Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2009-75 (genetically modified oilseed rape MS8 x RF3 x GT73) from Bayer and Monsanto under Regulation (EC) No. 1829/2003

30 September 2020
Ref. SC/1510/BAC/2020_0870

Context

Application EFSA-GMO-NL-2009-75 was submitted by Bayer and Monsanto for the marketing of genetically modified (GM) oilseed rape MS8 x RF3 x GT73 (Unique Identifier ACS-BN005-8 x ACS-BN003-6 x MON-00073-7), for food and feed uses, import and processing (excluding cultivation), with the exception of isolated seed protein for food, within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

The three-event stack oilseed rape MS8 x RF3 x GT73 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- MS8, expressing Barnase and the PAT protein for tolerance to glufosinate-ammonium herbicides;
- RF3, expressing Barstar (Barnase inhibitor) and the PAT protein;
- GT73, expressing the CP4 EPSPS and GOXv247 proteins which confer tolerance to glyphosate herbicides.

The application was validated by EFSA on 11 May 2012. A formal three-month consultation period of the Member States was started, lasting from 7 February 2013 until 14 May 2013, 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). Six 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 on 15 April 2013.

The opinion of the EFSA Scientific Panel on GMOs was published on 20 May 2016 (EFSA Journal 2016;14(5):4466[2]), together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period. The GMO Panel was not in the position to complete the safety assessment of products rich in protein from oilseed rape MS8 x RF3 x GT73 and its subcombinations MS8 x GT73 and RF3 x GT73, according to the scope as defined in the application EFSA-GMO-NL-2009-75, because of the lack of a 28-day toxicity study in rodents with the GOXv247 protein, in line with the applicable guidelines. Following receipt of additional information from the applicant, EFSA published a complementing statement on 30 July 2020 (EFSA Journal 2020;18(7):6200)[3].

[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/en/efsajournal/pub/4466
[3] See https://www.efsa.europa.eu/en/efsajournal/pub/6200

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In delivering the present advice the BAC considered in particular the following information:
- The comments formulated by the experts on application EFSA-GMO-NL-2009-75;
- The opinion of EFSA and its complementing statement;
- The advices already adopted by the BAC on the single events. The conclusions of the BAC for the most recent previous applications for the events were as follows:

Event	Application number	BAC advice	Conclusions
MS8, RF3 and MS8 x RF3	EFSA-GMO-RX-004	BAC/2018/0056 (30/01/2018)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.
GT73	EFSA-GMO-RX-002	BAC/2020/0869 (30/09/2020)	Unlikely to pose any risk to human and animal health. No risk identified for the European environment.

All GM oilseed rape events mentioned in the table above are authorised in the EU for food and feed uses[4].

Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of oilseed rape MS8 x RF3 x GT73 (i.e. during transport and/or processing) into the European environment[5] will lead to environmental harm.

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

Taking into account the previous assessment of the single events and the new data on compositional analysis provided by the applicant for the three-stacked event, the Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM oilseed rape MS8 x RF3 x GT73, in comparison with its conventional counterpart, do not raise safety concerns.

3.2. Assessment of toxicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed Barnase, Barstar, PAT, CP4 EPSPS and GOXv247 proteins in the context of previous applications, and no safety concerns were identified. Taking into account the updated information available in the current application, the Council is of the opinion that its previous conclusions remain valid.
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event does not raise toxicological concerns.

3.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed Barnase, Barstar, PAT, CP4 EPSPS and GOXv247 proteins in the context of previous applications, and no concerns were identified. Since no new information on allergenicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event does not raise concerns regarding the allergenicity.

[4] See EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
[5] As the application doesn't imply cultivation of the GM crop in the EU, a full environmental assessment is as in the case of a cultivation file is not warranted.

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 oilseed rape MS8 x RF3 x GT73-derived food and feed are not expected to differ from those of conventional oilseed rape varieties.

