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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**renewing the authorisation for the placing on the market for cultivation of genetically
modified maize MON 810 (MON-ØØ81Ø-6) seeds**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 (MON-ØØ81Ø-6) seeds

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed¹, and in particular Article 23(3) thereof,

Whereas:

- (1) The placing on the market of genetically modified maize MON810 seeds for cultivation was initially authorised pursuant to Council Directive 90/220/EEC² by Commission Decision 98/294/EC³. On 3 August 1998, France granted consent to Monsanto Europe SA (hereinafter "Monsanto") for the placing on the market of MON 810 maize products.
- (2) In July 2004, Monsanto notified MON 810 maize seeds for cultivation as "existing products" pursuant to the transitional provisions set out in Article 20(1)(a) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council. As a consequence, they could continue to be placed on the market pursuant to the regime of "existing products" under Regulation (EC) No 1829/2003.
- (3) On 18 April 2007 Monsanto Europe S.A. submitted to the Commission an application in accordance with Article 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing genetically modified maize MON 810 seeds for cultivation.
- (4) The application also covered the renewal of the authorisation for the placing on the market of genetically modified maize MON810 for additional uses to that for cultivation that were also covered by the initial authorisation. On 9 March 2016 Monsanto Europe S.A. sent a letter to the Commission requesting that the part of the application concerning cultivation is considered separately from the rest of the application. Therefore, this Regulation covers only the renewal of the authorisation for cultivation.
- (5) The genetically modified event MON 810 expresses the Cry1Ab protein, which is a Bt protein (derived from *Bacillus thuringiensis subsp. Kurstaki*) conferring protection

¹ OJ L 268, 18.10.2003, p. 1.

² Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L 117, 8.5.1990, p. 15).

³ Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (OJ L 131, 5.5.1998, p. 32).

against predation by certain lepidopteran insect pests, including the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia spp.*).

- (6) On 30 June 2009 (updated 30 July 2009), the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Article 18 of Regulation (EC) No 1829/2003⁴. It concluded that genetically modified maize MON 810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. EFSA also concluded that maize MON 810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place.
- (7) In this opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 18(4) of Regulation (EC) No 1829/2003 and concluded that the information available for genetically modified maize MON 810 addressed the scientific comments raised by Member States.
- (8) On 8 December 2011, EFSA issued a statement supplementing its evaluation of the environmental risk assessment and risk management recommendations on genetically modified maize Bt11 for cultivation⁵, following a request from the Commission. In that Statement, EFSA indicated that the conclusions on the risk to non-target Lepidoptera from genetically modified maize Bt11 apply equally to genetically modified maize MON 810.
- (9) On 11 December 2012, EFSA issued an opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified maizes Bt11 and MON 810⁶ (hereafter the "supplementing opinion of 11 December 2012"), following a request from the Commission to provide additional evidence and to further clarify certain elements of the 2011 EFSA statement. EFSA reiterated that risk managers should choose risk mitigation and management measures that are proportionate to the level of identified risk.
- (10) On 11 December 2012, EFSA issued another opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified maize MON 810⁷ (hereafter "the updating opinion of 11 December 2012"), following a request from the Commission to gather its previously adopted conclusions on maize MON 810 for each area of risk and take into account recent relevant scientific

⁴ Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMORX-MON810) for the renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal (2009) 1149, 1-84.

⁵ EFSA Panel on Genetically Modified Organisms (GMO); Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation. EFSA Journal 2011;9(12):2478. [44 pp.] doi:10.2903/j.efsa.2011.2478.

⁶ EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect resistant maize Bt11 and MON 810. EFSA Journal 2012;10(12):3016. [32 pp.] doi:10.2903/j.efsa.2012.3016.

⁷ EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810. EFSA Journal 2012; 10(12):3017. [98 pp.] doi:10.2903/j.efsa.2012.3017.

publications. EFSA concluded that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations on risk mitigation measures and monitoring, remained valid and applicable.

- (11) Following the publication in October 2014 of a study by Hofmann *et al.* on maize pollen deposition in relation to the distance from the nearest pollen source under common cultivation⁸, EFSA issued an opinion⁹ on 1 July 2015 updating its risk management recommendations to limit exposure, by means of imposition of isolation distances, to Bt-maize pollen of non-target Lepidoptera of conservation concern in protected habitats as defined under Directive 2004/35/EC of the European Parliament and of the Council¹⁰.
- (12) EFSA assessed and issued opinions on the Post-Market Environmental Monitoring ('PMEM') reports on the cultivation of MON 810 for the 2009¹¹, 2010¹², 2011¹³, 2012¹⁴, 2013¹⁵,¹⁶ and 2014¹⁷ seasons. In all those opinions, EFSA concluded that the data submitted by the applicant do not indicate any adverse effects on human and animal health or the environment arising from the cultivation of genetically modified maize MON 810. EFSA identified shortcomings in the methodology and provided

