



Brussels, **XXX**  
SANTE/10704/2016 CIS Rev. 3  
(POOL/E3/2016/10704/10704R3-EN  
CIS.doc)  
[...] (2016) **XXX** draft

**COMMISSION IMPLEMENTING DECISION**

**of XXX**

**concerning the placing on the market for cultivation of genetically modified maize 1507  
(DAS-Ø15Ø7-1) seeds**

(Text with EEA relevance)

(Only the Spanish text is authentic)

## COMMISSION IMPLEMENTING DECISION

of **XXX**

**concerning the placing on the market for cultivation of genetically modified maize 1507 (DAS-Ø15Ø7-1) seeds**

(Text with EEA relevance)

(Only the Spanish text is authentic)

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<sup>1</sup>, 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/ES/01/01) concerning the placing on the market of genetically modified maize 1507 was submitted in 2001 by Pioneer Overseas Corporation and Dow AgroSciences Europe Ltd (hereinafter 'the notifiers') to the competent authority of Spain pursuant to Council Directive 90/220/EEC<sup>2</sup>. An updated notification was submitted in 2003 pursuant to Directive 2001/18/EC.
- (3) The genetically modified event maize 1507 expresses the Cry1F protein, which is a Bt protein (derived from *Bacillus thuringiensis subsp. Kurstaki*) conferring resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests such as the pink borer (*Sesamia spp.*), fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and south-western corn borer (*Diatraea grandiosella*), 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 1507 for cultivation in the Union. Maize 1507 is approved for feed use under Directive 2001/18/EC in accordance with Commission Decision 2005/772/EC<sup>3</sup> and for

---

<sup>1</sup> OJ L 106, 17.4.2001, p. 1.

<sup>2</sup> 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).

<sup>3</sup> Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (OJ L 291, 5.11.2005, p. 42).

food use under Regulation (EC) No 1829/2003 of the European Parliament and of the Council<sup>4</sup> in accordance with Commission Decision 2006/197/EC<sup>5</sup>.

- (5) Pursuant to Article 14 of Directive 2001/18/EC, the competent authority of Spain prepared an assessment report, in which it concluded that, for the considered uses, according to knowledge at the time, there was no scientific evidence to indicate that the placing on the market of maize 1507 poses any risk to human and animal health or the environment.
- (6) The assessment report was submitted to the Commission in August 2003 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 3 March 2005 the European Food Safety Authority ('EFSA') issued an opinion<sup>6</sup> in which it concluded that the information available for 1507 maize addresses the outstanding questions raised by Member States and that there is no evidence indicating that placing of maize 1507 on the market 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 convened 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 the Bt protein on non-target organisms and their monitoring.
- (9) The Commission subsequently requested EFSA to complement its opinion on maize 1507 by providing more specific information concerning the lepidopteran species referred to in the EFSA opinion of 3 March 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<sup>7</sup> in which it re-affirmed its former conclusions with respect to the potential impact of the Bt protein on non-target organisms, stating that maize 1507 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 to confirm its risk assessment of maize 1507 or comment on whether those studies

---

<sup>4</sup> 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).

<sup>5</sup> Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 70, 9.3.2006, p. 82).

<sup>6</sup> 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.

<sup>7</sup> 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.

would lead EFSA to alter its conclusions. On 31 October 2008 EFSA issued opinion<sup>8</sup>, in which it concluded that the publications did not provide new information that would change previous risk assessments conducted on maize 1507. Having also considered other recent scientific publications, EFSA reaffirmed its previous conclusions on the environmental safety of maize 1507.

