Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC/2015_0585

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/BE/2012/110 from Monsanto under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/BE/2012/110 was submitted by Monsanto on 21 June 2011 for the marketing of genetically modified maize MON87427 for food and feed uses, import and processing within the framework of Regulation (EC) No. 1829/2003[1]. Maize MON87427 contains a single insert expressing the CP4 EPSPS protein conferring tolerance to the herbicidal active substance glyphosate. Expression of this new protein is however absent or limited in male reproductive tissues.

The application was officially acknowledged by EFSA on 03 January 2013. 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 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). Seven experts answered positively to this request, and formulated a number of comments to the dossier, which were edited by the coordinator. See Annex I for an overview of all the comments and for the list of comments actually placed on the EFSAnet on 29 March 2013.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 27 May 2015 (EFSA Journal 2015; 13(6):4130[2], and published together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 22 July 2015 the opinion of EFSA was forwarded to the Belgian experts. They were invited to give comments and to react if needed to the answers given by the EFSA GMO Panel, in particular in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA. The comments formulated by the experts together with the opinion of EFSA including the answers of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council given below.

[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 http://www.efsa.europa.eu/en/efsajournal/pub/4130.htm

Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of maize MON87427 seeds (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 MON87427, in comparison with its conventional counterpart do not raise safety concerns.

3.2. Assessment of toxicity

The Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns. The toxicity of CP4 EPSPS protein has been assessed in several (about 20) applications and no safety concerns were identified.

3.3. Assessment of allergenicity

The potential allergenicity of the newly expressed CP4 EPSPS protein has been assessed in the context of this application but also in the context of several previous applications. No concerns in relation to allergenicity were identified.

With regard to the allergenicity of the whole GM plant, to date maize is not considered to be a common allergenic food. Based on the available information, the Biosafety Council considers that there is no evidence that overall allergenicity of maize MON87427 is changed as a result of the genetic modification.

3.4. Nutritional value

Based on compositional data the Biosafety Advisory Council agrees with the EFSA GMO panel that the nutritional value of food and feed derived from maize MON87427 is not expected to differ from that of food and feed derived from non-GM maize varieties.

[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 achieved.

4. Monitoring

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 answers of the EFSA GMO Panel to the questions 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 is of the opinion that in the context of its proposed uses, maize MON87427 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 monitoring systems.

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

Annex I: Full comments of experts in charge of evaluating application EFSA/GMO/BE/2012/110 and *comments submitted on the EFSAnet (ref. BAC_2013_0222)*

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Bioveiligheidsraad
Conseil de Biosécurité

29-03-2013

Secretariaat
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/BE/2012/110
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 14 January 2013
Coordinator: Prof. Dirk Reheul
Experts: Leo Fiems (ILVO), Rony Geers (KUL), Johan Grooten (UGent), André Huyghebaert (UGent), Peter Smet (Consultant), Michel Van Koninckxloo (Hainaut Développement territorial – CARAH), Hadewijch Vanhooren (KUL)
Domains of expertise of experts involved: Toxicology in vitro/in vitro, general biochemistry, human nutrition, animal nutrition, biochemistry of food/feed, food/feed processing, food/feed safety, allergology, agronomy, agro-ecology, maize;
SBB: Didier Breyer, Fanny Collard, Adinda De Schrijver, Martine Goossens, Philippe Herman, Katia Pauwels

♦ INTRODUCTION

Dossier **EFSA/GMO/BE/2012/110** concerns an application submitted by the company **Monsanto** for authorisation to place on the market genetically modified **Maize MON87427** 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 3 January 2013.

The scope of the application is:
(a) GM food
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
(b) GM feed
☒ Feed containing or consisting of GM plants
☒ Feed produced from GM plants
(c) GM plants for food or feed use
☒ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in the EU

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 received from the experts

GENERAL COMMENTS

Comments/Questions of the expert

Comment 1

Assuming that only CP4 EPSPS protein was inserted, without plasmid vector PV-ZMAP1043 backbone sequences, the potential toxic effects of MON 87427 maize to humans and animals could be considered as negligible. Moreover, EFSA (2008) assessed soybean MON 89788, containing CP4 EPSPS protein, and concluded that CP4 EPSPS protein does not raise any safety concern.