⁸ Frieder Hofmann, Mathias Otto and Werner Wosniok, 2014. Maize pollen deposition in relation to distance from the nearest pollen source under common cultivation - results of 10 years of monitoring (2001 to 2010), *Environmental Sciences Europe* 2014, 26:24 doi:10.1186/s12302-014-0024-3 (<http://www.enveurope.com/content/26/1/24>)

⁹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to Bt-maize pollen. *EFSA Journal* 2015;13(7):4127, 31 pp. doi:10.2903/j.efsa.2015.4127.

¹⁰ Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L143, 30.4.2004, p. 56).

¹¹ EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON810 in 2009. *EFSA Journal* 2011;9(10):2376. [66 pp.] doi:10.2903/j.efsa.2011.2376.

¹² EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2010. *EFSA Journal* 2012;10(4):2610. [35 pp.] doi:10.2903/j.efsa.2012.2610.

¹³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2011. *EFSA Journal* 2013;11(12):3500, 38 pp. doi:10.2903/j.efsa.2013.3500.

¹⁴ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2012. *EFSA Journal* 2014;12(6):3704, 29 pp. doi:10.2903/j.efsa.2014.3704.

¹⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2013. *EFSA Journal* 2015;13(3):4039, 11 pp. doi:10.2903/j.efsa.2015.4039.

¹⁶ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific opinion on the revised annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2013 from Monsanto Europe S.A. *EFSA Journal* 2015;13(11):4295, 37 pp. doi:10.2903/j.efsa.2015.4295.

¹⁷ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014 from Monsanto Europe S.A. *EFSA Journal* 2016;14(4):4446, 26 pp. doi:10.2903/j.efsa.2016.4446.

specific recommendations for improvement of the strategy, methodology and reporting for the post-market environmental monitoring of genetically modified maize MON810.

- (13) A number of Member States have adopted national bans on the cultivation of genetically modified maize MON 810, based on safeguard clauses of Union legislation. EFSA issued opinions on the scientific arguments^{18, 19, 20, 21, 22, 23, 24} and in all cases EFSA concluded that there is no new scientific evidence that would invalidate the previous risk assessments of genetically modified maize MON 810.
- (14) Consequently, authorisation for the placing on the market of genetically modified maize MON 810 seeds for cultivation should be renewed.
- (15) In order to ensure that operators are adequately informed and to facilitate better management practices, the label, or, in the case of non-pre-packaged seeds, an accompanying document, should include the information that the maize MON 810 protects itself against the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia spp*).
- (16) A unique identifier has been assigned to maize MON 810 in accordance with Commission Regulation (EC) No 65/2004²⁵, in the context of the initial authorisation of maize MON 810. That unique identifier should continue to be used.
- (17) In its abovementioned opinions, EFSA recommended that cultivation is accompanied by appropriate risk management strategies to tackle the development of resistance of target lepidopteran pests and to minimize the exposure of non-target Lepidoptera to Bt proteins. Therefore, appropriate management measures should be put in place, such as the use of non-Bt border rows as refuge areas for the target lepidopteran pests that would also reduce exposure of non-target Lepidoptera to Bt maize pollen, and the

¹⁸ EFSA (European Food Safety Authority), 2014. Statement on a request from the European Commission related to the emergency measure notified by Bulgaria on genetically modified maize MON 810 according to Article 34 of Regulation (EC) 1829/2003. EFSA Journal 2014;12(12):3962, 9 pp., doi:10.2903/j.efsa.2014.3962.

¹⁹ European Food Safety Authority, 2014. Statement on a request from the European Commission related to the emergency measure notified by Greece on genetically modified maize MON 810 according to Article 18 of Directive 2002/53/EC. EFSA Journal 2014;12(6):3732, 7 pp., doi:10.2903/j.efsa.2014.3732.

²⁰ EFSA (European Food Safety Authority), 2014. Statement on a request from the European Commission related to an emergency measure notified by France under Article 34 of Regulation (EC) 1829/2003 to prohibit the cultivation of genetically modified maize MON 810. EFSA Journal 2014;12(8):3809, 18 pp., doi:10.2903/j.efsa.2014.3809.

²¹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. EFSA Journal 2013;11(9):3371, 7 pp. doi:10.2903/j.efsa.2013.3371

²² EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on a request from the European Commission related to the emergency measure notified by Luxembourg on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. EFSA Journal 2013;11(9):3372, 7 pp. doi:10.2903/j.efsa.2013.3372.

²³ Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC. The EFSA Journal (2008) 756, 1-18.