- (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 1507, 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 consider whether those recent advances in methodology might require a revision of the conclusions of its previous opinions on maize 1507. Consequently, EFSA issued an opinion<sup>9</sup> on 18 November 2011 (updated on 24 February 2012) which updates both the environmental risk assessment and the risk management recommendations on insect resistant genetically modified maize 1507 for cultivation. EFSA concluded that, subject to appropriate management measures, maize 1507 cultivation, in comparison with conventional maize, is unlikely to raise safety concerns for the environment. EFSA supplemented<sup>10</sup> this opinion on 6 November 2012, by providing additional evidence and further clarifications with regard to the potential exposure of non-target Lepidoptera to maize 1507 and the factors affecting the development of resistance.
- (12) In order to have all necessary and up-to-date elements related to cultivation of maize 1507 in a single opinion, the Commission requested EFSA to gather their previously adopted conclusions on each area of risk and to take into account recent relevant scientific publications. EFSA issued an opinion<sup>11</sup> on 25 October 2012 (updated on 9 November 2012) in which it did not identify new scientific publications reporting new information that would invalidate its previous conclusions on the safety of maize 1507. That opinion has also integrated the findings of the opinion of 6 November 2012, as those two opinions were prepared in parallel.
- (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<sup>12</sup>, EFSA issued an opinion<sup>13</sup> on 1 July 2015 updating its risk

---

<sup>8</sup> 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.

<sup>9</sup> EFSA Panel on Genetically Modified Organisms (GMOs); Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation. EFSA Journal 2011;9(11):2429. [73 pp.] doi:10.2903/j.efsa.2011.2429.

<sup>10</sup> EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations on the genetically modified insect resistant maize 1507 for cultivation. EFSA Journal 2012;10(11):2934. [36 pp.] doi:10.2903/j.efsa.2012.2934.

<sup>11</sup> 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.

<sup>12</sup> 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>).

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<sup>14</sup>.

- (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 1507 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 the maize 1507 protects itself against the European corn borer (*Ostrinia nubilalis*), pink borers (*Sesamia spp.*), fall armyworms (*Spodoptera frugiperda*), black cutworms (*Agrotis ipsilon*) and south-western corn borers (*Diatraea grandiosella*).
- (16) According to the notifiers, in spite of the presence of the pat gene for glufosinate ammonium tolerance, maize 1507 is not intended to be cultivated in the Union 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<sup>15</sup> amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate. 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 1507 includes the information that plant protection products containing glufosinate ammonium cannot be used on maize 1507 during its cultivation
- (17) A unique identifier has been assigned to maize 1507, in accordance with Commission Regulation (EC) No 65/2004<sup>16</sup>, when authorising uses of maize 1507 other than for cultivation. That unique identifier should also be used for maize 1507 for cultivation.
- (18) A detection method for maize 1507 has been validated by the European Union Reference Laboratory, in accordance with Commission Regulation (EC) No 641/2004<sup>17</sup>, as regards uses of maize 1507 other than for cultivation, and the relevant certified reference materials are available. That detection method should also be used for maize 1507 for cultivation.

---

<sup>13</sup> 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.

<sup>14</sup> 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).

<sup>15</sup> OJ L 111, 23.4.2013, p. 27.

<sup>16</sup> 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).

<sup>17</sup> 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 should be 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 refugia 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 1507 should be applied in fields greater than 5 hectares, as recommended by EFSA in its opinion of 18 November 2011. Furthermore, when applying the refuge areas account should also be taken of further recommendations of EFSA from its opinions of 2011 and 2012. In particular, EFSA advised in its opinion of 18 November 2011 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 1507) 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, 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 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 supplementing opinion of 6 November 2012 that, if a maize 1507 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 opinion of 18 November 2011, EFSA concluded that non-target lepidopteran species of conservation concern with unknown sensitivity to the Cry1F protein occurring in protected habitats as defined in Directive 2004/35/EC require additional protection and recommended that maize 1507 is not cultivated within 30 metres of the boundary of those habitats. In its opinion of 1 July 2015, EFSA re-evaluated this 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 1507 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 "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 Cry1F 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.
- (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 20 metres between 1507-maize fields and protected habitats.
- (27) For the purpose of best possible handling and use of the maize 1507 seeds, a leaflet detailing information about these seeds and practices for their use should be distributed equally across operators.
- (28) In addition to the general surveillance for unanticipated adverse effects, case-specific monitoring should be undertaken to address, on the one hand, resistance evolution to the Cry1F protein in lepidopteran target pests, and, on the other hand, the risk of exposure of sensitive non-target Lepidoptera to maize 1507 pollen.
- (29) Besides the consent holders, other companies may lawfully develop and place maize 1507 seeds 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 holders 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 holders, with the appropriate adaptations. Companies acting as mere intermediaries in the distribution of the seeds should not be concerned by these 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 holders and the other companies concerned.

