



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 12 November 2013
(OR. es)**

16120/13

**Interinstitutional File:
2013/0368 (NLE)**

**AGRILEG 151
ENV 1062**

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	12 November 2013
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	COM(2013) 758 final
Subject:	Proposal for a COUNCIL DECISION concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (<i>Zea mays</i> L., line 1507) genetically modified for resistance to certain lepidopteran pests (Text with EEA relevance)

Delegations will find attached document COM(2013) 758 final.

Encl.: COM(2013) 758 final



Brussels, 6.11.2013
COM(2013) 758 final

2013/0368 (NLE)

Proposal for a

COUNCIL DECISION

concerning the placing on the market for cultivation, 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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Decision concerns the authorisation of genetically modified 1507 maize, for which a request for the placing on the market of seeds for cultivation was submitted by Pioneer Hi-Bred International, Inc. and Mycogen Seeds to the competent authority of Spain in 2001, under Directive 2001/18/EC on the deliberate release into the environment of GMOs.

In accordance with the procedure under Article 14 of Directive 2001/18/EC, the competent authority of Spain prepared an assessment report, which concluded that there is no scientific evidence to indicate that the placing on the market of the *Zea mays* L. line 1507 poses any risk to human and animal health or the environment for the requested uses.

The assessment report was submitted in August 2003 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.

The opinion of EFSA, adopted on 19 January 2005, concluded that *Zea mays* L. line 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use.

The Commission convened a technical meeting with national competent authorities on 19 June 2006, to address the remaining objections of Member States in view of the EFSA opinion and subsequently requested EFSA to complement its opinion on 1507 maize by providing more specific information concerning the lepidopteran species referred to in the EFSA opinion of 19 January 2005. EFSA was also asked to recommend whether more precise risk management measures, notably monitoring plans, should be implemented. EFSA adopted the annex complementing its opinion on non-target organisms on 7 November 2006 (published 21 November 2006). After the publication of the above annex, the Commission requested EFSA on 24 July 2008 to review eleven scientific studies, published after the adoption of the EFSA opinion of 19 January 2005, as well as any other relevant study, and to confirm its risk assessment of 1507 maize.

On 29 October 2008 EFSA adopted its opinion which concluded that these publications do not provide new information that would change previous risk assessments conducted on 1507 maize. Having also considered other recent scientific publications, EFSA reaffirmed its previous conclusions on the environmental safety of 1507 maize.

Against this background, a draft Commission Decision to place the product on the market, in accordance with Article 18 of Directive 2001/18/EC, was presented to the Regulatory Committee for vote on 25 February 2009. The Committee delivered no opinion: 6 Member States (91 votes) voted in favour, 12 Member States (127 votes) voted against, 7 Member States (95 votes) abstained and 2 Member States (32 votes) were not represented.

Following a request of the Commission on 14 June 2010 to consider whether new scientific elements might require a revision of the conclusions of its scientific opinion adopted on 19 January 2005, EFSA adopted on 19 October 2011 a Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation. The EFSA GMO Panel concludes that, subject to appropriate management measures, maize 1507 cultivation is unlikely to raise safety concerns for the environment. In addition, on 18 October 2012, EFSA

adopted a Scientific Opinion supplementing the 2011 opinion and providing with additional evidence and further clarifications.

Following a further request of the Commission on 20 June 2012 for a consolidated opinion, EFSA adopted on 18 October 2012 a Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize 1507. The GMO EFSA Panel did not identify new scientific publications reporting new information that would invalidate its previous conclusions on the safety of maize 1507.

On 26 September 2013, the General Court of the European Union delivered its Judgement on the case T-164/10, Pioneer Hi-Bred International v. European Commission, and declared that "the European Commission has failed to fulfil its obligations under Article 18 of 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 by failing to submit to the Council a proposal relating to the measures to be taken pursuant to Article 5(4) of Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission".

Consequently, pursuant to Article 30(2) of Directive 2001/18/EC and Article 5 of Council Decision 1999/468/EC, the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority, and inform the Parliament.

