Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2014-123 from Pioneer under Regulation (EC) No. 1829/2003

03 July 2018
Ref. SC/1510/BAC/2018_0463

Context

Application EFSA-GMO-NL-2014-123 was submitted by Pioneer Overseas Corporation on 27 November 2014 for the marketing of genetically modified (GM) maize 4114 (Unique Identifier DP-ØØ4114-3) for food and feed uses, import and processing (excluding cultivation) within the European Union (EU), within the framework of Regulation (EC) No. 1829/2003[1].
Maize 4114 was developed by *Agrobacterium tumefaciens*-mediated transformation to confer resistance against specific lepidopteran and coleopteran pests by the expression of the cry1F, cry34Ab1 and cry35Ab1 genes derived from *Bacillus thuringiensis* (Bt) and tolerance to the herbicidal active ingredient glufosinate-ammonium by expression of the PAT gene derived from *Streptomyces viridochromogenes*.

The application was officially acknowledged by EFSA on 30 March 2015 and a formal three-month consultation period of the Member States was started, lasting until 1st of July 2015, 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 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 Service Biosafety and Biotechnology (SBB). Nine experts answered positively to this request, and formulated a number of comments to the dossier. See Annex I for an overview of all the comments and the comments forwarded to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 19 April 2018 (EFSA Journal 2018;16(5):5280[2]), and published on 24 May 2018 together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

In delivering the present advice the Biosafety Advisory Council considered in particular the comments formulated by the experts on application EFSA-GMO-NL-2014-123 and the opinion of EFSA.

[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] See https://www.efsa.europa.eu/fr/efsajournal/pub/5280

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Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of maize 4114 (i.e. during transport and/or processing) into the European environment[3] will lead to any unwanted effects.

2. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

3. Assessment of food/feed safety and nutritional value

3.1. Assessment of compositional analysis

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM maize 4114, in comparison with its conventional counterpart, does not raise safety concerns.

3.2. Assessment of toxicity

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM maize 4114, in comparison with its conventional counterpart, does not raise safety concerns.

3.3. Assessment of allergenicity

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the allergenicity of GM maize 4114, in comparison with its conventional counterpart, does not raise safety concerns.

3.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of GM maize 4114-derived food and feed are not expected to differ from those of conventional maize varieties.

4. Monitoring

With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

[3] As the application doesn't imply a cultivation of the GM crop in the EU, a full environmental assessment is not required in EFSA procedure and was not performed.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the answers of the EFSA GMO panel to the question raised by the Belgian experts, the answers of the applicant to the EFSA GMO panel questions and considering the data presently available, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that the potential environmental release of maize 4114 is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, maize 4114 is unlikely to pose any risk to human and animal health;

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

Dr. Corinne Vander Wauven
President of the Belgian Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2014/123 and Comments submitted on the EFSAnet on mandate of the Biosafety Council (ref. BAC_2015_0355)

Bioveiligheidsraad
Conseil de Biosécurité

16/06/2015

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2015_0355
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2014/123
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 21 April 2015.
Coordinator: Michel Van Koninckxloo
Experts: Jan Van Doorsselaere (KATHO), Leo Fiems (ILVO), André Huyghebaert (UGent), Hadewijch Vanhooren (KUL), Peter Smet (Consultant), Johan Grooten (UGent), Michel Van Koninckxloo (HEP Hainaut-Condorcet), Jacques Dommes (ULg), Frank Van Beusegem (UGent).
Domains of expertise of experts involved: Molecular characterisation, DNA/RNA/protein analysis, herbicide tolerance, animal and human nutrition, food/feed processing, toxicology, general biochemistry, statistics, immunology, alimentary allergology, plant allergens, agronomy, ecology, breeding techniques, plant biology.
SBB: Didier Breyer, Fanny Coppens, Adinda De Schrijver, Martine Goossens, Aiko Gryspeirt, Philippe Herman, Katia Pauwels

♦ INTRODUCTION

Dossier **EFSA/GMO/NL/2014/123** concerns an application submitted by the company **Pioneer** for authorisation to place on the market genetically modified **4114 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 1st April 2014.

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. Comments placed on the EFSAnet are indicated in grey.

