COMMISSION IMPLEMENTING DECISION

of XXX

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the Dutch and French texts are authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[[1]](#footnote-1), and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

1. On 27 November 2014, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International Inc., United States, submitted to the national competent authority of the Netherlands an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (‘the application’). The application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize 4114. The application also covered the placing on the market of products containing or consisting of genetically modified maize 4114 for uses other than food and feed, with the exception of cultivation.
2. In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[[2]](#footnote-2). It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.
3. On 24 May 2018, the European Food Safety Authority (‘the Authority’) issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[[3]](#footnote-3). The Authority concluded that genetically modified maize 4114, as described in the application, is as safe as the non-GM comparator(s) and the tested non-genetically modified maize reference varieties with respect to potential effects on human and animal health and the environment.
4. In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
5. The Authority also concluded that the monitoring plan for environmental effects consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
6. Taking those considerations into account, the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 should be authorised for the uses listed in the application.
7. A unique identifier should be assigned to genetically modified maize 4114 in accordance with Regulation (EC) No 65/2004[[4]](#footnote-4).
8. On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council[[5]](#footnote-5), appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize 4114, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
9. In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC[[6]](#footnote-6).
10. The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
11. All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
12. This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[[7]](#footnote-7).
13. The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1
Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) 4114, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-ØØ4114-3, in accordance with Regulation (EC) No 65/2004.

Article 2
Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified maize 4114;

(b) feed containing, consisting of or produced from genetically modified maize 4114;

(c) products containing or consisting of genetically modified maize 4114 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3
Labelling

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.

2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified maize 4114, with the exception of foods and food ingredients.

Article 4
Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize 4114.

Article 5
Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

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

Article 6
Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7
Authorisation holder

The authorisation holder shall be Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium.

Article 8
Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9
Addressee

This Decision is addressed to Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels, Belgium.

Done at Brussels,

 For the Commission,

 Vytenis ANDRIUKAITIS

 Member of the Commission

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ANNEX

**(a) Applicant and Authorisation holder:**

Name: Pioneer Hi-Bred International, Inc.

Address: 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, U.S.A.

Represented by: Pioneer Overseas Corporation, Avenue des Arts, 44, 1040 Brussels, Belgium.

**(b) Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified maize 4114;

(2) feed containing, consisting of or produced from genetically modified maize 4114;

(3) products containing or consisting of genetically modified maize 4114 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize 4114 expresses the Cry1F (truncated version), Cry34Ab1 and Cry35Ab1 proteins providing protection against specific lepidopteran and coleopteran pests, and the PAT protein conferring tolerance to glufosinate-ammonium based herbicides.

**(c) Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.

(2) The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize 4114, with the exception of products referred to in point (b)(1) of this Annex.

**(d) Method for detection:**

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize DP-ØØ4114-3.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: ERM®-BF439 is accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

**(e) Unique identifier:**

DP-ØØ4114-3

**(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

**(g) Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

**(h) Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the register of genetically modified food and feed*]

**(i) Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.*

**Environmental monitoring plan for maize 4114**

**1. Introduction**

As required by Articles 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for genetically modified (GM) maize 4114 has been developed according to 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. The PMEM also takes into account the Scientific Opinion on guidance on the Post-Market Environmental Monitoring of genetically modified plants[[8]](#footnote-8).

EFSA has carried out the scientific assessment of the genetically modified maize 4114 and considered that maize 4114 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

EFSA evaluated the environmental monitoring plan proposed by the authorisation holder and considered that there is no need for a case-specific monitoring since no adverse effects were identified[[9]](#footnote-9). The monitoring plan consisting in a general surveillance plan is in line with the intended uses for the GMO.

**2. General surveillance for unanticipated adverse effects**

2.1. Approach

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (e.r.a).

The genetically modified maize 4114 is authorized for import, processing and food and feed uses, but not for cultivation.

Therefore, exposure to the environment will be limited to unintended release of maize 4114, which could occur for example via substantial losses during loading/unloading of the viable commodity including maize 4114 destined for processing into animal feed or human food products. Such exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides with the exception of glufosinate-ammonium based herbicides.

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., general surveillance on maize 4114 shall be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to the extent of imports of maize 4114 and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system shall be used, which involves the authorisation holder and operators handling and using viable maize 4114. The operators shall be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable maize 4114.

A detailed description of the methodology proposed for general surveillance of maize 4114 is provided in Section 2.6.

2.2. Baselines

Since the intended use of maize 4114 is the same as that of any other commercial maize, the procedures for the import, handling and processing of maize 4114 will be the same and have been considered in the development of the monitoring plan. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM maize as comparable reference where necessary.

2.3. Time-period

General surveillance of maize 4114 shall be undertaken for the duration of the authorisation period for maize 4114 for import and processing.

2.4. Assigning responsibilities

The authorisation holder is responsible for ensuring that the monitoring plan is put in place and properly implemented in accordance with the conditions of the authorisation.

The authorisation holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

* That the monitoring networks as specified in the monitoring plan collect the information relevant for the monitoring of maize 4114;
* That the members of these networks have agreed to make available that information to the authorisation holder before the date of the submission of the monitoring report.

The third parties involved in the general surveillance shall report any potential unanticipated adverse effects to the authorisation holder, who shall immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003[[10]](#footnote-10), as described in Section 3.

2.5. Existing systems

*Primary sources of information*

The authorisation holder is not involved in commodity trade with maize 4114. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable maize 4114. They are exposed to the imported viable maize 4114 and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles as reflected on the website of the trade associations representing the operators involved in the PMEM (see below).

Since traders may commingle maize 4114 with other commercial maize, including authorised GM maize, the authorisation holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The following networks are currently involved:

* Importers / Traders

COCERAL is the European association of trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro-supply. It represents the interests of the European collectors, traders, importers, exporters and port silo storekeepers of the above mentioned agricultural products. The main importers of cereals and feedstuffs into the EU are members of COCERAL.

Also see: <http://www.coceral.com/>

* Silo Operators

UNISTOCK is the European association representing professional storekeepers for agribulk commodities in the EU. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: <http://www.unistock.be/>

* Processors

FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseed meal producers and vegetable oil producers/processors. Its members represent 85% of the EU industry and hold oilseeds processing and vegetable oils and fats production facilities across Europe.

Also see: [http://www.fediol.eu](http://www.fediol.be/1/main1.php)

These associations represent the majority of European operators importing, handling and processing viable maize commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003, and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of maize 4114, because they focus on processed, non-viable material.

*Additional sources of information*

In addition to the aforementioned existing monitoring systems, extensive independent research by scientists with a wide range of expertise is another valuable source of information on potential adverse effects arising from the use of GMOs. The authorisation holder will actively screen relevant reports and peer-reviewed publications on the use of maize 4114, in order to identify potential unforeseen adverse effects linked to maize 4114.

2.6. Monitoring Methodology

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, shall implement general surveillance of viable GM maize, including maize 4114, with the help of the selected networks described in Section 2.5.

The different parties agreed on a general framework for monitoring of GMOs including maize 4114, as follows:

* The **authorisation holder** represented by EuropaBio shall:
	+ Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed PMEM plan.
	+ Inform operators concerning the authorisation, safety and general characteristics of maize 4114 and of the conditions as to general surveillance.
	+ Set up and maintain a website dedicated to operators including detailed information on maize 4114.

The website, hosted on the EuropaBio website under [www.europabio.org/information-operators-introduction](http://www.europabio.org/information-operators-introduction), contains the following information:

* An introduction to the purpose of the website
* A table giving an overview of all currently approved GM plant products subject to general surveillance
* A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
* A contact point at EuropaBio for information exchange on any of the GM plant products

The website shall be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

* Contact the selected networks of operators annually reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).
	+ The selected **networks of operators** (European trade associations) shall:
		- Inform and remind their member organisations and companies on an annual basis:
* to monitor for potential unanticipated adverse effects;
* that, in the framework of their management or safety standards (ISO, HACCP, …), procedures must be in place and implemented to limit losses and spillage of viable maize and to routinely eradicate adventitious populations on their premises - any such adventitious populations, resisting routine eradication procedures, shall be treated as a potential adverse effect;
* to inform and remind their own member companies of this requirement;
* to report back any adverse effect reported to them to the European trade associations.
* Report to the authorisation holders directly or via EuropaBio:
* at least annually, regardless of whether an adverse effect was observed or not;
* immediately any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL shall notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio, shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission, as described in Section 3.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder shall immediately investigate to determine and confirm whether a significant correlation between the effect and maize 4114 can be established. If the investigation establishes that maize 4114 was present when the adverse effect was identified, and confirms that maize 4114 is the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission, as described in Section 3.

**3. Reporting the results of monitoring**

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of maize 4114 and that alters the existing risk assessment becomes available, the authorisation holder shall immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the confirmed effect.

The authorisation holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable maize 4114.

The report shall include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of maize 4114 and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts of such report shall be submitted in separate documents.

**4. Review and adaptation**

The PMEM plan and associated methodology will be reviewed and updated or adapted as necessary.

1. OJ L 268, 18.10.2003, p. 1. [↑](#footnote-ref-1)
2. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1). [↑](#footnote-ref-2)
3. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123). EFSA Journal 2018; 16(5):5280, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5280> [↑](#footnote-ref-3)
4. 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). [↑](#footnote-ref-4)
5. 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/EC (OJ L 268, 18.10.2003, p. 24). [↑](#footnote-ref-5)
6. 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). [↑](#footnote-ref-6)
7. Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1). [↑](#footnote-ref-7)
8. EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8):2316, 40 pp. <https://doi.org/10.2903/j.efsa.2011.2316> [↑](#footnote-ref-8)
9. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123). EFSA Journal 2018; 16(5):5280, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5280> [↑](#footnote-ref-9)
10. 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. [↑](#footnote-ref-10)