²⁴ Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC. The EFSA Journal (2008) 891, 1-64.

²⁵ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

imposition of isolation distances from protected habitats to limit exposure of non-target lepidopteran species of conservation concern to Bt maize pollen. Instructions should be provided to farmers as regards the implementation of such measures.

- (18) Refuge areas equivalent to at least 20% of the surface planted with maize MON 810 should be applied in fields greater than 5 hectares, as recommended by EFSA in its opinion of 30 June 2009. Furthermore, EFSA also recommended that, in the case of a cluster of fields with an aggregate area greater than 5 hectares of Bt-maize (any Bt maize, including maize MON810), there should be refuge areas equivalent to at least 20% of this aggregate area, irrespective of individual field and farm size. In its updating opinion of 25 October 2012²⁶ for maize 1507, EFSA recommended that in regions where maize expressing the Cry1F protein, such as maize 1507, and genetically modified maize expressing the Cry1Ab protein, such as maize MON 810, are cultivated together, refuge areas equivalent to at least 20% of the total surface planted with those two types of Bt maize are established due to the potential for cross-resistance between the Cry1Ab protein and the Cry1F protein.
- (19) EFSA further indicated in its opinion of 11 December 2012 that, if a maize MON 810 field has margins, then planting the refuge area as border rows along the field margins is considerably more effective at reducing expected mortality than a single block of non-Bt maize of comparable area, wherever the latter is planted. This method of planting refuge areas should therefore be used in fields which have margins.
- (20) In its opinion of 2011, EFSA concluded that non-target lepidopteran species of conservation concern with unknown sensitivity to the Cry1Ab protein occurring in protected habitats as defined in Directive 2004/35/EC require additional protection and recommended that maize MON 810 is not cultivated within 20 metres of the boundary of these habitats. In its opinion of 1 July 2015, EFSA re-evaluated the isolation distance by considering three factors: the exposure of non-target lepidopteran species of conservation concern to Bt maize pollen, the acceptable local mortality of those species and the sensitivity of those species to Bt proteins. For each of these factors, EFSA analysed different possible scenarios or levels. Therefore, it is necessary to determine, for each of the three factors considered, the most appropriate scenario or level, among those mentioned by EFSA, to be used as a basis for determining the most appropriate isolation distance between a maize MON 810 field and a protected habitat.
- (21) As regards exposure, EFSA considered three scenarios: the "Direct Comparison", the "Most realistic" and the "Conservative". EFSA considers the "Direct Comparison" scenario as unrealistic since it takes no account of the uncertainties associated with exposure. EFSA also emphasises that caution is required in the interpretation of the "Conservative" scenario, because for every site-occasion for which exposure is nine-fold higher than the expected value, which is the approach followed by the "Conservative" scenario, there will be a site-occasion for which exposure is nine-fold lower than expected, and that the overall average exposure remains as in the Most Realistic" scenario. Finally, the "Most Realistic" scenario takes into account the new information provided by the Hofmann et al. study as well as parameters affecting the exposure of protected non-target lepidopteran species to Bt-maize pollen. EFSA indicated that it gives the most realistic measure of exposure. That scenario also takes into account uncertainties. Therefore it is appropriate to follow that scenario.

²⁶ EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize 1507. EFSA Journal 2012; 10(10):2933. [46 pp.] doi:10.2903/j.efsa.2012.2933.

- (22) As regards local mortality, EFSA considered two levels of acceptable local mortality (0.5% and 1%). It is appropriate to choose the level of local mortality of below 0.5% since, below that level, mortality is considered negligible.
- (23) As regards sensitivity, EFSA also considered a range of lepidopteran species, including hypothetical ones that might exist but are not known to exist, with a wide spectrum of sensitivities to Bt proteins. *Plutella xylostella* is the most sensitive lepidopteran species known. However, other species more sensitive to the Cry1Ab protein might exist, even though they are not known. Therefore, it is appropriate to apply a margin of precaution by determining the isolation distances on the basis of a higher level of sensitivity than that of *Plutella xylostella*. The protection of hypothetical species with a level of sensitivity that is up to 5-fold higher than that of *Plutella xylostella* provides a sufficient margin of precaution.
- (24) Based on the abovementioned determinations concerning each of the three factors considered by EFSA, and their combination in accordance with the data provided in the opinion of EFSA of 1 July 2015, it is appropriate to apply an isolation distance of at least 5 metres between MON 810 maize fields and protected habitats.
- (25) For the purpose of best possible handling and use of maize MON 810 seeds, a leaflet detailing information about these seeds and practices for their use should be distributed to operators.
- (26) In addition to the general surveillance for unanticipated adverse effects, the authorisation holder should undertake case-specific monitoring to address resistance evolution to the Cry1Ab protein in lepidopteran target pests.
- (27) Besides the authorisation holder, other companies may lawfully develop and place maize MON 810 on the market. In order to ensure the same level of protection of human and animal health and of the environment in the entire Union, certain obligations of the authorisation holder that are important for the appropriate implementation of the risk management measures and of the monitoring requirements should be extended to those other companies, which operate at the same level in the distribution chain as the authorisation holder, with the appropriate adaptations. Companies acting as mere intermediaries in the distribution of the seeds should not be concerned by those obligations.
- (28) A single annual monitoring report should be submitted to the Commission, in order to provide an integrated and complete analysis of the results of monitoring activities in the entire Union carried out by all companies. That analysis should be carried out by a third party to ensure the protection of confidential information of all companies. The costs arising from the use of that third party should be shared among the authorisation holder and the other companies concerned.
- (29) Commission Implementing Decision (EU) 2016/321 of 5 March 2016²⁷ adjusted the geographical scope of the authorisation for cultivation of maize MON 810 on the basis of the demands communicated by a number of Member States pursuant to Article 26c(2) of Directive 2001/18/EC of the European Parliament and of the Council²⁸. The