List of comments/questions received from the experts

GENERAL COMMENTS

Comment 1

Single events dealing with Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins have already been assessed and approved by EFSA. Approved genetically modified events that have been combined by conventional plant breeding, and containing genetically modified traits that are not likely to interact in a manner affecting safety, such as in the case of DP-ØØ4114-3 maize, can be considered to be as safe as their conventional counterparts (Pilacinski et al., 2011).
Therefore, DP-ØØ4114-3 maize is considered as safe as conventional maize in animal and human nutrition.

However, a side effect of this dossier is the herbicide use of glufosinate ammonium, which may result in autism-like phenomena, and the accuracy of the current safety tests of pesticide exposure may cause concerns. Further investigation is desirable.

SBB Comment:
Assessing pesticide safety is out of the remits of the Biosafety Council.

Comment 2

The information provided in the application is sufficient.

Comment 3

No comment.

Comment 4

No comments.

A. HAZARD IDENTIFICATION AND CHARACTERISATION

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

Comment 1

The information provided in the application is sufficient.

Comment 2

No comment, adequate information is provided.

Comment 3

No comments.

Comment 4

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

The information provided in the application is sufficient.

Comment 2

No comment, adequate information is provided.

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 major comments. But from the dossier it is not obvious to deduce how the identities of the various PCR-generated probes (e.g. by sequencing, exact size verification) used in the Southern blot analyses were verified.

Comment 3

Page 12 mentions that 4114 Maize is one cultivar (breeding line). Figure 1.2.2 (p 20) mentions three hybrid crosses.

This is somewhat confusing. I was expecting a breeding scheme which results in one commercial cultivar.

For instance is 4114 F1(9), F1(13) or F1(5)? Because I suppose that these F1 hybrids are different from each other since there are several inbred lines involved? Or should I interpret that 4114-3 is one cultivar combining the three hybrids mentioned in the figure. This could be clarified.

No further comments.

A.3. COMPARATIVE ASSESSMENT

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

Comment 1

The information provided in the application is sufficient.

Comment 2

The safety was evaluated in a comparison of 4114 maize with non-GM near isogenic control maize and other non-GM maize hybrids.

This approach is in line with previous dossiers.

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

Comment 1

The information provided in the application is sufficient.

Comment 2

The study was conducted during the 2011 growing season at six sites in het US and during the 2012 season at four sites (three in de the US and one in Canada).

A randomized complete block design, containing four blocks, was applied. Each block contained:

- conventional herbicide 4114 maize (CHT),
- intended herbicide-treated 4114 maize (IHT),
- non-GM near isoline CHT control maize (control maize),
- three of six non-GM CHT commercial maize lines.

Samples of grain and forage were taken for nutrient analysis.

No further comments.

A.3.3. COMPOSITIONAL ANALYSIS

Comment 1

The compositional analysis showed that, from the 71 components that were analysed, 23 were different ($P<0.05$) in comparison with the reference maize, and 8 tended to be different ($P<0.10$) for samples coming from a conventional herbicide treatment, whereas 30 were different ($P<0.05$) in comparison with the reference maize, and 7 tended to be different ($P<0.10$) for samples coming from a herbicide treatment with glufosinate ammonium. Agapito-Tenfen et al. (2014) reported that stacking transgenic inserts into the genome of a genetically modified maize hybrid variety may impact the overall expression of endogenous genes: observed protein changes differ significantly from those of single event lines and a conventional counterpart. However, mean values of the analysed components were within the range of reference maize varieties, so that differences are not really relevant from a food or feed safety perspective.

Comment 2

The information provided in the application is sufficient.

Comment 3

Nutrients were analysed in accordance with OECD guidelines.

Grain analysis included proximate, fiber, fatty acids, amino acids, minerals, vitamins, secondary metabolites and anti-nutrients.

Forage analysis included proximates, fiber and minerals.

