SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 30 November 2016

doi: 10.2903/j.efsa.2017.4659

Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC

EFSA Panel on Genetically Modified Organisms (GMO),
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Abstract

Following the submission of application EFSA-GMO-RX-001 under Regulation (EC) No 1829/2003 from Pioneer Overseas Corporation and Dow Agrosciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the frame of a renewal of authorisation application of the insect-resistant and herbicide-tolerant genetically modified (GM) maize 1507. The data package received in the frame of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, an updated bioinformatics analysis and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed this data package for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the frame of the original application. Under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009).

Keywords: Maize 1507, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2015-00342

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Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output: the members of its standing Working Groups on Molecular Characterisation, Food and Feed Safety Assessment and Environmental Risk Assessment for the preparatory work on this scientific output.

Suggested citation: EFSA GMO Panel (EFSA Panel on genetically modified organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M , Álvarez F, Ardizzone M, Mestdagh S and Ramon M, 2017. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA Journal 2017;15(1):4659, 11 pp. doi:10.2903/j.efsa.2017.4659

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Following the submission of application EFSA-GMO-RX-001 under Regulation (EC) No 1829/2003[1] from Pioneer Overseas Corporation and Dow Agrosciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific opinion on the data submitted in the frame of a renewal of authorisation application of the insect-resistant and herbicide-tolerant genetically modified (GM) maize 1507. The scope of renewal application EFSA-GMO-RX-001 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

At the time of submission of the renewal application EFSA-GMO-RX-001, no EFSA Guidance document was in place to assist the applicant in the preparation and presentation of their renewal application. Therefore, the applicant submitted data in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. At the time EFSA validated renewal application EFSA-GMO-RX-001, the 'Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003' (EFSA GMO Panel, 2015) was published and the GMO Panel requested the applicant to update the data package to be in line with these guidelines.

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-001, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data package received in the frame of the renewal application EFSA-GMO-RX-001 contained: post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed this data package for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the frame of the original application.

In conclusion, under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009).

[1] 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. 1–23.

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1 Introduction

1.1. Background

On 18 May 2015, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-001 for the renewal of authorisation of genetically modified (GM) maize 1507 for food and feed uses, import and processing submitted by Pioneer Overseas Corporation and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003. Before sending the application to EFSA, the European Commission (DG SANTE) checked whether the data submitted in the frame of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving the application EFSA-GMO-RX-001, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and made the summary of the application available to the public on the EFSA website.[2]

On 3 July 2015, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had 3 months after the opening of the Member State commenting period (until 7 October 2015) to make their opinion known.

Following the submission of notifications and applications C/NL/00/10, C/ES/01/01, EFSA-GMO-NL-2004-02 and EFSA-GMO-RX-1507 and the publication of EFSA scientific opinions (EFSA 2004, 2005a,b, 2009), the placing on the market of maize 1507 for food/feed uses, except cultivation, was authorised by Commission Decisions 2005/772/EC[3], 2006/197/EC[4], DGM SAS C/NL/00/10 and 2011/365/EU[5]. A copy of these authorisations was provided by the applicant.[6]

On 21 September 2015, 19 October 2015, 18 March 2016, 12 February 2016, 11 March 2016, 18 March 2016, 11 July 2016 and on 10 October 2016, EFSA received additional information (requested on 10 July 2015, 21 July 2015, 11 December 2015, 18 December 2015, 11 January 2016, 25 April 2016 and 13 May 2016, respectively). The applicant also spontaneously submitted additional information on 19 November 2015 and 25 November 2015.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of 6 months from the acknowledgement of the valid application. As additional information was requested by the GMO Panel, the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1) and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the frame of a renewal of authorisation application for maize 1507 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment

[2] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2015-00342

[3] Commission Decision 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. 42–44.

[4] Commission Decision 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. 82–86.

[5] Commission Decision of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed 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 163, 23.6.2011, p. 52–54.

[6] Dossier: Part II – Section 1.

and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

2. Data and methodology

2.1. Data

The data for application EFSA-GMO-RX-001 submitted by the applicant at the time of submission, spontaneously submitted or in reply to requests for additional information are specified below. In the frame of this renewal application, no new sequencing study was submitted among the additional documents or studies performed by or on behalf of the applicant. However, the applicant clarified that the maize 1507 sequence information submitted in the original application (EFSA-GMO-NL-2004-02, C/ES/01/01, C/NL/00/10) was subsequently corrected for sequencing errors affecting four single nucleotides.[7]

According to the EFSA guidelines for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015), the GMO Panel evaluated the data provided in the frame of this maize 1507 renewal application under the assumption that the event sequence is identical to the corrected sequence of the originally assessed event.

2.1.1. Post-market monitoring reports[8]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food/feed was not required by the authorising decisions. The implementation of a post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment or human health arising from handling maize 1507, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize 1507 (EFSA, 2004, 2005a,b, 2009), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from 16 March 2006 till June 2014. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in maize (or bulk grain) import and processing) to report any observed adverse effect(s) of the GMO on the environment or human health arising from handling of maize 1507; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed publications retrieved from literature searches.

The applicant provided an overall assessment of the annual PMEM reports in the renewal dossier. The GMO Panel requested on 10 July 2015 further information on the implementation of the annual PMEM and general surveillance plan, for which a response was provided by the applicant on 19 October 2015.

2.1.2. Systematic search and evaluation of literature[9]

In addition to the literature searches submitted within the annual PMEM reports, the applicant conducted two additional literature searches, covering a part of the authorisation period from 2009 till 2015. To be in line with the guidelines for renewal applications (EFSA GMO Panel, 2015), the GMO Panel requested the applicant on 10 July 2015 to submit a systematic literature search covering the complete duration of the event's authorisation (from 2006 till 2015) and following the principles outlined in the EFSA guidance on the application of systematic review methodology for food and feed safety assessment (EFSA, 2010). The applicant responded to that request on 19 October 2015. Further clarifications on the eligibility criteria used by the applicant for inclusion or exclusion of relevant publications after the initial systematic literature search were requested by the GMO Panel on 11 January 2016. The applicant responded to this request on 11 March 2016. The outcome of the literature search is presented in Section 3.2.

[7] Additional information 10/10/2016
[8] Dossier: Part II – Section 2 and additional information: 19/10/2015.
[9] Dossier: Part II – Section 3.2.3 and additional information: 19/10/2015, 11/3/2016.

2.1.3. Updated bioinformatics[10]

At the time of submission of the renewal dossier, the applicant provided a bioinformatics package for maize 1507, including data on the insert sequences and sequences flanking the inserts and an analysis of all possible open reading frames (ORFs) within the insert and spanning the junction sites, defined from stop to stop, and newly expressed proteins for potential identity to allergens or toxins. This bioinformatics package was based on the original sequence corrected for four sequencing errors.[7] The applicant spontaneously submitted a new updated bioinformatics package, including an analysis of possible horizontal gene transfer (HGT), on 21 September 2015. This bioinformatics package, however, was based on the original sequence corrected for only one of the four sequencing errors. Therefore, the applicant spontaneously submitted another updated bioinformatics package based on the original sequence corrected for the four sequencing errors, and included an analysis of all possible ORFs within the insert and spanning the junction sites for potential identity to allergens or toxins and a new HGT analysis (19 November 2015). This package also included an analysis of newly expressed proteins for similarity to toxins. EFSA requested further analysis of the potential for expression of the putative ORFs that showed 35% or more identity with possible allergens. The applicant provided these data on 18 March 2016. On 25 April 2016, the GMO Panel requested further clarification on the exact sequences used in the different bioinformatics packages. The applicant provided the requested clarification on 10 October 2016. Therefore, all elements of the bioinformatics analyses were performed on the original sequence corrected for four sequencing errors.

2.1.4. Additional documents or studies provided by the applicant[11]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize 1507. The GMO Panel requested the applicant on 10 July 2015 (1) to list and provide the summary of all unpublished studies produced, controlled or sponsored by the applicant or provided to the applicant by a third party, performed over the course of the authorisation period and not previously submitted to the EU, and (2) to assess their relevance for molecular characterisation, human and animal safety and the environment. On 19 October 2015, the applicant submitted a list with 10 study titles and a summary for three of them, and evaluated the relevance for molecular characterisation, food and feed safety and the environment (Table 1). Based on the information provided, the GMO Panel requested from the applicant on 11 December 2015 the summary of the PHI-2014-178 study and the full study reports of the six food and feed related studies listed and considered potentially relevant for the assessment. The applicant submitted the requested information on 12 February 2016 and spontaneously sent the full study report of the PHI-2014-178 study.

Table 1: List of additional studies performed by Pioneer Overseas Corporation or Dow Agrosciences LLC over the course of the authorisation period (2006–2015) with regard to the evaluation of the safety of the food/feed and the risks of the food/feed to humans, animal or the environment from maize 1507

Study identification	Title
PHI-2011-139[(a)]	Event confirmation by polymerase chain reaction analysis of DAS-Ø15Ø7-1 maize seed
PHI-2008-100[(a)]	Expressed trait protein concentration of maize lines containing event DAS-Ø15Ø7-1: Johnston, IA
PHI-2009-102[(a)]	Sequencing characterization of plasmid PHP8999
PHI-2014-178[(a)]	Sequence characterization of insert and flanking genomic regions of DAS-Ø15Ø7-1 maize
PHI-2007-177[(a)]	Field production of maize grain containing event DAS-Ø15Ø7-1: Chile location
PHI-2010-204[(a)]	Field production and characterization of grain from a maize line containing the event DAS-01507-1: Chile test site
PHI-2013-291[(a)]	Nutrient compositional and contaminant analyses of maize grain from lots R10CN204-CH-6091 and R10CN-204-CH-5001
121156[(b)]	PAT: Acute oral toxicity study in Crl:CD1(ICR) mice. 2013
120937[(b)]	Effect of heat treatment on phosphinothricin acetyltransferase (PAT) protein

[10] Dossier: Part II – Section 3.2.2 and additional information: 21/9/2015, 19/11/2015, 18/3/2016, 10/10/2016.
[11] Dossier: Part II – Sections 2.3.1.1, Section 3.1 and additional information: 19/10/2015, 12/2/2016.

Study identification	Title
131205[(b)]	Influences of pH on phosphinothricin acetyltransferase (PAT) protein

(a): Performed by Pioneer Hi-Bred International, Inc.
(b): Performed by Dow Agrosciences LLC.

2.1.5. Overall assessment as provided by the applicant[12]

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015), the GMO Panel requested the applicant on 10 July 2015 to submit an evaluation on whether the collected information leads to the identification of new hazards or modified exposure, or adds new scientific uncertainties. The applicant provided its assessment on 19 October 2015. All the additional information received after 19 October 2015 also included an assessment by the applicant for the identification of new hazards or modified exposure, or new scientific uncertainties.

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[13]

The applicant indicated in the dossier that the environmental monitoring plan was appropriate and does not need any changes to the conditions of release and use as laid down in the initial authorisation.

2.2. Methodologies

The GMO Panel carried out a scientific risk assessment on the data submitted in the frame of a renewal of authorisation application for maize 1507 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015).

The comments raised by Member States are addressed in Annex G of EFSA's overall opinion[14] and were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market environmental monitoring reports

In the general surveillance activities covering the authorisation period of maize 1507, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The applicant performed a systematic literature search to identify scientific publications related to maize 1507 covering the authorisation period between 2006 and 2015. The applicant used Scopus and CAB Direct as scientific literature databases. The search strings were adapted for each database. The search terms used for the literature search included synonyms, scientific and common names, brand and generic names and British and US variants (e.g. maize and corn). Boolean operators (i.e. OR, AND) were used to combine terms, while wild card symbols allowed to retrieve spelling variants. No restrictions (e.g. language, publication type) were applied with the exception of the time period. Altogether 974 unique entries were identified which were manually screened for their relevance for the molecular characterisation, food and feed safety assessment and environmental safety assessment of maize 1507.

After a screen based on title, abstract or full text, the applicant identified 13 original scientific publications relevant for the risk assessment of maize 1507. Eleven publications related to the food and feed safety assessment, while two publications related to the ERA of maize 1507. Eleven of the 13 selected original scientific publications had been previously assessed by the GMO Panel (EFSA, 2009; EFSA GMO Panel, 2011, 2012) and it had been concluded that none of them raised concerns or new information that could change the conclusions of the original risk assessment. The GMO

[12] Additional information: 19/10/2015.
[13] Dossier: Part II – Section 2.5.
[14] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2016-00817

Panel assessed the two remaining original scientific publications, Jemison and Reberg-Horton (2010) and Bowers et al. (2014), and considered that neither of them raised any new concerns for human and animal health and the environment which could change the original risk assessment conclusion on maize 1507.

3.3. Evaluation of the updated bioinformatics

The latest received updated bioinformatic analyses of the junction regions for the events in maize 1507 confirmed that no known endogenous genes were disrupted by any of the inserts.

Updated bioinformatic analyses of the amino acid sequence of the newly expressed Cry1F and PAT proteins revealed no significant similarities to toxins and allergens. In addition, updated bioinformatics analyses of the newly created ORFs within the inserts and at their junctions indicate that the expression of an ORF showing significant similarities to toxins or allergens is highly unlikely.

In order to assess the possibility for HGT by homologous recombination (HR), the applicant performed a sequence identity analysis of the regions of bacterial origin in maize 1507. No elements with sufficient length and identity to support HR were identified (EFSA, 2015). There is no information that would change the previous conclusion of the GMO Panel that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from maize 1507 to bacteria does not raise any environmental safety concern.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel has evaluated the summary and/or the full study reports of the relevant studies provided and this new information did not raise any concern for human and animal health, and the environment which would change the original risk assessment conclusion on maize 1507.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel assessed the information provided by the applicant and did not identify new hazards, relevant changes in the exposure to products containing maize 1507 or new scientific uncertainties which would change the original risk assessment conclusions of maize 1507.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The GMO Panel is of the opinion that the PMEM plan and the general surveillance system implemented by the applicant is in line with the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

4. Conclusions

Under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009).

Documentation provided to EFSA

1) Letter from the European Commission received on 18 May 2015 for the continued marketing of genetically modified maize 1507 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences Ltd. (EFSA-GMO-RX-001).
2) Acknowledgement letter dated 27 May 2015 from EFSA to European Commission.
3) Letter from EFSA to applicant dated 3 July 2015 delivering the 'Statement of Validity' for application regarding genetically modified maize 1507 (EFSA-GMO-RX-001) submitted by Pioneer Overseas Corporation and Dow AgroSciences Ltd. under Regulation (EC) No 1829/2003.

4) Letter from EFSA to applicant dated 10 July 2015 requesting additional information and stopping the clock.
5) Letter from EFSA to applicant 21 July 2015 requesting additional information and maintaining the clock stopped.
6) Letter from applicant to EFSA received on 21 September 2015 providing additional information.
7) Letter from applicant to EFSA received on 19 October 2015 providing additional information.
8) Letter from applicant to EFSA received on 19 November 2015 providing additional information spontaneously.
9) Letter from EFSA to applicant 11 December 2015 requesting additional information and maintaining the clock stopped.
10) Letter from EFSA to applicant 18 December 2015 requesting additional information and maintaining the clock stopped.
11) Letter from EFSA to applicant 11 January 2016 requesting additional information and maintaining the clock stopped.
12) Letter from applicant to EFSA received on 12 February 2016 providing additional information.
13) Letter from applicant to EFSA received on 11 March 2016 providing additional information.
14) Letter from applicant to EFSA received on 18 March 2016 providing additional information.
15) Email from EFSA to applicant dated 21 March 2016 re-starting the clock from 18 March 2016.
16) Letter from EFSA to applicant dated 25 April 2016 requesting additional information and stopping the clock.
17) Letter from EFSA to applicant 13 May 2016 requesting additional information and maintaining the clock stopped.
18) Letter from applicant to EFSA dated 8 June 2016 asking for an extension of the deadline to submit information.
19) Letter from EFSA to applicant dated 16 June asking for clarification of the extension of deadline requested on 8 June 2106.
20) Letter from applicant to EFSA received on 5 July 2016 providing a timeline for submission of responses.
21) Letter from applicant to EFSA received on 11 July 2016 providing additional information.
22) Letter from applicant to EFSA received on 30 August 2016 providing a timeline for submission of responses.
23) Letter from applicant to EFSA received on 10 October 2016 providing additional information.
24) Email from EFSA to applicant dated 11 October 2016 re-starting the clock from 10 October 2016.

References

Bowers E, Hellmich R and Munkvold G, 2014. Comparison of fumonisin contamination using HPLC and ELISA methods in Bt and near-isogenic maize hybrids infested with european corn borer or western bean cutworm. Journal of Agricultural and Food Chemistry, 62, 6463–6472.

EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds. EFSA Journal 2004;2(10):124, 18 pp. doi: 10.2903/j.efsa.2004.124

EFSA (European Food Safety Authority), 2005a. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/ES/01/01) or 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. EFSA Journal 2005;3(3):181, 33 pp. doi:10.2903/j.efsa.2005.181

EFSA (European Food Safety Authority), 2005b. Opinion of the Scientific Panel on Genetically Modified Organisms on an application for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International/Mycogen Seeds. EFSA Journal 2005;3(3):182, 22 pp. doi:10.2903/j.efsa.2005.182

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. EFSA Journal 2009;7(6):1138, 11 pp. doi:10.2903/j.efsa.2009.1138

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. doi:10.2903/j.efsa.2010.1637

EFSA (European Food Safety Authority), 2015. Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA Supporting Publication 2015:12(12);EN-916, 10 pp. doi:10.2903/sp.efsa.2015.EN-916

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. 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

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2012. 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

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13 (6):4129, 8 pp. doi:10.2903/j.efsa.2015.4129

Jemison J and Reberg-Horton C, 2010. Assessing Bt silage corn in Maine. Crop Management CM-2010-1022-2001-RS.

Abbreviations

ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
HGT	horizontal gene transfer
HR	homologous recombination
ORFs	open reading frames
PAT	phosphinothricin acetyltransferase
PMEM	post-market environmental monitoring