Proposal for a

COUNCIL DECISION

concerning the placing on the market for cultivation, 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

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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/EEC¹, and in particular the first subparagraph of Article 18(1) thereof,

Having regard to the proposal from the Commission,

After consulting the European Food Safety Authority (hereinafter, EFSA),

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 a genetically modified maize product (*Zea mays* L., line 1507, hereinafter also "1507 maize") was submitted in 2001 by Pioneer Hi-Bred International, Inc. and Mycogen Seeds to the competent authority of Spain.
- (3) The notification covers the placing on the market of seeds of varieties derived from the *Zea mays* L., line 1507 for cultivation in the Union. The scope of the notification, as confirmed by the consent-holder on 23 February 2007, does not cover the commercial use of the product as a plant tolerant to glufosinate in the Union, since the *pat* gene for glufosinate tolerance was only to be used as a marker gene. In addition, 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)

¹ OJ L 106, 17.4.2001, p. 1.

No 365/2013² amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate. Therefore broadcast applications on maize fields cannot be authorised.

- (4) In accordance with the procedure under Article 14 of Directive 2001/18/EC, the competent authority of Spain prepared an assessment report, which concluded that there is no scientific evidence to indicate that the placing on the market of the *Zea mays* L. line 1507 poses any risk to human and animal health or the environment for the requested uses.
- (5) The assessment report was submitted in August 2003 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.
- (6) The opinion of EFSA, adopted on 19 January 2005³, concluded that *Zea mays* L. line 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use.
- (7) The Commission convened a technical meeting with national competent authorities on 19 June 2006, to address the remaining objections of Member States in view of 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 toxin on non-target organisms and their monitoring.
- (8) The Commission subsequently requested EFSA to complement its opinion on *Zea mays* L. line 1507 by providing more specific information concerning the lepidopteran species referred to in the EFSA opinion of 19 January 2005; EFSA was also asked to recommend 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. EFSA adopted the annex complementing its opinion on non-target organisms on 7 November 2006 (published 21 November 2006). After the publication of the above annex, eleven scientific studies, published after the adoption of the EFSA opinion of 19 January 2005, came to the attention of the Commission. Therefore the Commission requested EFSA on 24 July 2008 to review these studies, as well as any other relevant study, and confirm its risk assessment of 1507 maize or comment on whether these studies would lead EFSA to alter its conclusions or refine them.
- (9) On 29 October 2008 EFSA adopted its opinion which concluded that these publications do 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.
- (10) Following a request of the Commission to consider whether new scientific elements might require a revision of its scientific opinion of 19 January 2005, EFSA adopted on 19 October 2011⁴ a Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically

² OJ L 111, 23.4.2013, p.27.

³ The EFSA Journal (2005) 181, 1-33.

⁴ The EFSA Journal (2011), 9(11):2429.

modified maize 1507 for cultivation. The EFSA GMO Panel concludes that, subject to appropriate management measures, maize 1507 cultivation is unlikely to raise safety concerns for the environment. In addition, on 18 October 2012, EFSA adopted a Scientific Opinion⁵ supplementing the 2011 opinion and providing with additional evidence and further clarifications.

- (11) Following a further request of the Commission for a consolidated opinion, EFSA adopted on 18 October 2012⁶ a Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize 1507. The GMO EFSA Panel did not identify new scientific publications reporting new information that would invalidate its previous conclusions on the safety of maize 1507.
- (12) An examination of each of the Member State objections in the light of (i) Directive 2001/18/EC, (ii) the information submitted in the notification and (iii) the opinions of EFSA, discloses no evidence to indicate that the placing on the market of *Zea mays* L. line 1507 is likely to cause adverse effects on human and animal health or the environment in the context of its proposed use.
- (13) *Zea mays* L., line 1507 has been approved for feed use under Directive 2001/18/EC in accordance with Commission Decision 2005/772/EC⁷ and for food use under Regulation (EC) No 1829/2003 in accordance with Commission Decision 2006/197/EC⁸.
- (14) A unique identifier has been assigned to the *Zea mays* L., line 1507 for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC⁹ and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms¹⁰.
- (15) Prior to the placing on the market of the *Zea mays* L., line 1507, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applied. A detection method for the *Zea mays* L., line 1507 has been validated by the European Union Reference Laboratory as referred to in the Annex of Regulation (EC) No 1829/2003, in accordance with Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003¹¹.
- (16) For the purpose of appropriate information for operators and consumers, and to facilitate better management practices, the label, or an accompanying document, should also indicate that the product protects itself against the European corn borer

⁵ The EFSA Journal (2012), 10(11):2934.

⁶ The EFSA Journal (2012), 10(10):2933.

⁷ OJ L 291, 5.11.2005, p. 42.

⁸ OJ L 70, 9.3.2006, p. 82.

⁹ OJ L 268, 18.10.2003, p. 24.

¹⁰ OJ L 10, 16.1.2004, p. 5.

¹¹ OJ L 102, 7.4.2004, p. 14.

(*Ostrinia nubilalis*), pink borers (*Sesamia* spp.), fall armyworms (*Spodoptera frugiperda*), black cutworms (*Agrotis ipsilon*) and south-western corn borers (*Diatraea grandiosella*).

- (17) As EFSA indicated in its opinion of 19 January 2005, "the only adverse effect identified was the possibility that resistance to Bt toxin might evolve in corn borers exposed to 1507 maize following cultivation for some years. The Panel accepts the monitoring plan developed by the applicant to monitor specifically for resistance in corn borers and recommends that cultivation should be accompanied by appropriate risk management strategies to minimise exposure of both target and non-target insects to Bt toxins". Therefore the consent holder should carry out monitoring and provide instruction to farmers in order to ensure the implementation by them of required measures, such as the planting of refuge maize and monitoring, to minimise development of resistance in target pests and to assist farmers in cultivating *Zea mays* L., line 1507.
- (18) In accordance with the EFSA Opinion of 19 January 2005, "(..) management recommendations for the cultivation of 1507-maize, as given by the applicant to users of 1507 maize, considers measures to reduce exposure of non-target lepidoptera (as well as the target pest), such as the use of non-transgenic border rows as refugia for the target that would also reduce exposure of field margin weeds (and hence non-target lepidoptera) to pollen from Bt maize".
- (19) The refugia strategy should take into account further recommendations of EFSA in its opinions of 19 October 2011 and 18 October 2012. In particular, EFSA advises in its opinion of 2011 that "In the case of a cluster of fields with an aggregate area greater than 5 ha of Bt-maize, there shall be refugia equivalent to 20% of this aggregate area, irrespective of individual field and farm size". In its updating opinion of 2012, EFSA recommends that "in regions where maize 1507 and Cry1Ab-expressing maize events would be cultivated together, refuge areas equivalent to 20% of the total Lepidoptera-active Bt-maize area are established due to the potential for cross-resistance between Cry1Ab and Cry1F". EFSA further recommends in its Supplementing opinion of 2012 that "If a maize 1507 field has margins, then sown strips of non-Bt-maize, placed between the edges of the Bt-maize crop and each margin, are considerably more effective as a mitigation measure at reducing expected mortality than a single block of non-Bt-maize of comparable area, wherever the latter is planted".
- (20) For the purpose of best possible handling and use of the product, the consent holder should distribute with each bag of seeds to the operators a leaflet detailing information about the product and practices for its use.
- (21) Monitoring should be conducted in accordance with Article 20(1) of Directive 2001/18/EC, the monitoring plan and revisions submitted by the notifier including commitments made in response to requests from competent authorities, and the opinions of EFSA.
- (22) It is appropriate to provide for post-marketing surveillance measures to address unanticipated effects of maize lines expressing Bt proteins on non-target organisms in particular.

- (23) As indicated in the notification, the consent holder should undertake a monitoring study of unanticipated potential adverse effects on non-target organisms from cultivation of 1507 maize and report the outcome of this study to the rapporteur competent authority and the European Commission; the consent holder should also report to the competent authorities of the other Member States.
- (24) The Committee established under Article 30(1) of Directive 2001/18/EC has not delivered an opinion within the time-limit laid down by its Chairman;

HAS ADOPTED THIS DECISION:

Article 1
Consent

1. Without prejudice to other Union legislation, in particular Directive 2002/53/EC, written consent shall be granted by the competent authority of Spain to the placing on the market for cultivation, in accordance with this Decision, of the product identified in Article 2, as notified (Reference C/ES/01/01) by Pioneer Hi-Bred International, Inc. and Mycogen Seeds.
2. The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas, which are set out in Articles 3 (conditions for placing on the market) and 4 (monitoring).

Article 2
Product

1. The genetically modified organisms to be placed on the market as or in products, hereinafter ‘the product’, are seeds of maize (*Zea mays* L., line 1507), with resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests and with tolerance to the herbicide glufosinate-ammonium, derived from *Zea mays* L., line 1507, which has been transformed using particle acceleration technology with the linear DNA fragment PHI8999A containing the following DNA in two expression cassettes:
 - (a) Cassette 1:

A synthetic version of the truncated *cry1F* gene derived from *Bacillus thuringiensis* subsp. *aizawai*, which confers 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*), under the regulation of the ubiquitin promoter *ubiZM1(2)* derived from *Zea mays* and the ORF25PolyA terminator from *Agrobacterium tumefaciens* pTi15995;
 - (b) Cassette 2:

A synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* strain Tü494, which confers tolerance to the herbicide glufosinate-ammonium, under the regulation of the CaMV 35S promoter and terminator sequences.