Some comments on the selection of nutrients in grain:
- proximates
no remarks on moisture, crude fat, crude protein and ash.
- fibre
as in previous submissions data of crude fibre, acid detergent fibre and neutral detergent fibre are presented; this approach is relevant for animal feed; data of dietary fibre, soluble and insoluble dietary fibre are more relevant in human nutrition.
- carbohydrates
only data of the carbohydrate fraction as a whole are included, no data are available on the starch and sugar content
- fatty acids
relevant fatty acids from C8 to C24, including saturates, mono- unsaturates and poly-unsaturates, have been studied.
- amino acids
the whole range of amino acids, particularly the indispensible (essential) amino acids, has been evaluated
- minerals
no particular remark as relevant minerals have been studied.
- vitamins
relevant vitamins have been studied with the exception of tocotrienols; from a human nutrition standpoint there is growing interest in tocotrienols in addition to tocopherols.
- secondary metabolites and anti-nutrients
no further comments.
- phytosterols
are not mentioned in the OECD guidelines however it is well documented that phytoterols reduce cholesterol absorption; maize oil is a good source of phytosterols in our food.

Comparative analysis
The applicant considers 91 analytes. Results were statistically evaluated with exclusion of some results below the LOQ, limit of quantification.
All compounds studied via difference and equivalence testing fell into outcome 1 to 4 or not categorized for both 4114 maize entries. No analytes were found in category 5 to 7.
Results were further explained in detail. If differences were found, results were discussed in term of biological significance.

As an overall conclusion the applicant states that all nutrient changes fell within the range of biological variation.

Although I have some comments on the selection of nutrients I agree with the overall conclusion of the applicant.

Comment 4
The amounts of anti-nutrients in 1441 maize seem to be in the normal range and therefore of no concern.

A.3.4. AGRONOMIC AND PHENOTYPIC CHARACTERISTICS

Comment 1
The information provided in the application is sufficient.

A.3.5. EFFECTS OF PROCESSING

Comment 1

The information provided in the application is sufficient.

Comment 2

Two major processes of maize grain are applied in the EU: the wet milling and the dry milling processes.
The applicant concludes that none of the processing outcomes will be affected by the traits introduced in 4114 maize.

I agree with this conclusion.

A.4. TOXICOLOGICAL ASSESSMENT

A.4.1. METHODOLOGY USED FOR TOXICITY TESTS

Comment 1

The amounts of Cry1F, Cry34Ab1, Cry35Ab1, and PAT proteins expressed in 4114 maize are comparable to those in similar events (1507, 59122 and 1507x59122).

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

Based on the weight of evidence in this dossier it is unlikely that DP-ØØ4114-3 maize will pose serious risks for toxicity.

However, with regard to glufosinate ammonium, results of Laugeray et al. (2014), using 7-week old female C57Bl6 mice, provided new 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 as DP-ØØ4114-3 maize.

SBB Comment:
Assessing pesticide safety is out of the remits of the Biosafety Council.

Comment 2

4114 maize is a new GM event with the 4 genes all integrated into 1 single locus in the maize nuclear genome. No new genetic modifications have been introduced in maize 4114. The genes are the same as the genes inserted in maize 1507 and maize 59122: the same gene expression cassettes were used. The proteins expressed are identical to the proteins expressed in the maize events 1507, 59122, 1507x59122. The

equivalency of the proteins was shown by sequencing of the protein coding regions of the insertion, comparative immunoblot analysis, field tests showing comparable expression of the proteins in maize 4114, 1507, 59122, and 1507x59122. The safety of the proteins CRY1F, CRY34Ab1, CRY35Ab1, PAT has been confirmed in detail (bioinformatics analysis, mammalian toxicity studies, resistance to proteolytic enzymes, stability testing, ...) in accordance with the applications of authorisation of maize 1507 (and renewal) and maize 59122. The safety of the combination of the Cry proteins with PAT has been confirmed in several EFSA opinions. Updated bioinformatics evaluations were provided.
No further questions.

Comment 3
No comment, adequate information is provided.

Comment 4
All proteins have been tested in previous notifications. No toxic effects could be detected. All proteins do rapidly degrade in SGF and/or SIF. Up-to-date homology searches have been conducted, which raised no concerns.

A.4.3. ASSESSMENT OF NEW CONSTITUENTS OTHER THAN PROTEINS

Comment 1
No comments.

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

Comment 1
No change in compositional constituents was aimed with this genetic modification.

Comparative compositional analysis of 4114 maize grain and forage (Linderblood et al, 2014; Hong 2014; Zimmermann, 2014: Annex 13, 14, 15).
The nutrient compositional analysis was performed on grain and forage of the field studies with maize grown in the 2011-2012 growing seasons in the USA (9 locations) and Canada (1 location) (Nubel et al., 2014; Linderblood et al, 2014: Annex 8, 9).
Groups used in the statistical analysis (Difference test) : 1) Near-isoline PH09BxPH581 F1 hybrid: conventional herbicide-treated; 2) 4114 maize: conventional herbicide-treated (CHT); 3) 4114 maize: glufosinate treated.
Groups used in the statistical analysis (Equivalence test) : 1) 12 non-GM conventional herbicide-treated commercial reference maize lines; 2) 4114 maize: conventional herbicide-treated (CHT); 3) 4114 maize: glufosinate treated.

Grain:
Sodium, Vitamin B5, Trypsin inhibitor: Not categorised for CHT and glufosinate treated 4114 maize
Raffinose: Equivalence more likely than not (cat II)
Forage:
Phosphorus: Equivalence more likely than not (cat II)
All values from the CHT and glufosinate treated maize grains and forage fell within the reference range.

Furthermore, the observed changes did not have an impact on the nutritional properties of the GM 4114 maize derived feed as tested in the 42-day poultry study.

No particular natural constituents of maize are considered to be of significant concern to require additional information or further risk assessment.

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

Comment 1

The applicant submitted two 90-day feeding toxicity studies in rodents and a nutritional performance study.

90-day feeding studies in rodents (Mukerji, 2012; Pathology working group, 2011; Mukerji, 2014: Annex 20a,b,c, annex 23)

No further comments and questions concerning the tumours.

Initial study: There is a trend in decrease in body weight (bw) and bw gain in both sexes for the 4114GLU group (the 4114maize group treated with glufosinate). This is not seen in the 4114maize group treated with conventional herbicides. In the repeated study no 4114GLU group was tested because no tumours were found in this group in the initial study. As such, it could not be verified if the decrease in bw (gain) was incidental.

However, the bw (gain) in the 42-day poultry study was not affected for this test group in both males and females. The trend in decrease in bw (gain) observed in the initial 90-day feeding study in rodents is of no biological relevance.

42-day poultry feeding study (Smith, 2011: Annex 31, 31a, 31b)

Groups: 1) Non transgenic near-isogenic control maize 091 grain: conventional herbicide-treated; 2) 4114 maize grain: conventional herbicide-treated; 3) 4114 maize grain: glufosinate treated, and 3 reference maize grains 4) 32D78, 5) 33N29, 6) 34P88. No adverse effects could be detected.

Remark: 4114 maize is developed to be able to use an herbicide regime with glufosinate. Data concerning the use of the herbicides in the field trials is available. However, no data is made available concerning the identification and quantification of the herbicide glufosinate and metabolite residues in the GM plants and grain used for food/feed. As the use of the herbicide is linked to the genetic modification, the applicant should make the residue data available (a diet pesticide analysis is available but without data concerning glufosinate).

Comment 2

A 90-day rat feeding study raised concerns regarding renal effects of the product under notification. A second study was conducted, showing no renal effects at all. So, based on this study, it can be concluded that incorporation of the event in animal feed up to 32% (w/w) does not raise any concern regarding health effects.

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

Based on the weight of evidence in this dossier it is assumed that DP-ØØ4114-3 maize does not pose a serious allergenic risk, and that it is comparable with conventional maize with regard to allergenicity.

Comment 2

The 4114 Maize GMO combines in a single genetic construct traits that otherwise were inserted as separate events in several GMOs that have been scrutinized before by EFSA for safety. The weight-of-evidence assessment then performed did not indicate that the insert encoded proteins possessed an allergenic potential. An updated amino acid sequence comparison with known allergens along with the safe use since 2003-2006 of those Cry1F, Cry34Ab1, Cry35Ab1 and/or PAT protein containing commercial maize varieties, further substantiate a lack of allergenic potential of the introduced proteins.

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

Comment 1

The host plant not being considered as an allergenic food along with the apparent lack of allergenicity of the introduced proteins indeed support the applicant's conclusion that it is unlikely that the 4114 Maize plant will possess an altered allergenicity as a result of the genetic modification.