Comment 2

What's the benefit of producing this new GMO maize containing CP4 EPSPS protein? This company already developed modified maize containing this glyphosate-tolerant protein.
Additional comment SBB:
See also comment under A.2.2.
The assessment of the benefits of a new GMO is outside the remit of the Biosafety Council.

Comment 3

See A.2.2.

A. HAZARD IDENTIFICATION AND CHARACTERISATION

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

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient

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

Comments/Questions of the expert

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

Comments/Questions of the expert

Comment 1

Comment: to understand clearly the traits and characteristics which have been introduced or modified in MON 87427 it is necessary to read both Part II Scientific information and the confidential reference Dohleman and Ahmad 2012a (CBI).

A.3. COMPARATIVE ASSESSMENT

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

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

Comment 2

In the study maize MON87427 was compared with the conventional counterpart. Several conventional commercial reference varieties were included to provide a range of comparative values. They represent a range of genetic backgrounds and phenotypic characteristics.
No remarks.

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

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

Comment 2

No remarks

A.3.3. COMPOSITIONAL ANALYSIS

Comments/Questions of the expert

Comment 1

Although statistical differences have been reported (P<0.05) for some proximates (palmitic acid, oleic acid, and linolenic acid), or tendencies (P<0.10) for a compositional difference (moisture), the differences may not be biologically relevant, without further consequences from a food and feed safety perspective.

Comment 2

There seems to be no problem with the amounts of secondary metabolites and anti-nutrients.

Comment 3

The information provided in the application is sufficient.

Comment 4

As it is always the case, the OECD document was used as a guideline. The composition of maize MON87427 was compared with the conventional counterpart and commercial varieties.
This consensus document emphasises quantitative measurements of:

- essential nutrients,
- anti-nutrients,
- toxicants.

Essential nutrients cover the well known nutrients in maize grain: proximates, fibre constituents, carbohydrates by calculation, amino acids, fatty acids, vitamins and minerals. No attention is given to important constituents of maize like tocotrienols, in addition to tocopherols, and to carotenoids.The analysis of forage was limited to constituents important in animal feed.

Anti-nutrients assessed in grain include phytic acid, raffinose and secondary metabolites like furfural, ferulic and p-coumaric acid. No attention is given to the presence of mycotoxins, in particular aflatoxins.

Results of the comparative analysis of grain and forage are presented for:

- maize MON87427 treated with glyphosate,
- maize MON87427 untreated with glyphosate.

The file contains a detailed analysis of the results. The applicant concludes that maize MON87427, treated and untreated, does not contribute to compositional variability in maize.

Although I have some comments on the selection of the constituents studied, I agree with this conclusion.
The applicant demonstrated indeed that there is compositional equivalence between maize MON87427 and conventional maize according to the OECD guidance document.

My first series of comments are related to the type of constituents, mentioned in the document and the methods used:

- obsolete methods are used for the determination of fibre, important in human nutrition; these methods are however still used for animal feed,
- the concept of carbohydrates by calculation is not at all accepted in human nutrition (see food tables),
- the presence of particular nutrients, present in minor amounts, is overemphasised; they do not contribute at all to human nutrition; on the other hand constituents like tocotrienols, important anti-oxidants, are not included;
- in addition significant nutrients in maize like carotenoids are not included. I mention carotenoids like β – carotene, lutein, zeaxanthin, cryptoxanthin; it is well recognized that they have important anti-oxidative properties (e.g. lutein and zeaxanthin in eye health).

The guidance documents has to be urgently revised and updated in order to cope with the actual knowledge in human nutrition.

My second comment is related to the resistance to the formation of mycotoxins, particularly aflatoxins. It is well known that maize is quite sensitive to the formation of particular mycotoxins. The presence of mycotoxins is a real human health issue. Taking into account the experimental design the determination of particular mycotoxins would really contribute to the comparative analysis in relation to human and animal health.

Additional comments SBB:
- As said by the expert the nutritional and compositional parameters have been analysed according the OECD recommendations (OECD, 2002).
Also the method used for the determination of Dietary fibres (TDF) is the one recommended in the OECD consensus document.
- As regards the assessment of the carbohydrates, the following comment has been transmitted to EFSA within the context of the evaluation of previous dossiers:
"It is noted that the carbohydrates are reported in values 'by difference'. This way of reporting is no longer accepted for the inclusion in nutrient labels. We recommend to alter this into reporting in the form of 'available carbohydrates'.

