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COMMISSION IMPLEMENTING DECISION

of XXX

concerning the placing on the market for cultivation of genetically modified maize Bt11 (SYN-BTØ11-1) seeds

(Text with EEA relevance)

(Only the French text is authentic)

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THE EUROPEAN COMMISSION,

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

Having regard to 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[1], and in particular Article 18(1) thereof,

Whereas:

(1) Pursuant to Directive 2001/18/EC the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product, in accordance with the procedure laid down in that Directive.

(2) A notification (Reference C/F/96/05.10) concerning the placing on the market of genetically modified maize Bt11, was submitted in 1996 by Syngenta Seeds SAS (formerly Novartis Seeds) (hereinafter 'the notifier') to the competent authority of France pursuant to Council Directive 90/220/EEC[2]. An updated notification was submitted in 2003 pursuant to Directive 2001/18/EC.

(3) The genetically modified event maize Bt11 expresses the Cry1Ab protein, which is a Bt protein (derived from *Bacillus thuringiensis subsp. Kurstaki*) conferring resistance to the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn borer (*Sesamia nonagrioides*), and the Pat protein, which confers tolerance to the herbicide glufosinate-ammonium.

(4) The notification covers the placing on the market of seeds of varieties derived from maize Bt11 for cultivation in the Union. The notification initially also covered uses of maize Bt11 other than for cultivation. However, those uses were considered separately and are currently approved pursuant to Regulation (EC) No 1829/2003 of the

[1] OJ L 106, 17.4.2001, 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).

European Parliament and of the Council[3] in accordance with Commission Decision 2010/419/EU[4].

(5) Pursuant to Article 14 of Directive 2001/18/EC, the competent authority of France prepared an assessment report, in which it concluded that according to knowledge at the time, the placing on the market of maize Bt11 did not present a greater risk to human health or the environment than any other variety of maize. That conclusion was confirmed in the assessment of the updated version of the notification.

(6) In July of 2003, the assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised and maintained objections to the placing on the market of the product.

(7) On 19 May 2005, the European Food Safety Authority ('EFSA') issued an opinion[5] in which it concluded that the information available for Bt11 maize addresses the outstanding questions raised by the Member States and that there is no evidence indicating that placing on the market of maize Bt11 is likely to cause adverse effects on human or animal health or the environment in the context of its proposed use and subject to appropriate risk management measures.

(8) The Commission held a technical meeting with the national competent authorities on 19 June 2006, to address the remaining objections of Member States after the EFSA opinion. Certain Member States raised their concerns relating to the risk assessment of the product and requested a better explanation of the potential effects of Bt protein on non-target organisms and their monitoring.

(9) The Commission subsequently requested EFSA to complement its opinion on maize Bt11 by providing more specific information concerning the lepidopteran species referred to in the EFSA opinion of 19 May 2005. EFSA was also asked whether more precise risk management measures, notably monitoring plans, including specific scientific research studies on non-target organisms and taking account of geographical regions, should be implemented. On 19 November 2006, EFSA published an Annex complementing its opinion on non-target organisms[6] in which it re-affirmed its former conclusions with respect to the potential impact of Bt protein on non-target organisms, stating that maize Bt11 is unlikely to have adverse effects on human and animal health or the environment in the context of its proposed uses.

(10) Subsequently eleven scientific studies came to the attention of the Commission which requested EFSA to review those studies, as well as any other relevant study, and either

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3 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, p. 1).

4 Commission Decision 2010/419/EU of 28 July 2010 renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC (OJ L 197, 29.7.2010, p. 11).

5 Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507, for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, The EFSA Journal (2005) 181, 1-33.

6 Annex to the Opinions of the Scientific Panel on Genetically Modified Organisms on the insect resistant genetically modified Bt11 and 1507 maize: Clarifications of the Scientific Panel on Genetically Modified Organisms following a request from the Commission related to the opinions on insect resistant genetically modified Bt111 (Reference C/F/96/05.10) and 15072 (Reference C/ES/01/01) maize.

to confirm its risk assessment of maize Bt11 or comment on whether those studies would lead EFSA to alter its conclusions. On 31 October 2008, EFSA issued an opinion[7], in which it concluded that the publications did not provide new information that would change previous risk assessments conducted on maize Bt11. Having also considered other recent scientific publications, EFSA reaffirmed its previous conclusions on the environmental safety of maize Bt11.