- (31) Directive (EU) 2015/412 of the European Parliament and of the Council<sup>18</sup> 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 1507, such demands had to be presented from 2 April 2015 until 3 October 2015.
- (32) Nineteen Member States demanded, pursuant to Article 26c of Directive 2001/18/EC, the prohibition of cultivation of maize 1507 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 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 1507 is concerned. In accordance with Article 26c(2) of that Directive, the geographical scope of the authorisation granted to maize 1507 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<sup>19</sup>. 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 1507 seeds for cultivation has already been discussed in February 2009 at the Committee established under Article 30(1) of Directive 2001/18/EC, and at the Council in February 2014. Neither the Committee nor the Council delivered an opinion. In the meantime, EFSA issued a new opinion on 1 July 2015 which was relevant to maize 1507 and was based on new and substantial scientific elements provided by Hofmann *et al.* in 2014. Moreover, the geographical scope needs to be adjusted in accordance with Directive (EU) 2015/412. Given the importance of these latest developments and their potential impact on the voting positions of the Member States, and in the light of the case-law of the Court of Justice

---

<sup>18</sup> 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).

<sup>19</sup> 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 European Union on comitology procedures<sup>20</sup>, 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 Spain to the placing on the market for cultivation of the products referred to in Article 2, as notified by Pioneer Overseas Corporation, Brussels, Belgium and Dow AgroSciences Europe Ltd., Abingdon, United Kingdom (reference C/ES/01/01).
2. The consent shall explicitly specify the conditions set out or referred to in Articles 3 to 7 of this Decision.

*Article 2*  
*Products*

The following genetically modified organisms ("maize 1507") may be placed on the market for cultivation:

- a) seeds of maize 1507;
- b) seeds from genetically modified progeny derived from crosses of maize 1507 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 1507'.
2. The label of each bag of maize 1507 seeds, or, for non-pre-packaged products, the accompanying document, shall contain an indication that the product protects itself against the European corn borer (*Ostrinia nubilalis*), pink borers (*Sesamia spp.*), fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and south-western corn borer (*Diatraea grandiosella*).
3. The label of each bag of maize 1507, 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 1507 during cultivation.

*Article 4*  
*Identification and detection*

1. Maize 1507 shall be assigned the unique identifier DAS-Ø15Ø7-1.
2. The method set out in point 1 of the Annex shall apply for the detection of maize 1507.

---

<sup>20</sup> 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 1507 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 1507 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 1507 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 1507 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 1507 and marketing it shall ensure that the monitoring plan for environmental effects, referred to in point 3 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, on the one hand, resistance evolution to the Cry1F protein in lepidopteran target pests, and, on the other hand, the risk to sensitive non-target Lepidoptera of maize 1507 pollen.

2. The consent holders 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<sup>21</sup>.

That report shall consolidate the results of the monitoring activities of the companies referred to in paragraph 1. For that purpose, the consent holders 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 holders 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 of the consent*

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

---

<sup>21</sup> 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).

maize 1507 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 1507 in an official national catalogue of plant varieties publicly available.

*Article 8*  
*Addressee*

This Decision is addressed to the Kingdom of Spain.

Done at Brussels,

*For the Commission*  
*Vytenis ANDRIUKAITIS*  
*Member of the Commission*