²⁷ Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (*Zea mays* L.) MON 810 (MON-ØØ81Ø-6) (OJ L 60, 5.3.2016, p. 90).

²⁸ 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, p. 1), as last amended by Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards

same Member States communicated the same demands for the adjustment of the geographical scope of the renewal of that authorisation before 3 October 2015. The Commission presented those demands to the applicant. The applicant did not object within the thirty-day period provided by Article 26c(2) of Directive 2001/18/EC and thereby did not confirm the geographical scope of its renewal application. In accordance with Article 26c(2) of that Directive, the geographical scope of this authorisation should therefore be adjusted in accordance with the demands of the Member States concerned.

- (30) All relevant information on the authorisation of the product should be entered in the Community register of genetically modified food and feed, in accordance with Regulation (EC) No 1829/2003.
- (31) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Genetically modified organism and unique identifier

Genetically modified maize MON 810 seeds for cultivation, as specified in point 2 of the Annex to this Regulation, are assigned the unique identifier MON-ØØ81Ø-6, in accordance with Regulation (EC) No 65/2004.

Article 2
Renewal of authorisation

The authorisation for the placing on the market of maize MON810 seeds for cultivation is renewed in accordance with the conditions set out in this Regulation.

Article 3
Labelling

Maize MON 810 seeds may be placed on the market for cultivation subject to the labelling requirements set out in point 3 of the Annex.

Article 4
Method of detection

The method set out in point 4 of the Annex shall apply for the detection of maize MON810.

Article 5
Conditions or restrictions on the placing on the market, use or handling of the products

- 1. Maize MON 810 seeds may be placed on the market for cultivation subject to the conditions and restrictions for placing on the market, use or handling set out in point 6 of the Annex.

the possibility for the Member states to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.3.2015, p. 1).

2. Companies breeding or producing maize MON 810 and marketing it shall provide instructions and advice to farmers concerning the implementation of the risk management measures referred to in point 6.2 of the Annex.
3. Companies breeding or producing maize MON 810 and marketing it shall provide to other operators a leaflet containing information set out in point 8 of the Annex about the product and practices for its use.

That leaflet shall accompany each bag of maize MON 810 seeds, or it shall be attached to the accompanying document for non-pre-packaged products, at every stage of their commercialisation.

Article 6

Monitoring of environmental effects

1. Companies breeding or producing maize MON 810 and marketing it shall ensure that the monitoring plan for environmental effects, as set out in point 7 of the Annex, is put in place and implemented.

It shall include, in addition to general surveillance for unanticipated adverse effects, case-specific monitoring to address resistance evolution to the Cry1Ab protein in lepidopteran target pests.

2. The authorisation holder shall submit to the Commission an annual report on the implementation and the results of the activities set out in the monitoring plan, in accordance with the format set out in Commission Decision 2009/770/EC²⁹.

That report shall consolidate the results of the monitoring activities of the companies referred to in paragraph 1. For that purpose, the authorisation holder and the other companies referred to in paragraph 1 shall submit the results of their monitoring activities to an independent third party, designated by the authorisation holder to prepare the annual report.

The costs of the recourse to that third party shall be equitably shared between the authorisation holder and the other companies concerned. The third party shall ensure the protection of confidential business information it receives from the companies concerned.

Article 7

Community register

The information set out in the Annex to this Regulation shall be entered in the Community register of genetically modified food and feed, referred to in Article 28 of Regulation (EC) 1829/2003.

Article 8

Authorisation holder

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

²⁹ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

Article 9
Entry into force and validity

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union and shall apply during 10 years as from that date.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission