Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC/2017_0186

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA-GMO-RX-001 for renewal of authorisation of genetically modified maize 1507 from Pioneer Overseas Corporation and Dow AgroSciences LLC under Regulation (EC) No. 1829/2003

Context

The application EFSA-GMO-RX-001 was submitted by Pioneer and Dow AgroSciences on 18 May 2015 for the renewal of authorisation for the marketing of genetically modified (GM) maize 1507 for food and feed uses, import and processing within the framework of Regulation (EC) No. 1829/2003[1]. Maize 1507 contains a single insert expressing the Cry1F protein, which confers protection against lepidopteran pests, and the PAT protein for tolerance to glufosinate-ammonium herbicides.

The placing on the market of maize 1507 for food/feed uses, except cultivation, is currently authorised by:
- Commission Decision 2005/772/EC[2] (application C/NL/00/10): Positive opinion of EFSA on 24 September 2004 (EFSA Journal 2004;2(10):124, 18 pp.) - No advice of the Biosafety Advisory Council (BAC);
- Commission Decision 2006/197/EC[3] (application EFSA-GMO-NL-2004-02): Positive opinion of EFSA on 3 March 2005 (EFSA Journal 2005;3(3):182) - No advice of the BAC;
- Commission Decision and 2011/365/EU[4] (application EFSA-GMO-RX-1507): Positive opinion of EFSA on 11 June 2009 (EFSA Journal 2009;7(6):1138, 11 pp.) - Advice of the BAC (BAC_2009_01368 of 2 October 2009) positive concerning the environment and inconclusive concerning feed safety due to the lack of quality of animal trials used for testing toxicity and the nutritional value.

The application EFSA-GMO-RX-001 was officially acknowledged by EFSA on 3 July 2015. On the same date EFSA started the formal three-month consultation period of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC

[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).
[2] Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium. OJ L 291, 5.11.2005, p. 42–44.
[3] Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJ L 70, 9.3.2006, p. 82–86.
[4] Commission Decision 2011/365/EU 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.

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designated by each Member State in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Biosafety and Biotechnology Unit (SBB). Eight experts answered positively to this request, and evaluated the dossier. None of the comments made by the experts were transmitted to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 30 November 2016 (EFSA Journal 2017;15(1):4659[5]), and published together with the responses from the EFSA GMO Panel to comments submitted by the member states during the three-month consultation period.

The comments formulated by the experts together with the opinion of EFSA, as well as the advices already adopted by the BAC on stacked events containing maize 1507 and the advices already adopted by the BAC on other GM single events expressing the Cry1F and/or the PAT protein, form the basis of the advice of the Biosafety Advisory Council given below.

Scientific evaluation

1. Post-market environmental monitoring

The Biosafety Advisory Council welcomes the annual post-market environmental monitoring (PMEM) reports provided by the applicant during the period March 2006 - June 2014, and takes note of the absence of adverse effects during the authorisation period of maize 1507.

2. Systematic search and evaluation of literature

The Biosafety Advisory Council welcomes the systematic literature search covering the complete duration of the event's authorisation conducted by the applicant following the principles outlined in the relevant EFSA guidance.
The Council agrees with the GMO panel of EFSA that none of the scientific publications relevant for the risk assessment of maize 1507 identified from this literature search raise any new concerns regarding the safety for human or animal health or the environment.

3. Updated bioinformatics

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the updated bioinformatics analyses for GM maize 1507 do not indicate any safety concern, as no known endogenous genes are interrupted by the inserts, the newly expressed proteins do not present significant similarities to known toxins or allergens, and the expression of an open reading frame showing significant similarities to toxins or allergens is highly unlikely.

4. Additional documents or studies

The Biosafety Advisory Council welcomes the reports of additional studies performed by the applicant over the course of the authorisation period with regard to the evaluation of the

[5] See http://www.efsa.europa.eu/en/efsajournal/pub/4659

safety of the food/feed and the risks of the food/feed to humans, animal or the environment from maize 1507.
The Council agrees with the GMO panel of EFSA that this new information does not raise any concern for human and animal health, and the environment.

5. Overall assessment

The Biosafety Advisory Council agrees with the GMO panel of EFSA that no new information has given rise to any concern for human or animal health or the environment.

6. Monitoring plan and proposal for improving the conditions of the original authorisation

Since the allergenicity of the whole GM maize has not been fully assessed, it is recommended to take up monitoring of allergenicity as part of the general surveillance.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the previous advice of the BAC on maize 1507, the advices already adopted by the BAC on stacked events containing maize 1507 and the advices already adopted by the BAC on other GM single events expressing the Cry1F and/or the PAT protein, and considering the new information provided by the applicant, the Biosafety Advisory Council is of the opinion that in the context of its proposed uses, maize 1507 is unlikely to pose any risk to human and animal health.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM maize could pose to the European environment.

In addition the Biosafety Advisory Council recommends following up any unanticipated allergenicity aspects of the GM maize in the existing allergenicity monitoring systems.

Prof. Maurice De Proft
President of the Belgian Biosafety Advisory Council

Annex I: Minority declaration
Annex II: Compilation of comments of experts in charge of evaluating application EFSA/GMO/RX-001 (ref. BAC_2015_0669).

Minority declaration of P. Baret

A first assesment by the Biosafety Advisory Council (BAC_2009_01368 of 2 October 2009) of Maize 1507 was inconclusive concerning feed safety due to the lack of quality of animal trials used for testing toxicity and the nutritional value.
Considering the lack of statistically convincing studies on toxicity, proofs of the non-toxicity of Maize 1507 are still missing. In consequence, the advice of Biosafety Advisory Council should be inconclusive on toxicity.

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06/10/2015

Compilation of comments of experts in charge of evaluating the application EFSA-GMO-RX-001-Maize1507
and
Comments submitted on the EFSAnet on mandate of the Biosafety Council

Mandate for the Group of Experts: Mandate of the Biosafety Advisory Council (BAC) of 3 August 2015.
Coordinator: Michel Van Koninckxloo
Experts: Eddy Decuypere (KUL), Jacques Dommes (ULg), Leo Fiems (ILVO), Johan Grooten (UGent), André Huyghebaert (UGent), Peter Smet (Consultant), Frank Van Breusegem (UGent), Michel Van Koninckxloo (HEP Hainaut-Condorcet).
Domains of expertise of experts involved: Molecular characterisation, DNA/RNA/protein analysis, animal and human nutrition, food/feed processing, toxicology, general biochemistry, statistics, immunology, alimentary allergology, plant allergens, agronomy, breeding techniques, plant biology.
SBB: Didier Breyer, Fanny Coppens, Martine Goossens, Katia Pauwels.

♦ INTRODUCTION

Dossier **EFSA-GMO-RX-001-Maize1507** concerns an application submitted by the companies **Pioneer and Dow** for a renewed authorisation to place on the market genetically modified **1507 Maize** in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed.
The application has been officially acknowledged by EFSA on 07 July 2015.

The scope of the application is:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

Depending on their expertise, the experts were asked to evaluate the genetically modified plant considered in the application on its 1) molecular, 2) environmental, 3) allergenicity, 4) toxicity and/or 5) food and feed aspects. It was expected that the expert should evaluate if the information provided in

the application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses, will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

The comments are structured as in the "Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA Journal (2004), 99, 1-94). Items are left blank when no comments have been received either because the expert(s) focused on other related aspects, or because for this dossier the panel of experts who accepted to evaluate the dossier didn't have the needed expertise to review this part of the dossier.
It should be noted that all the comments received from the experts are considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council. No comments were placed on the EFSAnet for dossier **EFSA-GMO-RX-001-Maize1507**.

List of comments/questions received from the experts

GENERAL COMMENTS

Comment 1

There is no strict reason to prohibit the import of 1507 maize and the use for food and feed purposes in the EU.

EFSA has concluded that maize containing 1507 event stacked with other GM events, such as MON 89034 x 1507 x MON 88017 x 59122 maize (EFSA, 2010a) and MON 89034 × 1507 × NK603 maize (EFSA, 2010b) is unlikely to have adverse effects on human and animal health and the environment, in the context of its intended use. So, it would be illogical to formulate constraints with regard to 1507 maize.

However, there may be some concern about the safe use of glufosinate ammonium in genetically modified herbicide tolerant crops, such as 1507 maize.

SBB Comment

The assessment of the safety of pesticides is not within the remits of the BAC.

Comment 2

No comment, adequate information is provided

Comment 3

No questions about the technical aspects for this application for renewal of authorization of 1507maize for feed and food use in EU.

I would like to refer here that the broader debate, and certainly in the case for application of a renewal, is far beyond the technical aspects, and has to do with sustainability of GM crops and certainly with stakeholder responses.

The 3 arguments that seem to be central in the debate on GM crops may be the following:

-the uncertainty linked to insertion of DNA-constructs by means of genetic modification, as to increase risks of unforeseen and adverse effects; this is unsolvable as it is at the heart of the scientific method which by definition never generates 100% certainty

-the second argument refers to concepts of naturalness.

-the third refers to power relationships in market chains, and in particular to power linked with intellectual property rights

Although science and scientists are only one of the many players in the debate, and scientists have no specific moral authority, this should not be confounded with a completely wrong relativistic thinking (particularly in our European societies) that science is just one out of many avenues to acquiring knowledge.

I refer here to editorials of “Netherlands Journal of Agricultural Sciences” 2014.

Comment 4

General information: the information provided in the application is sufficient.

Information to be submitted according to articles 11 and 23 of regulation n° 1829:2003: sufficient.

Comment 5

The 1507 maize is already authorized in the EU. This application is related to the renewal of the authorization based upon the monitoring from 2006 - to date. My comments refer to the report of the monitoring study.

Comment 6
No comments.

A. HAZARD IDENTIFICATION AND CHARACTERISATION

A.1. INFORMATION RELATED TO THE RECIPIENT OR (WHERE APPROPRIATE) THE PARENTAL PLANT

Comment 1
No comment, adequate information is provided

Comment 2
No comments.

Comment 3
No comments.

A.2. MOLECULAR CHARACTERISATION

A.2.1. INFORMATION RELATING TO THE GENETIC MODIFICATION including:

- Description of the methods used for the genetic modification
- Source and characterization of nucleic acid used for transformation
- Nature and source of vector(s) used

Comment 1
No comment, adequate information is provided.

Comment 2
No comments.

Comment 3
No comments.

A.2.2. INFORMATION RELATING TO THE GM PLANT including:

- Description of the trait(s) and characteristics which have been introduced or modified
- Information on the sequences actually inserted or deleted
- Information on the expression of the insert
- Genetic stability of the inserted/modified sequence and phenotypic stability of the GM plant

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

Comment 3

No comments.

A.3. COMPARATIVE ASSESSMENT

A.3.1. CRITERIA FOR THE SELECTION OF COMPARATOR(S)

Comment 1
No questions.

A.3.2. FIELD TRIALS: EXPERIMENTAL DESIGN AND STATISTICAL ANALYSIS

Comment 1
No questions.

A.3.3. COMPOSITIONAL ANALYSIS

Comment 1
No questions.

Comment 2
The monitoring applied is described in detail.

No adverse effects on human and animal health or the environment during the nine year reporting period are declared. The report covers information obtained from importers, traders, silo operators and processors.
In the reports there are no indications of any effect upon the composition of the 1505 maize and the derived products: oil and meal.

Taking into account the wide range of different handling, transport, storage and processing conditions applied, any effect upon the composition or the processing would undoubtedly have been mentioned. This also applies for the multitude of uses for maize derived products such as oil, starch, maize gluten and other products.

A.3.4. AGRONOMIC AND PHENOTYPIC CHARACTERISTICS

Comment 1
No questions.

A.3.5. EFFECTS OF PROCESSING

Comment 1
No questions.

Comment 2
From the reports it can be concluded that no particular adverse effects have been observed during processing into oil and oilseed meal.

A.4. TOXICOLOGICAL ASSESSMENT

A.4.1. METHODOLOGY USED FOR TOXICITY TESTS

Comment 1
No questions.

A.4.2. ASSESSMENT OF NEWLY EXPRESSED PROTEINS including:

- Molecular and biochemical characterisation of the newly expressed proteins
- Up-to-date bioinformatic search for homology
- Information on the stability of the protein under the relevant processing and storage conditions for the food and feed derived from the GM plant
- Data concerning the resistance of the newly expressed protein to proteolytic enzymes
- Repeated dose toxicity studies using laboratory animals

Comment 1
A side effect of the use of 1507 maize may be an increased use of herbicides in genetically modified herbicide tolerant crops. Herbicide use in the USA on soybean, corn and cotton declined slightly in the first years following introduction of herbicide resistant GM crops, but increased moderately in recent years (Fernandez-Cornejo et al., 2014), whereas Benbrook (2012) reported that herbicide-resistant crop technology has led to a 239 million kg increase in herbicide use in the USA between 1996 and 2011.
From experiment involving 7-week old female C57Bl6 mice, Laugeray et al. (2014) provided data on the link between pre- and postnatal exposure to the glufosinate ammonium and the onset of autism-like symptoms later in life. Moreover, these authors were concerned about the current safety tests of pesticide exposure during critical developmental periods. It may therefore be desirable to conduct extra experiments to verify these findings, because the use of glufosinate ammonium may be increased by the use of genetically modified herbicide tolerant crops.
1507 maize is not intended for cultivation in Europe, but there may be some concern about the safe use of glufosinate ammonium in 1507 maize, and the import of 1507 maize products to Europe for food and feed purposes.

SBB Comment
The assessment of the safety of pesticides is not within the remits of the BAC.

Comment 2
No questions.

Comment 3
Bioinformatic search for Cry1F (Mirsky, H., 27/06/2014 annex17)

None of the protein sequences returned by the BLASTP search identified safety concerns that might arise from the expression of Cry1F in genetically modified plants.

Bioinformatic search for PAT (Chang, P. and Mirsky, H., 25/06/2014 annex19)

None of the protein sequences returned by the BLASTP search identified any safety concerns from the expression of PAT protein in genetically modified plants.

A.4.3. ASSESSMENT OF NEW CONSTITUENTS OTHER THAN PROTEINS

Comment 1
Not applicable.

A.4.4. ASSESSMENT OF ALTERED LEVELS OF FOOD AND FEED CONSTITUENTS

Comment 1
Not applicable.

A.4.5. ASSESSMENT OF THE WHOLE FOOD AND/OR FEED DERIVED FROM GM PLANTS

Comment 1
No questions.

A.5. ALLERGENICITY ASSESSMENT

A.5.1. ASSESSMENT OF ALLERGENICITY OF THE NEWLY EXPRESSED PROTEIN including:

- Amino acid sequence homology comparison between the newly expressed protein and known allergens using a comprehensive database
- Specific serum screening
- Pepsin resistance and in vitro digestibility tests
- Additional tests

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

Comment 3
An analysis of the risk of allergenicity has been performed recently in the framework of application 1507 x 59122 x MON 810 x NK603 maize (EFSA-GMO-NL-2011-92) with Maize1507 being a stacked event in this GMO. The conclusion of this expert was: "*Thus when looking at the individual traits, there are in my opinion no objective reasons to expect an increased risk*." No new evidence for nor indications pointing towards an increased risk for allergenicity have since been raised. Furthermore, being on the market already since 2005 and being monitored on a yearly basis for possible adverse effects on human health by operators involved in the import, handling and processing of the GMO, field data are available. In line with the previous risk assessments, these annual monitoring reports confirm the absence of adverse effects on human (and animal) health.

I have no further comments.

A.5.2. ASSESSMENT OF ALLERGENICITY OF THE WHOLE GM PLANT

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

Comment 3
Referring to the previous recent analysis of 1507 x 59122 x MON 810 x NK603 maize (EFSA-GMO-NL-2011-92) and the annual monitoring reports, no evidence is available that would indicate an increased risk for allergenicity of the whole plant.

A.5.3. ADJUVANTICITY

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

Comment 3
There are no indications for an increased risk of adjuvant activity.

A.6. NUTRITIONAL ASSESSMENT

A.6.1. NUTRITIONAL ASSESSMENT OF FOOD DERIVED FROM GM PLANTS

Comment 1
No questions.

A.6.2. NUTRITIONAL ASSESSMENT OF FEED DERIVED FROM GM PLANTS

Comment 1
No questions.

B. EXPOSURE ASSESSMENT - ANTICIPATED INTAKE/EXTENT OF USE

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

C. RISK CHARACTERISATION

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

D. POST MARKET MONITORING (PMM) OF FOOD AND FEED DERIVED FROM GM PLANTS

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E. ENVIRONMENTAL RISK ASSESSMENT

E.1. INTRODUCTION

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.2. GENERAL APPROACH OF THE ERA

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.3. SPECIFIC AREAS OF RISK

As stated in the EFSA guidance on the environmental risk assessment of genetically modified plants (EFSA Journal 2010, 8(11):1879) the objective of the ERA is on a case-by-case basis to identify and evaluate potential adverse effects of the GM plant, direct and indirect, immediate or delayed (including cumulative long-term effects) on the receiving environment(s) where the GM plant will be released.
For each specific risk the ERA consists of the six steps described in Directive 2001/18/EC:
1. Problem formulation including hazard identification,
2. Hazard characterisation,
3. Exposure characterisation,
4. Risk characterisation,
5. Risk management strategies,
6. Overall risk evaluation and conclusions.

E.3.1. PERSISTENCE AND INVASIVENESS INCLUDING PLANT-TO-PLANT GENE FLOW

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.3.2. PLANT TO MICRO-ORGANISMS GENE TRANSFER

Comment 1
No comment, adequate information is provided.

Comment 2

Not applicable.

E.3.3. Interaction between the GM plant and target organisms

Comment 1
No comment, adequate information is provided.

Comment 2
Not applicable.

E.3.4. Interaction between the GM plant and non-target organisms (NTOs)

Comment 1
No comment, adequate information is provided.

Comment 2
Not applicable.

E.3.5. Impacts of specific cultivation and management and harvesting techniques

Comment 1
No comment, adequate information is provided.

Comment 2
Not applicable.

E.3.6. Effects on biogeochemical processes

Comment 1
No comment, adequate information is provided.

Comment 2
Not applicable.

E.3.7. Effects on human and animal health

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.3.8. Overall risk evaluation and conclusions

Comment 1
No comment, adequate information is provided.

Comment 2

No questions.

E.4. Post Market Environmental Monitoring plan

E.4.1. Interplay between environmental risk assessment and monitoring

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.4.2. Case-specific GM plant monitoring

Comment 1
No comment, adequate information is provided.

E.4.3. General surveillance for unanticipated adverse effects

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

E.4.4. Reporting the results of monitoring

Comment 1
No comment, adequate information is provided.

Comment 2
No questions.

References

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