A.5.3. ADJUVANTICITY

Comment 1

No comments. I agree with the applicant's conclusion that for the foreseen use of the 4114 GMO, there is no risk of adjuvancy.

A.6. NUTRITIONAL ASSESSMENT

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

Comment 1

The information provided in the application is sufficient.

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

Comment 1

Based on the information from this dossier, and from the articles referred to in this dossier, it can be assumed that the mean nutritional value of DP-ØØ4114-3 maize is similar to its conventional counterpart.

Comment 2

The information provided in the application is sufficient.

B. EXPOSURE ASSESSMENT - ANTICIPATED INTAKE/EXTENT OF USE

Comment 1

Proteins: No further questions. The assessment made is sufficiently documented.
Remark: 4114 maize is developed to be able to use an herbicide regime with glufosinate. No data is made available concerning the identification and quantification of the herbicide glufosinate and its metabolite residues in

the GM plants and grain used for food/feed. As the use of the herbicide is linked to the genetic modification, it is in my opinion very logical that the applicant should make the residue data available and make an estimation of the anticipated intake (food/feed). I know that this is not the opinion of EFSA and the SBB.

Comment 2
The information provided in the application is sufficient.

C. RISK CHARACTERISATION

Comment 1
The information provided in the application is sufficient.

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

Comment 1
Post-market monitoring is not necessary.

E. ENVIRONMENTAL RISK ASSESSMENT

E.1. INTRODUCTION

Comment 1
The information provided in the application is sufficient.

Comment 2
No comment.

E.2. GENERAL APPROACH OF THE ERA

Comment 1
Herbicide use in the USA on soybean, corn and cotton declined slightly in the first years following introduction of herbicide resistant genetically modified 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.

Although DP-ØØ4114-3 maize is not intended for cultivation in the EU, it may have consequences in countries were DP-ØØ4114-3 maize is cultivated. The continued application of the same herbicide in subsequent rotations may lead to increased selection pressure for herbicide resistant weed populations. Furthermore, concerns about the autism-like phenomena, provoked by glufosinate ammonium, and the accuracy of current safety tests of pesticide exposure (Laugeray et al., 2014), necessitates at least to rigorously respect the application doses of this herbicide in weed management.

Comment 2
The information provided in the application is sufficient.

Comment 3

No comment, adequate information is provided.

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

The information provided in the application is sufficient.

Comment 2

No comment, adequate information is provided.

E.3.2. PLANT TO MICRO-ORGANISMS GENE TRANSFER

Comment 1

The information provided in the application is sufficient.

Comment 2

No comment, adequate information is provided.

E.3.3. INTERACTION BETWEEN THE GM PLANT AND TARGET ORGANISMS

Comment 1

Not relevant.

Comment 2

No comment, adequate information is provided.

E.3.4. INTERACTION BETWEEN THE GM PLANT AND NON-TARGET ORGANISMS (NTOS)

Comment 1

Not relevant.

Comment 2
No comment, adequate information is provided.

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

Comment 1
Not applicable.

Comment 2
No comment.

E.3.6. Effects on biogeochemical processes

Comment 1
Not applicable.

Comment 2
No comment.

E.3.7. Effects on human and animal health

Comment 1
The information provided in the application is sufficient.

Comment 2
No comment.

E.3.8. Overall risk evaluation and conclusions

Comment 1
The information provided in the application is sufficient.

Comment 2
Adequate information was provided, supporting the conclusion that intended use of the 4114 maize in the EU will pose negligible risks to human and animal health or the environment.

E.4. Post Market Environmental Monitoring plan

E.4.1. Interplay between environmental risk assessment and monitoring

Comment 1
The information provided in the application is sufficient.

E.4.2. CASE-SPECIFIC GM PLANT MONITORING

Comment 1

The information provided in the application is sufficient.

E.4.3. GENERAL SURVEILLANCE FOR UNANTICIPATED ADVERSE EFFECTS

Comment 1

The information provided in the application is sufficient.

E.4.4. REPORTING THE RESULTS OF MONITORING

Comment 1

The information provided in the application is sufficient.

References

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