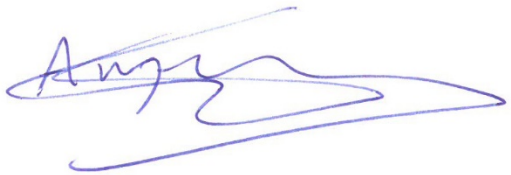
4. Monitoring

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

Conclusion

Based on the whole set of data on oilseed rape MS8 x RF3 x GT73 provided by the applicant, the scientific assessment of the dossier done by the Belgian experts, the opinion of EFSA and its complementing statement, the answers of the EFSA GMO panel to the questions raised by the Belgian experts, and the advices already adopted by the BAC on the three single events, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that the potential environmental release of oilseed rape MS8 x RF3 x GT73 resulting from accidental spillage is unlikely to pose any threat to the European environment;
2) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that could impact on the food or feed safety;
3) Agrees with the GMO panel of EFSA that in the context of its proposed uses, oilseed rape MS8 x RF3 x GT73 is unlikely to pose any risk to human and animal health;



Dr. ir. Geert Angenon
President of the Belgian Biosafety Advisory Council

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA-GMO-NL-2009-75 and Comments submitted on the EFSAnet on mandate of the Biosafety Council (ref. BAC_2013_0291)

Bioveiligheidsraad
Conseil de Biosécurité

15-04-2013

Secretariaat
Secrétariat

N./réf. : WIV-ISP/41/BAC_2013_0291
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2009/75
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 20 February 2013
Coordinator: Dr. René Custers
Experts: Armand Christophe (UGent), Jacques Dommes (ULg), Leo Fiems (ILVO), Johan Grooten (UGent), Peter Smet (Consultant), Michel Van Koninckxloo (Hainaut Développement territorial – CARAH)
Domains of expertise of experts involved: Molecular characterisation, plant biology, human and animal nutrition, biochemistry of food/feed, toxicology, immunology, alimentary allergology , plant allergens, agronomy, ecology, oilseed rape
Secretariat (SBB): Didier Breyer, Fanny Collard, Adinda De Schrijver, Martine Goossens, Philippe Herman, Katia Pauwels

INTRODUCTION

Dossier **EFSA/GMO/NL/2009/75** concerns an application of the companies **Bayer** and **Monsanto** for the marketing of the genetically modified **Oilseed rape MS8 x Rf3 x GT73** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 7 February 2013.

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 received from the experts

GENERAL COMMENTS

Comments/Questions of the expert(s)

Comment 1

There is no evidence that interactions occur from the combination of the different events in MS8xRF3xGT73.

Comment 2

The number of genetically modified crops by combination of two or more single transgenic events, produced by conventional crossing between GM parents, is rapidly increasing and it is likely that this tendency will continue in the future.
EFSA (2012) considered that Ms8, Rf3 and Ms8×Rf3 are unlikely to have adverse effects on human and animal health, or on the environment, in the context of their intended uses. If parent single-trait GM plants, which were cross-bred to produce plants containing stacked transformation events, have received prior regulatory approval, it can be assumed that their progeny will also be safe. Weber et al. (2012) reported that there is no readily identifiable biological reason why genomic changes occurring in the breeding of a GM stack would be different in nature, scale, or frequency from those taking place in conventional crops or in GM crops with a single event. Pilacinski et al. (2011) concluded that combined GM event plants, produced through conventional breeding, can be considered to be safe, given the expected safety of the parent plants.
Therefore, it can be assumed that MS8xRF3xGT73 is safe for human and animal health.

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

No comment, appropriate information is provided.

Comment 2

The information provided in the application is sufficient.

B. INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

No comment, appropriate information is provided.

Comment 3

The information provided in the application is sufficient.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

No comment, appropriate information is provided.

Comment 2

The information provided in the application is sufficient.

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAITS AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comments/Questions of the expert(s)

Comment 1

The information given is clear.

Comment 2

No comment, appropriate information is provided.

Comment 3

The information provided in the application is sufficient.

D.2. INFORMATION ON THE SEQUENCES ACTUALLY INSERTED OR DELETED

Comments/Questions of the expert(s)

Comment 1

No comment, appropriate information is provided.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

Appropriate data are provided. Obviously there is a typing mistake one page 48 of the technical dossier where reference is made to table 8a. This table is not relevant. It should be replaced by table 11.

D.4. INFORMATION ON HOW THE GM PLANT DIFFERS FROM THE RECIPIENT PLANT IN: REPRODUCTION, DISSEMINATION, SURVIVABILITY

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D5. GENETIC STABILITY OF THE INSERT AND PHENOTYPIC STABILITY OF THE GM PLANT

Comments/Questions of the expert(s)

Comment 1

No comment, appropriate information is provided.

D.6. ANY CHANGE TO THE ABILITY OF THE GM PLANT TO TRANSFERR GENETIC MATERIAL TO OTHER ORGANISMS

Comments/Questions of the expert(s)

Comment 1

No comment, appropriate information is provided.

Comment 2

The information provided in the application is sufficient.

D.7. INFORMATION ON ANY TOXIC, ALLERGENIC OR OTHER HARMFUL EFFECTS ON HUMAN OR ANIMAL HEALTH ARISING FROM THE GM FOOD/FEED

D.7.1 Comparative assessment

Comments/Questions of the expert(s)

Comment 1

In contrast with what is claimed on page 67, paragraph 4 of the Technical dossier, differences were observed in some studies between MS8xRF3xGT73 treated with glufosinate + glyphosate or "conventionally" treated in both composition (Technical dossier, Tables 15, 16, 18) and in seed yield (Technical dossier, Table 40, Fig 8).

Question: Is the negative segregant which is present in MS8xRF3xGT73 (Technical dossier page 14) not killed by treatment with glufosinate + glyphosate herbicides?
Additional comment SBB:
The negative segregant present in the F2 grain that will be imported in the EU will probably be killed by treatment with glufosinate + glyphosate herbicides. But the imported grains will be used for food and feed and not for cultivation.

Minor comments:

1) The statistical methods are valid but the presentation of the results of the analytes is not conform to the EFSA opinion "Statistical considerations for GMOs safety" (EFSA Journal 2010, 8:1250)
2) The statement made on page 62 of the Technical dossier, two top lines, is not correct:

Linoleic acid and linolenic acid (Table 18) are essential fatty acids in vertebrates. Of course this has no impact on safety nor on nutritional concerns.

Comment 2

Why weren't the tannin and sinapine content determined.
There seems to be no problem with the phytic acid and glucosinolate content.

We note that the tannin and sinapine content were not determined. These components have in 2011 been taken up in the OECD consensus document list of key components to be analyzed in new varieties of oilseed rape.

Additional comment SBB:
In the OECD consensus document of 2001 tannin and sinapine are not listed in the key components to be analysed. In the new document of 2011 these 2 components have been taken on board.

Comment 3

The information provided in the application is sufficient.

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

The information provided in the application is sufficient.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

The comparative assessment was performed on grain only. As pointed out previously, rapes themselves are consumed in the EU.

Additional comment SBB:
To be consistent with comment for previous oilseed rape applications (AP101 & AP109) the following comment could be transmitted:
As not only grains but rapes themselves are consumed in the EU, the anti-nutritional/toxic compounds of oilseed rape MS8xRf3xGT73 (rape itself) should be evaluated.

Comment 2

The information provided in the application is sufficient.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.5 Product specification

Comments/Questions of the expert(s)

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1

Comment to page 101, first paragraph: Note that cold pressed rapeseed oil is on the market (Tynek et al., 2012) and that cold pressed oils contain more proteins, possibly the newly introduced ones, than refined oils (Martin-Hernandez et al., 2008).

Comment 2

The results of the animal feed dietary exposure assessment, as mentioned in the dossier (P. 101) are **not** presented in Table 25.
The applicant highlighted that the estimation of the newly inserted proteins is a conservative dietary exposure assessment. However, in the future exposure to these proteins can be underestimated because of the supplementation with other GM feeds, also containing one or more of these inserted proteins.
After all, these remarks are not very relevant because it is assumed that these newly inserted proteins will not exert a harmful effect on animal health.

Comment 3

No margins of safety are provided.

Comment 4

The information provided in the application is sufficient.

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

It is unlikely that MS8xRF3xGT73 rapeseed will have toxicological adverse effects.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

From the information given, the newly expressed proteins are not likely to pose a health hazard.

Comment 2

Amounts of the different proteins are comparable in the hybrid and single events.

7a) Degradation of the PAT, CP4 EPSPS and GOX protein in simulated gastric fluid ().
Tests performed earlier; rapid degradation.

7b) Degradation of the PAT, CP4 EPSPS and GOX protein in simulated intestinal fluid ().
Tests performed earlier; rapid degradation

7c) PAT, CP4 EPSPS and GOX: Acute Oral Toxicity Study in Mice ().
Tests performed earlier; no acute toxicity observed

7d) PAT, CP4 EPSPS and GOX: Sequence homology with known toxins (Capt 2009a and Capt 2009b)
Please provide a more recent study.

It is suggested to provide a more recent study on the sequence homology with known toxins.

Comment 3

The information provided in the application is sufficient.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

Note that acetylated glufosinate (and possibly its metabolites) and aminomethylphosphonic acid (AMPA) may be present when MS8xRF3xGT7 is sprayed with glufosinate + glyphosate. The toxicity of AMPA is reported to be low.

Comment 2

Not applicable

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

The whole food/feed was not tested. Arguments were provided by the applicant why this was not done. In my opinion, a 2 generation rodent study with the whole feed (in casu grain and rape itself) is always indicated to exclude unexpected effects.

Additional comment from SBB
According to the EFSA Guidance for risk assessment of food and feed from genetically modified plants (EFSA, 2011), if the composition of the food and/or feed derived from GM plant is not substantially modified, or if there are no indications for the potential occurrence of unintended effects based on the preceding molecular, compositional or phenotypic analyses no whole food/feed tests are required.

Comment 2

a) 42-day poultry feeding study ()

Not performed.

b) 90-Day rat feeding study ().
Not performed.
No further testing is needed at this moment.

Comment 3

The information provided in the application is sufficient.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

Note: 1) that rapeseed flour contains an aeroallergenic protein (Monsalve et al., 1997). Whether the concentration of this protein is affected in MS8xRF3xGT7 has not been determined.
2) “adjuvancy” has not been addressed.

Comment 2

It is unlikely that MS8xRF3xGT73 rapeseed will have allergenic adverse effects.

Comment 3

The potential risk for increased allergenicity has previously been assessed by EFSA for all individual traits. The apparent lack of interaction between the individual traits in the MS8xRF3xGT73 cross at the level of expression of the individual genes as well as the updated bioinformatics analyses indeed do not point to an increased risk of allergenicity when the individual traits are combined by conventional crossing. Yet I have a strong feeling that the dossier leans too heavily on these ‘older’ analyses and fails to take the opportunity to provide new supportive data. This is especially so because it is well recognized that the more genetic modifications are introduced in an organism, the more unpredictable the consequences become also and perhaps especially from an allergenic point of view.

Besides this more general comment, I have two specific concerns:
- The expression analyses of the recombinant proteins are limited to leaf and seed tissue. This makes sense when considering the intended use. However, humans are likely to become exposed directly or indirectly also to pollen microspores and pollen grains. Data on the expression levels of the recombinant proteins in these parts of the plant are therefore needed, yet are lacking in the dossier.
- No information is provided on whether or not the recombinant PAT protein exerts off-target enzymatic activity, thus acetylating endogenous proteins of the plant. As there is evidence that protein

modification by acetylation can affect allergenicity of proteins, analysis of this potential side-activity of the expressed PAT protein is needed.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

See above: D7.8.4 and D7.7

Comment 2

Concentration of proximate, vitamins and anti-nutritive factors is not different between GM MS8xRF3xGT73 and conventional rapeseed. Some mineral concentrations (Ca, Mg) differed, but differences may not be biologically relevant, without further consequences for food and feed safety.
The dossier did not mention any effect on antioxidant activity of GM MS8xRF3xGT73 rapeseed. However, Xu et al. (2011) reported significant differences ($P < 0.05$) for antioxidant activity between MS8xRF3 canola and their non-transgenic control. Nevertheless, these differences may neither be biologically relevant, and do not include safety risks.

Comment 3

The information provided in the application is sufficient.

D.7.11 Post-market monitoring of GM food/feed

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.8. MECHANISM OF INTERACTION BETWEEN THE GM PLANT AND TARGET ORGANISMS (IF APPLICABLE)

Comments/Questions of the expert(s)

Comment 1

Not applicable

D.9. POTENTIAL CHANGES IN THE INTERACTIONS BETWEEN THE GM PLANT WITH THE BIOTIC ENVIRONMENT RESULTING FROM THE GENETIC MODIFICATION

D.9.1. Persistence and invasiveness

Comments/Questions of the expert(s)

Comment 1

As pointed out previously, 1) persistence of seeds of oilseed rape outside cultivated fields has been shown (Pessel et al., 2001), 2) data have been published suggesting intraspecific transgene flow between escaped B. napus populations and introgression of an herbicide-resistance gene into related species (Aono et al., 2011), 3) a report has appeared on the potential for dispersal of herbicide tolerance genes from genetically-modified, herbicide-tolerant oilseed rape crops to wild relatives (Daniels et al., 2005). Although viable seeds could be imported, the risk for these events is negligible, as MS8xRF3xGT73 is not intended to be grown in the EU.

Comment 2

The information provided in the application is sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1

Not applicable

D.9.5 Interactions of the GM plant with non-target organism

Comments/Questions of the expert(s)

Comment 1

Not applicable

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

Note that rapes can be consumed as such by humans. No study was done to investigate compositional equivalence with non-GM rapes.

Comment 2

MS8 x RF3 rapeseed has been authorised by decision of the EU commission on March 26th, 2007. No interaction is expected by conventional crossing between MS8 x RF3 and GT73 rapeseed cultivars, so that safety risks will be negligible. EFSA (2004) concluded that GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health.
Hérouet et al. (2005) concluded that the safety risk from the inclusion of the PAT proteins in human food or in animal feed is negligible. Furthermore, EFSA (2008) concluded that CP4 EPSPS protein does not raise any safety concern.

Comment 3

The information provided in the application is sufficient.

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

Results of Li et al. (2008) demonstrated that stacked cottonseed meal had no adverse effects on feed consumption, weight gain, feed conversion, survival, and behaviour of the channel catfish. Similar results can be expected for MS8xRF3xGT73 rapeseed.
See also effects on human health.

Comment 2

The information provided in the application is sufficient.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.9.9 Impacts of the specific cultivation, management and harvesting techniques

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.11.4 General surveillance of the impact of the GM plant

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Additional comment SBB:
To be consistent with the remark of the Biosafety Council in previous advices on oilseed rape applications the following comment could be added:
The Biosafety Advisory Council wants to point out that the environmental monitoring plan proposed by the notifier in case of accidental spillage of reproducible material is not fully satisfactory and could be improved. In particular, it should be more precise at the level of the identity, training and expertise of the people involved in the monitoring, at the level of the monitoring methods (including types of unanticipated effects to be looked at and sites to be monitored) and time-frame planning, at the level of identification methods, and at the level of risk management procedures to avoid spillage of viable oilseed rape.

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

References

Aono M, Wakiyama S, Nagatsu M, Kaneko Y, Nishizawa T, Nakajima N, Tamaoki M, Kubo A, Saji H, (2011). Seeds of a possible natural hybrid between herbicide-resistant Brassica napus and Brassica rapa detected on a riverbank in Japan. GM Crops 2:201-210.

Daniels R., Boffey C., Mogg R., Bond J, Clarke R, (2005). The potential for dispersal of herbicide tolerance genes from genetically-modified, herbicide-tolerant oilseed rape crops to wild relatives. Final report to DEFRA. Dorchester: Winfrith Technology Centre. Retrieved January 13, 2009 from The National Archives

EFSA, (2004). Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. EFSA J. 2: 29, 19 pp.

EFSA, (2008). Opinion of the Scientific Panel on Genetically Modified Organisms on application (reference EFSA-GMO-NL-2006-36) for the placing on the market of the glyphosate-tolerant genetically modified soybean MON89788, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA J. 6: 758, 23 pp.

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