A.3.4. AGRONOMIC AND PHENOTYPIC CHARACTERISTICS

Comments/Questions of the expert

Comment 1

Except for the point seen in A.2.2., the information provided in the application is sufficient.

A.3.5. EFFECTS OF PROCESSING

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

Comment 2

As maize 87427 is substantially equivalent to conventional maize, no differences in the production and processing are expected.
The processes of the wet milling and dry milling processes are described as well as the products obtained.

I agree that no differences in processing are to be expected.

A.4. TOXICOLOGICAL ASSESSMENT

A.4.1. METHODOLOGY USED FOR TOXICITY TESTS

Comments/Questions of the expert

Comment 1

No further comments and 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

Comments/Questions of the expert

Comment 1

EFSA (2008) concluded that CP4 EPSPS protein does not raise any safety concern.

Comment 2

No further comments and questions.

Comment 3

The amounts of CP4 EPSP protein in maize grain are comparable with those in similar products (for instance dossiers 80 and 92)

7a) Degradation of the CP4 EPSPS protein in simulated gastric fluid (Harrison *et al*. (1996)).

Rapid degradation was demonstrated earlier.

7b) Degradation of the CP4 EPSPS protein in simulated intestinal fluid (Harrison *et al.* (1996)).

Rapid degradation was demonstrated earlier.

7c) CP4 EPSPS: Acute Oral Toxicity Study in Mice (Harrison *et al.*, 1996).

E. coli-produced CP4 EPSPS protein was administered as a single dose by gavage to three groups of 10 male and 10 female CD-1 mice at dose levels up to 572 mg/kg body wt (bw).

Therefore, the No Observable Adverse Effect Level (NOAEL) for CP4 EPSPS was considered to be 572 mg/kg bw, the highest dose tested.

A 28-day repeated dose study was not performed. For the moment, no further testing is needed.

7d) CP4 EPSPS: Sequence homology with known toxins (**From CBI:** Kang and Silvanovich, 2012b)

The results of this analysis indicate that no biologically relevant sequence similarities were observed between the CP4 EPSPS protein and any toxin, or biologically active proteins.

Comment 4

Two studies are reported in relation to toxicity studies with mice:
1) Naylor (1993): 3 treatment groups + 2 control groups: the statistical power for the male group is ok, but not for the female group, due to the high CV within each group
2) Harrison et al (1996): 3 treatments + 2 control groups: statistical power is ok for both sexes.

The difference between the two studies is strange, because treatments are the same, and the mean value of the results for each group is also the same, but not the reported sd-values, which explains the difference in power results.

A.4.3. ASSESSMENT OF NEW CONSTITUENTS OTHER THAN PROTEINS

Comments/Questions of the expert

Comment 1

No further comments and questions.

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

Comments/Questions of the expert

Comment 1

No further comments and questions.

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

Comments/Questions of the expert

Comment 1

No whole food/feed studies in animals available, however a detailed compositional analysis was carried out: No further animal testing needed.

Herbicide and herbicide metabolites: What are the residue levels in the grain (animal and human health)?
Data is lacking concerning the occurrence, levels and fate of residues of the herbicide and its metabolites in the plant tissues and the potential adverse health effects as indirect effects associated with the use on human and animal health. Although the effect of the herbicide on human and animal health falls under Directive 91/414/EC, it is the duty and responsibility of the toxicologist assessing the risk of the genetic modification to evaluate and discuss the complete picture of the genetic modification. As the herbicide is used as integral parts of the biotechnology-based weed management strategy, the risk assessment must also consider the potential impact on human and animal health.

Additional comment from the SBB:
The assessment of the safety of the herbicide and its residues is outside the remit of the Biosafety Council.

Comment 2

a) 42-day poultry feeding study ()

Not performed.
Was also conducted earlier (92).

b) 90-Day rat feeding study (author).

Not performed.
No further testing is needed at this moment.

Comment 3

The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1

Monsanto Company considered that an assessment of the allergenicity of the whole MON 87427 plant is not necessary. Fortunately for Monsanto, because IgE reactivity suggests that CP4-EPSP is not an allergen (Green et al., 2011).

Comment 2

The non-allergenic source, lack of structural similarities to known allergens and rapid digestion in simulated gastric fluid indeed comply with the conclusion of an absence of a significant allergenic risk of the newly expressed protein.

I have no further comments or questions.

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

Comments/Questions of the expert

Comment 1

The applicants propose on the basis of previously presented results that the MON87427 GM plant is comparable to and as safe as conventional maize. Therefore they consider as unnecessary a further assessment of the allergenicity of the whole MON87427 GM plant. I tend to agree with this conclusion also on the basis of two additional features of the GM plant:
1. The transgene is not expressed in pollen microspores and pollen grains, thus effectively limiting animal/human exposure to the intended food products.
2. The transgene does not introduce new enzymatic functions or a gain of function but instead introduces a loss of function (reduced affinity for the glyphosate inhibitor), thus reducing the risk for off-target effects that otherwise may increase allergenicity of the whole GM plant.

I have no further questions or comments.

A.5.3. ADJUVANTICITY

Comments/Questions of the expert

Comment 1

I have no further comments or questions.

A.6. NUTRITIONAL ASSESSMENT

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

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1

Taylor et al. (2005) showed that stacked maize grain from MON 88017, containing CP4 EPSPS and Cry3Bb1 proteins, is as nutritious as traditional maize when fed to broilers.

Comment 2

The information provided in the application is sufficient.

B. EXPOSURE ASSESSMENT - ANTICIPATED INTAKE/EXTENT OF USE

Comments/Questions of the expert

Comment 1

Intake of some species may be underestimated. Cow body weight used to calculate intake in the dossier is the initial body weight mentioned by Ouellet et al. (2003). However, body weight increased up to 620 kg at week 17 of the experiment. Moreover, daily milk yield at peak lactation may be close to, or even higher than 40 kg (Daniel et al., 2013). Furthermore, there is a tendency for increasing the use of distillers dried grains with solubles (DDGS) in animal nutrition as a by-product from the bio-fuel industry. Protein content, and consequently also CP4 EPSPS protein, is increased by approximately factor 3 in DDGS compared to maize grain. Nevertheless, the fact that CP4 EPSPS protein does not

raise any safety concern (EFSA, 2008) means that the underestimated intake has no implications for the risk assessment.

Comment 2

The information provided in the application is sufficient.

C. RISK CHARACTERISATION

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E. ENVIRONMENTAL RISK ASSESSMENT

E.1. INTRODUCTION

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E.2. GENERAL APPROACH OF THE ERA

Comments/Questions of the expert

Comment 1

Data indicate no correlation between CP4 EPSPS protein expression and any increased tendency for persistence or spread in the environment, alterations in reproductive biology affecting gene flow, or negative impacts on other organisms in the environment (CERA, 2010).

Comment 2

The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1

MON 87427 will not be cultivated in the EU and the information provided in the application is sufficient.

E.3.2. PLANT TO MICRO-ORGANISMS GENE TRANSFER

Comments/Questions of the expert

Comment 1

MON 87427 will not be cultivated in the EU and the information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1

Not applicable

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

Comments/Questions of the expert

Comment 1

Not applicable

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

Comments/Questions of the expert

Comment 1

MON 87427 will not be cultivated in the EU.

E.3.6. Effects on biogeochemical processes

Comments/Questions of the expert

Comment 1

MON 87427 will not be cultivated in the EU and the information provided in the application is sufficient.

E.3.7. Effects on human and animal health

Comments/Questions of the expert

Comment 1

EFSA (2008) assessed that CP4 EPSPS protein does not raise any safety concern.

Comment 2

The information provided in the application is sufficient.

E.3.8. Overall risk evaluation and conclusions

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E.4. Post Market Environmental Monitoring plan

E.4.1. Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E.4.2. Case-specific GM plant monitoring

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E.4.3. General surveillance for unanticipated adverse effects

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

E.4.4. Reporting the results of monitoring

Comments/Questions of the expert

Comment 1

The information provided in the application is sufficient.

References

CERA (2011). A review of the environmental safety of the CP4 EPSPS protein. Environ. Biosafety Res. 10: 5–25

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