(11) In 2009, in the context of the risk assessment of the renewal application of MON 810 maize, EFSA developed and used a new mathematical model that simulates and assesses potential adverse effects resulting from exposure of non-target lepidopteran species to GM maize pollen under representative cultivation conditions. To ensure an up-to-date environmental risk assessment for maize Bt11, as well as consistency of the environmental safety evaluation among Lepidoptera-resistant maize events (such as maize events 1507, MON 810 and Bt11), the Commission requested EFSA to further analyse the environmental risk assessment of maize Bt11 and to clarify its recommendations to risk managers. In addition, the Commission requested EFSA to reconsider the plan for post-market environmental monitoring (PMEM) of maize Bt11 in light of its 2011 Scientific Opinion providing guidance on PMEM of genetically modified plants[8]. EFSA issued a Statement on 8 December 2011 supplementing its evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation[9] and concluded that, subject to appropriate management measures, maize Bt11 cultivation, in comparison with conventional maize, is unlikely to raise additional safety concerns for the environment.

(12) On 11 December 2012, EFSA issued an opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of genetically modified insect resistant maize Bt11 and MON 810[10], following a request from the Commission to provide additional evidence and to further clarify certain elements of the 2011 EFSA Statement. In that opinion, EFSA provided background scientific information on non-target lepidopteran species.

(13) 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 cultivation[11], EFSA issued an opinion[12] on 1 July 2015, updating its risk

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7 Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507. The EFSA Journal (2008), 851, 1-27.

8 EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316. [40 pp.] doi:10.2903/j.efsa.2011.2316.

9 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.

10 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.

11 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).

12 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion updating risk management recommendations to limit exposure of non-target Lepidoptera of

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 Council[13].

(14) In the light of the abovementioned EFSA opinions, in which the environmental risk assessment has been continuously updated taking into account new scientific developments, there is no evidence that would indicate that the placing on the market of maize Bt11 for cultivation is likely to cause adverse effects on human and animal health or the environment in the context of its proposed use and subject to appropriate management measures.

(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 maize Bt11 protects itself against the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn borer (*Sesamia nonagrioides*).

(16) According to the notifier, the pat gene for glufosinate amonium tolerance was introduced to be used as a marker gene during the development phase of maize Bt11 and not to market maize Bt11 in the Union as a genetically modified organism to be cultivated in association with the use of glufosinate ammonium. In this context, it should be recalled that the conditions of approval of the active substance glufosinate have been restricted to uses as herbicide for band or spot application by Commission Implementing Regulation (EU) No 365/2013[14] amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate ammonium. Therefore broadcast applications of plant protection products containing glufosinate ammonium on maize fields cannot be authorised by the Member States. In order to ensure that those requirements are known and respected by farmers, it is appropriate to provide that the labelling of maize Bt11 includes the information that plant protection products containing glufosinate amonium cannot be used on maize Bt11 during its cultivation.

(17) A unique identifier has been assigned to maize Bt11, in accordance with Commission Regulation (EC) No 65/2004[15], when authorising uses of maize Bt11 other than for cultivation. That unique identifier should also be used for maize Bt11 for cultivation.

(18) A detection method for maize Bt11 has been validated by the European Union Reference Laboratory, in accordance with Commission Regulation (EC) No 641/2004[16], as regards uses of maize Bt11 other than for cultivation, and the relevant certified reference materials are available. That detection method should also be used for maize Bt11 for cultivation.

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conservation concern in protected habitats to Bt-maize pollen. EFSA Journal 2015;13(7):4127, 31 pp. doi:10.2903/j.efsa.2015.4127.

13 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 L 143, 30.4.2004, p. 56).

14 OJ L 111, 23.4.2013, p. 27.

15 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).

16 Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 (OJ L 102, 7.4.2004, p. 14).

(19) In the 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 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.

