: 0328 V3TS LHL SHP WT: 0.0 KG DATE: 27 OCT 2015
SHIP TO: EUROPEAN COMMISSION (DG SANTÉ) UNIT E1 BIOTECHNOLOGY AND PLANT HEALTH AVENUE DU BOURGET, 1 1140 EVERE	
	BEL 344 9-00 
UPS EXPRESS TRACKING #: 1Z 032 8V3 66 9482 5256	
	
BILLING: P/P	EDI
Referentienr. 1: 	
US 17.6.02. WNTIE100 69.0A 10/2015	

www.ups.com

2014/10/15