2. The consent shall cover seeds from genetically modified progeny derived from crosses of *Zea mays* L., line 1507 with any traditionally bred maize as or in products.

Article 3 *Conditions for placing on the market*

The product may be placed on the market subject to the following conditions:

- (a) In accordance with Article 15(4) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date at which the consent for *Zea mays* L., line 1507 is issued;
- (b) the unique identifier of the product shall be DAS-Ø15Ø7-1;
- (c) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall make available positive and negative control samples of the product and its genetic materials to the competent authorities of Member States as well as to the National Reference Laboratories in charge of official controls on request; the consent holder shall announce where the reference material¹² can be accessed;
- (d) the detection method specific to *Zea mays* L., line 1507, as validated by the European Union reference laboratory as referred to in the Annex of Regulation (EC) No 1829/2003 shall be used for the purpose of inspection and control;
- (e) the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified 1507 maize’ shall appear either on a label or in a document accompanying the product, except where other Union legislation sets a threshold below which such information is not required;
- (f) it shall also be indicated on the label, or in an accompanying document for non-pre-packaged products, 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*);
- (g) the practices of the insect resistance management plan as contained in the notification shall be applied to minimise development of resistance in target pests and exposure of non-target insects to Bt-toxins and shall be modified to comply with the following provisions:
 - the 20% refuge area shall be calculated in proportion to the total Lepidoptera-active Bt-maize area;

¹² Reference Material: ERM®-BF418 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

- the 20% refuge area shall also be applied in the case of a cluster of fields of Lepidoptera-active Bt-maize with an aggregate area greater than 5 ha, irrespective of individual field and farm size.

The practices of the insect resistance management plan shall include the recommendation to plant refuge maize in border rows along field margins where present.

- (h) the consent holder shall provide instruction to farmers in order to ensure the implementation by them of required measures including, where appropriate, the planting of refuge maize in border rows, and monitoring, to minimise development of resistance in target pests and exposure of non-target insects to Bt-toxins, and to assist farmers in cultivating *Zea mays* L., line 1507;
- (i) for the purpose of best possible handling and use of the product, the consent holder shall distribute with each bag of seeds to the operators a leaflet detailing information about the product and practices for its use, including the requirements indicated in paragraph (h). The content of this leaflet is listed in Annex II.

Article 4 *Monitoring by the consent holder*

1. The consent holder shall ensure that the monitoring plan with regard to cultivation contained in the notification is modified in accordance with Annex I and that through the period of validity of the consent it is put in place and implemented. The consent shall be granted only after the monitoring plan is modified and consolidated in accordance with the provisions of this Decision. The consolidated monitoring plan shall be made available on the website of the European Commission after consultation with the Member States (*web link to the consolidated monitoring plan to be added*).
2. The consent holder shall directly inform the operators and users of the introduction of *Zea mays* L., line 1507 into the Union as well as of the safety and general characteristics of the product and of the conditions for monitoring.
3. The following obligations are laid down for the consent holder:
 - (a) The consent-holder shall undertake case-specific monitoring of the possible development of resistance in target species through exposure to the CRY1F protein in accordance with the insect resistance management plan contained in the monitoring plan, and taking account of Annex I in order to:
 - (i) Measure the baseline susceptibility of target pests to CRY1F protein;
 - (ii) Detect changes relative to baseline susceptibility that cause inadequate field protection against target pests.
 - (b) The consent holder shall undertake general surveillance and establish a general surveillance network through use of farmer questionnaires and taking account of the additional measures referred to in Annex I. The consent holder shall continue to develop the content and format of the questionnaire.

- (c) In addition, the consent holder shall undertake a case-specific study on potential adverse effects on non-target organisms from cultivation of 1507 maize and report the outcome of this study to the rapporteur Competent Authority, the competent authorities of the other Member States and the European Commission.
 - (d) Without prejudice to Article 20 of Directive 2001/18/EC, the monitoring plan shall, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, be revised in line with the results of the monitoring activities by the consent holder, and/or by the competent authority of the Member State which received the original notification. Revised monitoring plans shall be submitted by the competent authority to the Commission and the competent authorities of the other Member States.
4. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:
- (a) that the networks for monitoring of resistance and general surveillance will gather the information necessary for the monitoring and surveillance of the products; and
 - (b) on the time schedule for receipt of the above information by the consent holder and its transmission to the Commission and the competent authorities of the Member States.
5. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of all monitoring activities, including general surveillance. The presentation of these reports shall be made in accordance with the Standard Reporting Format established by Commission Decision 2009/770/EC¹³ 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.

Article 5
Addressee

This Decision is addressed to the Kingdom of Spain.

Done at Brussels,

For the Council
The President

¹³ OJ L 275, 21.10.2009, p. 9.

ANNEX I

Monitoring by the consent holder

1. In the context of Article 4(3)(a) on case-specific monitoring, the consent holder shall increase the frequency of monitoring activities as appropriate, taking account of the rate at which potential resistance to the CRY1F protein is likely to evolve the resistance management strategy as well as the scale and the geographical dispersal of *Zea mays* L., line 1507, and shall revise the sampling protocol to detect resistance alleles frequency between 1% to 3%.
2. The consent holder shall carry out general surveillance of unanticipated potential effects on non-target insects in particular (including parasitoids), taking into account the possibility of both direct and indirect effects on those and other non-target organisms including other arthropods.
3. The consent holder shall also:
 - (a) assist in insect collections for relevant analyses in the context of general surveillance;
 - (b) encourage growers to report any observed adverse effects (including on non-target insects or derived from changes in conventional agricultural practices);
 - (c) participate in monitoring programmes developed by the EU Competent Authorities or other relevant national authorities appropriate to 1507 maize.
4. The farmer questionnaire referred to in Article 4, paragraph 3(b) shall include the following elements in line with EFSA opinions:
 - (a) a request to the farmer to provide factual information as opposed to only comments as to possible observed differences;
 - (b) a request to the farmer to provide data on fertilizer usage, soil fertility, crop rotations, crop performance, crop yield, pests and diseases, pesticide use, weed abundance and on regionally occurring lepidopteran pests other than corn borers;
 - (c) a particular focus on sites where *Zea mays* L., line 1507 is a significant proportion of the maize being grown and on years following cultivation. The selection of farms shall be done independently of the size of Bt-maize cultivation. In addition, the sampling strategy shall ensure that 2500 farmer questionnaires are collected over the period of cultivation to achieve an acceptable statistical power;
 - (d) a structure designed to elicit detailed information. The questions should be presented in a way that the respondent can choose from a selection of answers;
 - (e) an additional field for free answers or comments following the pre-formulated answers to allow comments on other factors not covered specifically in the questionnaire;

- (f) the standard procedures of univariate or multivariate and cumulative analysis of the questionnaire's key variables to be analysed by the consent-holder should be described precisely;
 - (g) questions regarding the occurrence of beneficial insects and other wildlife.
5. The consent holder shall ensure that the general surveillance network involves all necessary existing surveillance systems and any new surveillance systems required in addition to that established through the farmer questionnaire. The consent holder shall consult networks involved in relevant biodiversity surveys at local, national and Union level.
6. The monitoring plan shall include: observation parameters; survey methods, location and frequency; timetable for inspections; description and details of representativeness of the receiving environment; reference areas; relevant agreements with third parties; adaptation of the plan to regional conditions.

ANNEX II

Content of the leaflet for operators

Throughout the period of validity of the consent, the consent holder, when placing seeds from varieties derived from the *Zea mays* L., line 1507 on the market in a Member State, shall, based on the conditions for placing on the market set out in Article 3, distribute a leaflet with each bag of seeds of the *Zea mays* L., line 1507 indicating the following:

- (a) General description of the product, including general characteristics of and safety requirements for varieties derived from the *Zea mays* L., line 1507, and the unique identifier assigned to the GMO;
- (b) Mention of the requirement that the transmission of seed from varieties derived from the *Zea mays* L., line 1507, between operators be recorded by the operators, and that written information regarding the product must be provided as established by Article 4 of Regulation (EC) No 1830/2003;
- (c) Design and management of the planting, including guidance to the operators to design refuges;
- (d) An indication of the applicable national legislation on the cultivation of GMOs, including legislation on co-existence between GM maize crops and non-GM maize crops where applicable and its detailed provisions as regards treatment of equipment and product material, notification requirements if applicable, and distances or buffer zones where relevant, among others, and reminder of the basic obligations for the cultivation and use of the product at national and Union level;
- (e) Monitoring requirements according to the insect resistance management plan, and reference to the farmer questionnaire.