(20) Refuge areas equivalent to at least 20% of the surface planted with maize Bt11 should be applied in fields greater than 5 hectares, as recommended by EFSA in the Statement of 8 December 2011. Furthermore, when applying the refuge areas, account should also be taken of further recommendations of EFSA. In particular, in case of a cluster of fields with an aggregate area greater than 5 hectares of Bt maize (any Bt maize, including maize Bt11) there should be refuge areas equivalent to at least 20% of this aggregate area, irrespective of individual field and farm size. In its opinion of 25 October 2012 for maize 1507[17], EFSA recommended that, in regions where genetically modified maize expressing the Cry1F protein such as maize 1507, and genetically modified maize expressing the Cry1Ab protein, such as maize Bt11, 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.

(21) EFSA further indicated in its opinion of 11 December 2012 that, if a maize Bt11 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.

(22) In its Statement of 8 December 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 Bt11 is not cultivated within 20 metres of the boundary of those 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 those 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 Bt11 field and a protected habitat.

(23) As regards exposure EFSA considered three scenarios: the "Direct Comparison", the "Most realistic" and the "Conservative". EFSA considers the "Direct Comparison" scenario 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

[17] 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.

"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.

(24) 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 below 0.5% since, below that level mortality is considered negligible.

(25) As regards sensitivity, EFSA 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. 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.

(26) 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 Bt11-maize fields and protected habitats.

(27) For the purpose of best possible handling and use of the maize Bt11 seeds, a leaflet detailing information about these seeds and practices for their use should be equally distributed across operators.

(28) In addition to the general surveillance for unanticipated adverse effects, case-specific monitoring should be undertaken to address resistance evolution to the Cry1Ab protein in lepidopteran target pests.

(29) Besides the consent holder other companies may lawfully develop and place maize Bt11 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 consent holder that are important for the appropriate implementation of the risk management measures and of the monitoring requirements should be extended to other companies, which operate at the same level in the distribution chain as the consent holder, with the appropriate adaptations. Companies acting as mere intermediaries in the distribution of the seeds should not be concerned by those obligations.

(30) A single annual monitoring report should be submitted to the Commission and the Competent Authorities of the Member States, 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 equitably among the consent holder and the companies concerned.

(31) Directive (EU) 2015/412 of the European Parliament and of the Council[18] introduced the possibility, for a Member State, to demand that the geographical scope of an application for cultivation be adjusted to the effect that all or part of the territory be excluded from cultivation. In the case of maize Bt11, such demands had to be presented from 2 April 2015 until 3 October 2015.

(32) Nineteen Member States demanded, pursuant to Article 26c(2) of Directive 2001/18/EC, the prohibition of cultivation of maize Bt11 in all or part of their territory. Those demands were received by the Commission before 3 October 2015: on 3 July 2015 from Latvia; on 27 July 2015 from Greece; on 15 September 2015 from France; on 17 September 2015 from Croatia; on 18 September 2015 from Austria; on 21 September 2015 from Hungary; on 23 September 2015 from the Netherlands and Belgium; on 24 September 2015 from Poland; on 25 September 2015 from Lithuania and from the United Kingdom; on 30 September 2015 from Cyprus, Germany and Bulgaria; on 1 October 2015 from Italy and Denmark; and on 2 October 2015 from Slovenia, Luxembourg and Malta.

(33) All the demands received by the Commission cover the whole territory of the Member States concerned, except for Belgium, which communicated a demand covering only the territory of Wallonia, and for the United Kingdom, which communicated a demand covering only the territories of Northern Ireland, Scotland and Wales. The demand of Germany does not cover cultivation for research purposes.

(34) The Commission presented the demands of the Member States concerned to the notifiers. The notifiers 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 their notification as far as cultivation of maize Bt11 is concerned. In accordance with Article 26c(2) of that Directive, the geographical scope of the authorisation granted to maize Bt11 seeds for cultivation should therefore be adjusted in accordance with the demands of the Member States concerned.

(35) In accordance with Article 15(4), second subparagraph, of Directive 2001/18/EC, the written consent should expire ten years after the date of first inclusion of a maize variety derived from maize Bt11 in an official national catalogue of plant varieties in accordance with Council Directive 2002/53/EC[19]. The Commission should make that date publicly available on the basis of the information it receives from Member States concerning the registration of plant varieties in accordance with Council Directive 2002/53/EC.

(36) A draft decision authorising maize Bt11 seeds for cultivation has already been discussed in February 2009 at the Committee established under Article 30(1) of Directive 2001/18/EC. The Committee did not deliver an opinion. In the meantime, EFSA issued opinions on 8 December 2011, 11 December 2012 and 1 July 2015, which are relevant to maize Bt11 and are based on new and substantial scientific elements. Moreover, the geographical scope needs to be adjusted in accordance with Directive (EU) 2015/412. Given the importance of the latest developments, which entail substantial modifications in the draft Decision, and in the light of the case-law

[18] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.3.2015, p. 1).

[19] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

of the Court of Justice of the European Union on comitology procedures[20], a revised draft Decision was submitted to the Committee established under Article 30(1) of Directive 2001/18/EC.

(37) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30(1) of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

Article 1
Consent

1. Without prejudice to Directive 2002/53/EC, written consent shall be granted by the competent authority of France to the placing on the market for cultivation of the products referred to in Article 2, as notified by Syngenta Seeds S.A.S., Saint Sauveur, France (reference C/F/96/05.10).

2. The consent shall explicitly specify the conditions set out or referred to in Articles 3 to7 of this Decision.

Article 2
Products

The following genetically modified organisms ("maize Bt11") may be placed on the market for cultivation:

a) seeds of maize Bt11;

b) seeds from genetically modified progeny derived from crosses of maize Bt11 with conventional maize.

Article 3
Labelling

1. For the purposes of the labelling requirements laid down in Article 4(6) of Regulation No 1830/2003 the name of the organism shall be 'maize Bt11'.

2. The label of each bag of maize Bt11, or, for non-pre-packaged products, the accompanying document, shall contain an indication that maize Bt11 protects itself against the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn borer (*Sesamia nonagrioides*).

3. The label of each bag of maize Bt11, or, for non-pre-packaged products, the accompanying document, shall contain an indication that plant protection products containing glufosinate-ammonium cannot be used on maize Bt11 during cultivation.

Article 4
Identification and detection

1. Maize Bt11 shall be assigned the unique identifier SYN-BTØ11-1.

2. The method set out in point 1 of the Annex shall apply for the detection of maize Bt11.

[20] In particular Case T-240/10, Hungary v Commission.

Article 5

Conditions for placing on the market, use or handling of the product

1. Maize Bt11 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 2 of the Annex.

2. Companies breeding or producing maize Bt11 and marketing it shall provide instructions and advice to farmers concerning the implementation of risk management measures referred to in point 2.2 of the Annex.

3. Companies breeding or producing maize Bt11 and marketing it shall provide to other operators a leaflet containing the information set out in point 3 of the Annex about the product and practices for its use.

   The leaflet shall accompany each bag of maize Bt11 seeds or it shall be attached to the accompanying document for non-prepackaged products at every stage of their commercialisation.

Article 6

Monitoring of environmental effects

1. Companies breeding or producing maize Bt11 and marketing it shall ensure that the monitoring plan for environmental effects referred to in point 4 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 consent holder shall submit to the Commission and to the Competent Authorities of the Member States 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/EC[21].

   The report shall consolidate the results of the monitoring activities of the companies referred to in paragraph 1. For that purpose, the consent 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 consent holder to prepare the annual report.

   The costs of the recourse to that third party shall be equitably shared between the consent 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

Validity

1. The consent shall be valid from the date on which it is granted and shall expire 10 years after the date of the first inclusion of the first plant variety derived from maize

[21] 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).

Bt11 in an official national catalogue of plant varieties in accordance with Council Directive 2002/53/EC.

2. The Commission shall make the date of the first inclusion of the first plant variety derived from maize Bt11 in an official national catalogue of plant varieties publicly available.

Article 8
Addressee

This Decision is addressed to the French Republic.

Done at Brussels,

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission