Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC/2017_0260

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2013-119 from Monsanto Company and Bayer CropScience under Regulation (EC) No. 1829/2003

Context

Application EFSA-GMO-NL-2013-119 was submitted by Monsanto Company and Bayer CropScience on 5 December 2013 for the marketing of genetically modified (GM) oilseed rape MON 88302 × MS8 × RF3 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].

The three-event stack oilseed rape MON 88302 × MS8 × RF3 was obtained by conventional crossing (no new genetic modification involved) of the corresponding single events:
- MON 88302, expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein;
- MS8, expressing Barnase and phosphinothricin acetyltransferase (PAT) proteins;
- RF3, expressing Barstar and PAT proteins.

It was therefore developed to achieve herbicide tolerance by the expression of CP4 EPSPS protein from *Agrobacterium sp.* strain CP4, and PAT from *Streptomyces hygroscopicus*. The expression of Barnase and Barstar proteins from *Bacillus amyloliquefaciens* constitutes the basis of a male fertility control system, through the use of the barnase gene, which removes male fertility in order to promote hybridisation, and the barstar gene which restores male fertility with oilseed rape lines MS8 and RF3 for obtaining heterosis (hybrid vigour).

The application was officially acknowledged by EFSA on 24 April 2014. On 17 June 2014 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). Eight 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 submitted to EFSA on 11 September 2014.

[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).

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The opinion of the EFSA Scientific Panel on GMOs was adopted on 1st March 2017 (EFSA Journal 2017;15(4):4767 [25 pp.][2]), and published on 10 April 2017 together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.
On 11 April 2017 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 comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

It is important to note that the EFSA opinion on application EFSA-GMO-NL-2013-119 covers the three-event stack oilseed rape MON 88302 × MS8 × RF3 but also subcombinations MON 88302 × MS8, MON 88302 × RF3 and MS8 × RF3 that can spontaneously arise in the seed of the three-event stack.
The two-event stack oilseed rape MS8 × RF3 has been assessed previously by EFSA and the Council, and no safety concerns were identified.
The two-event stacks oilseed rape MON 88302 × MS8 and MON 88302 × RF3 have not been previously assessed by EFSA, and no experimental data specific for these two subcombinations were provided in this application. For these two subcombinations, EFSA assessed possible interactions between the events, and concluded that different combinations of the events MON 88302, MS8 and RF3 would not raise safety concerns in these subcombinations. These two subcombinations are therefore expected to be as safe as the single oilseed rape events, the previously assessed two-event oilseed rape stack MS8 × RF3, and three-event stack oilseed rape MON 88302 × MS8 × RF3.

In delivering the present advice the Biosafety Advisory Council considered in particular the information below:
- The comments formulated by the experts on application EFSA-GMO-NL-2013-119;
- The opinion of EFSA including the answers of the EFSA GMO Panel to these comments;
- The advices already adopted by the BAC on the single events and one possible subcombination. The conclusions of the BAC were as follows:

Event	Application number	BAC advice	Conclusions
MON 88302	BE-2011-101	BAC/2014/0592 (02/09/2014)	No major risks for human and animal health or concerning the environment were identified. A general consideration was made to improve the environmental monitoring plan. A minority declaration was issued by three members asking for a negative advice regarding the environmental safety of the event.
MS8, RF3 and MS8 × RF3	RX-MS8-RF3	BAC/2009/01570 (11/12/2009)	No major risks for human and animal health or concerning the environment were identified.
MS8, RF3 and MS8 × RF3	BE-2010-81	BAC/2012/1010 (07/12/2012)	No major risks for human and animal health or concerning the environment were identified. A general consideration was made to improve the environmental monitoring plan.

The four GM oilseed rapes mentioned in the table above are all authorised in the EU for food and feed uses[3].

[2] See http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4767/full
[3] See EU register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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 MON88302 × MS8 × RF3 seeds (i.e. during transport and/or processing) into the European environment[4] 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

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 MON88302 × MS8 × RF3, 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 CP4 EPSPS and PAT proteins in the context of previous applications, and no safety concerns were identified. Taking into account the updated information considered in the current application, the Council is of the opinion that its previous conclusions remain valid.
The expression of the Barnase and Barstar proteins is limited to a plant tissue which is not relevant as food and feed (tapetum cells during anther development).
The Biosafety Advisory Council is also of the opinion that the combined expression of the newly expressed proteins in the stacked event should not raise toxicological concerns.

3.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly expressed CP4 EPSPS and PAT 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.

With regard to the allergenicity of the whole GM plant, oilseed rape is not considered to be a common allergenic food. Based on the available information, the Biosafety Advisory Council considers that there are no indications or concerns that the overall allergenicity of oilseed rape MON88302 × MS8 × RF3 would be changed as a result of the genetic modifications.

[4] 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.

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 MON88302 × MS8 × RF3 -derived food and feed are not expected to differ from those of conventional oilseed rape varieties.

4. Monitoring

According to the Biosafety Advisory Council the main potential risks concerning the environment relates to the accidental release into the environment of imported viable oilseed rape seeds during transportation and processing.
The Biosafety Advisory Council supports the view that appropriate management systems should be in place to minimize accidental loss and spillage of this GM oilseed rape during transportation, storage and handling in the environment and processing into derived products. The general surveillance should include specific measures to actively monitor the occurrence of feral oilseed rape plants in areas where seed spillage and plant establishment are likely to occur (such as harbours, transit road-sides and vicinity of processing plants).

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the advices already adopted by the BAC on the three single events and one of the possible subcombinations, and considering the data presently available, the Biosafety Advisory Council:

1) Agrees with the GMO panel of EFSA that there is no reason to expect interactions between the newly expressed proteins that would negatively impact the food or feed safety;
2) Agrees with the GMO panel of EFSA that in the context of its proposed uses, oilseed rape MON88302 × MS8 × RF3 is unlikely to pose any risk to human and animal health;
3) Considers that the conclusions of the Biosafety Advisory Council on the single events and one possible subcombination that have been assessed previously (MON88302, MS8, RF3 and MS8 × RF3 – see table on pages 2) remain unchanged;
4) Agrees with the GMO panel of EFSA that the potential environmental release of oilseed rape MON88302 × MS8 × RF3 is unlikely to pose any threat to the European environment;
5) Supports the views that appropriate management systems should be in place to minimize accidental loss and spillage of this GM oilseed rape during transportation, storage and handling in the environment and processing into derived products and that, within general surveillance, specific measures should be introduced to actively monitor the occurrence of feral oilseed rape plants in areas where seed spillage and plant establishment are likely to occur.

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

Annex I: Compilation of comments of experts in charge of evaluating the application EFSA-GMO-NL-2013-119 and comments submitted on the EFSAnet on mandate of the Biosafety Council (ref. BAC_2014_0598)

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11/09/2014

Secretariaat
Secrétariat

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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2013/119
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 24 June 2014
Coordinator: René Custers
Experts: Eddy Decuypere (KUL), Jacques Dommes (Ulg), Leo Fiems (ILVO), Rony Geers (KUL), Johan Grooten (UGent), Peter Smet (Consultant), Jan Van Doorsselaere (KATO), Michel Van Koninckxloo (Hainaut Développement Territorial – CARAH).
Domains of expertise of experts involved: Molecular characterisation, DNA/RNA/protein analysis, herbicide tolerance, animal and human nutrition, metabolism, food/feed processing, agronomy, ecology, oilseed rape, immunology, alimentary allergology, plant allergens, toxicology, general biochemistry, statistics.
SBB: Didier Breyer, Fanny Collard, Adinda De Schrijver, Martine Goossens, Aiko Gryspeirt, Philippe Herman, Katia Pauwels

♦ INTRODUCTION

Dossier **EFSA/GMO/NL/2013/119** concerns an application submitted by the companies **Monsanto and Bayer CropScience** for authorisation to place on the market genetically modified **Oilseed rape MON 88302 x MS8 x RF3** 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 17June 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 received from the experts

GENERAL COMMENTS

Comments/Questions of the experts:

Comment 1
MON 88302 x MS8 x RF3 has been developed for glyphosate and glufosinate tolerance, respectively by the expression of a glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthase and the expression of a phosphinothricin acetyl transferase, an enzyme that metabolizes phospinothricin to an inactive acetylated derivative.
Moreover, barnate and barnstar proteins are expressed in tapetal cells during anther development for a well characterized hybridization system in oilseed rape.
MON 88302 x MS8 x RF3 was obtained by traditional breeding.

Comment 2
It is believed that MON 88302 x MS8 x RF3 oilseed rape is as safe as conventional oilseed rape. However, the tendency for a higher concentration of some anti-nutrient factors (phytic acid and sinapine) must be taken into account, especially when using MON 88302 x MS8 x RF3 oilseed rape as a feed in the nutrition of monogastric animals.

Comment 3
Adequate information is provided.

A. HAZARD IDENTIFICATION AND CHARACTERISATION

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

Comments/Questions of the experts:

Comment 1
No questions.

Comment 2
Adequate information is provided.

Comment 3
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 experts:

Comment 1
No questions.

Comment 2
Adequate information is provided.

Comment 3
No comments.

Comment 4
The information provided in the application is sufficient.

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 questions.

Comment 2
Adequate information is provided, no safety concerns.

Comment 3
No comments.

A.3. COMPARATIVE ASSESSMENT

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

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

A.3.3. COMPOSITIONAL ANALYSIS

Comments/Questions of the experts

Comment 1
Why such a detailed comparison for many components between the GM-plant (T or NT) and the near isogenic controls (outcome type 1) as well as with a set of conventional reference varieties (outcome type 2) if the overall conclusion is that irrespective of the outcome type, the difference between GM and the control is of no relevance from a food and feed safety perspective?

Comment 2
Most components in MON 88302 x MS8 x RF3 oilseed rape were compositionally equivalent to conventional oilseed rape. However, a tendency ($P < 0.10$) occurred for higher in concentrations of phytic acid and sinapine in glyphosate and glufosinate treated MON 88302 x MS8 x RF3 (Taylor et al., 2013a; Table 7).

Comment 3
The concentrations of CP4 EPSPS and PAT proteins are comparable to the levels in the parental lines.
Some differences (compared to the control) in anti-nutrient content were present but these were rather small and of no concern.

Comment 4
The information provided in the application is sufficient.

A.3.4. AGRONOMIC AND PHENOTYPIC CHARACTERISTICS

Comments/Questions of the experts/

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

A.3.5. EFFECTS OF PROCESSING

Comments/Questions of the experts:

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

A.4. TOXICOLOGICAL ASSESSMENT

A.4.1. METHODOLOGY USED FOR TOXICITY TESTS

Comments/Questions of the experts:

Comment 1
Based on a comparison of composition with data from the literature, it is concluded that there are no risks for consumption, so that new trials for testing are not necessary.

Comment 2
No comments.

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 experts:

Comment 1
No questions.

Comment 2
Based on the weight of evidence in this dossier:

- PAT and CP4 EPSPS proteins have a demonstrated history of safe use
- PAT and CP4 EPSPS proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals, using FASTA algorithm
- PAT and CP4 EPSPS proteins do not exert any acute toxicity at doses several orders of magnitude higher than anticipated human exposure
- PAT and CP4 EPSPS proteins have large margins of exposure
- PAT and CP4 EPSPS proteins are rapidly digested in simulated digestive fluids

it is unlikely that MON 88302 x MS8 x RF3 oilseed rape will pose serious risks for toxicity. This is in line with Qi et al. (2012), who stated that stacked GM crops that are derived from conventionally bred parental GM crops whose safety has already been established do not need to be subjected to rat toxicology testing.

Comment 3

No comments.

Comment 4

- The rapid degradation of both CP4 EPSPS and PAT proteins in simulated gastric and intestinal fluids was demonstrated earlier.
- Results from earlier studies demonstrated that both CP4 EPSPS and PAT proteins are not acutely toxic and do not cause any adverse effects.
- A 28 day repeat dose toxicity study was not performed. No further testing is needed at this moment.
- No significant similarities were found between the Barnase protein and any toxic protein from the toxin database.
- No significant similarities were found between the Barstar protein and any toxic protein from the toxin database.
- No significant similarities were found between the PAT protein and any toxic protein from the toxin database.
- CP4 EPSPS: Sequence homology with known toxins (Kang and Silvanovich, 2013c).
  This study seems to be missing in the reference list.
- 90-Day rat feeding study.
  Not performed. No further testing is needed at this moment.

A.4.3. ASSESSMENT OF NEW CONSTITUENTS OTHER THAN PROTEINS

Comment 1

No comments.

Comment 2

No comments.

Comment 3

The information provided in the application is sufficient.

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

Comments/Questions of the experts:

Comment 1

No questions.

Comment 2

No comments.

Comment 3

The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
No comments.

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 experts:

Comment 1
No questions.

Comment 2
Based on the weight of evidence in this dossier:

- PAT and CP4 EPSPS proteins were obtained from non-allergenic sources
- PAT and CP4 EPSPS proteins lack structural similarity to known allergens, using FASTA; it appears that FASTA is an improved method for the regulatory assessment of transgenic proteins for possible allergenic cross reactivity (Song et al., 2014)
- PAT and CP4 EPSPS proteins are rapidly digested in simulated digestive fluid

it is assumed that MON 88302 x MS8 x RF3 oilseed rape does not pose a serious allergenic risk, and that it is comparable with conventional oilseed rape with regard to allergenicity.

Comment 3
No comments.

Comment 4
All three newly expressed proteins have been the subject of previous separate evaluations by EFSA establishing the lack of allergenic potential. The weight-of-evidence analysis in these previous dossiers assessed the AA sequence homology with known allergens, allergenicity of the source organism, and in vitro digestibility.
No new test data are reported in the dossier with the exception of an updated bioinformatics analysis using 2013 databases for AA sequence comparison between CP4 EPSPS, PAT, Barnase and Barstar with known allergens. Based on these historical and further updated weight-of-evidence analyses, the applicant correctly concludes that the newly expressed proteins are unlikely to have any allergenic

potential, and that MON 88302 x MS8 x RF3 is as safe as conventional oilseed rape regarding the risk for allergenicity.
I have no further comments.

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

Comments/Questions of the experts:

Comment 1
Based on a comparison of composition with data from the literature, it is concluded that there are no risks for allergenicity, so that new trials for testing are not necessary.

Comment 2
No questions.

Comment 3
No comments.

Comment 4
No data are presented in the dossier with regards to the allergenicity of the whole GM plant. The potential allergenicity of the parental lines MON 88302 and MS8 x RF3 has been assessed before. There are no indications that combining these traits will alter or increase allergenicity.
I have no further comments.

A.5.3. ADJUVANTICITY

Comments/Questions of the experts:

Comment 1
No questions.

Comment 2
No comments.

Comment 3
No consequences with regard to adjuvanticity are to be expected from the introduced traits.

A.6. NUTRITIONAL ASSESSMENT

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

Comment 1
No questions.

Comment 2
The information provided in the application is sufficient.

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

Comment 1
Based on a comparison of composition with data from the literature, it is concluded that the free intake is within the limits defined in the literature.

Comment 2
No questions.

Comment 3
Phytic acid is important, especially in monogastric nutrition, as it makes dietary phosphorus less soluble, resulting in an increased phosphorus emission into the environment. However, this drawback can be remediated by adding extra phytase to the diets of monogastric animals.
In laying hens sinapine has been implicated with the production of a fishy taint in brown-shelled eggs, due to the accumulation of trimethylamine (Khajali and Slominski, 2012).

Comment 4
The information provided in the application is sufficient.

B. EXPOSURE ASSESSMENT - ANTICIPATED INTAKE/EXTENT OF USE

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
The information provided in the application is sufficient.

C. RISK CHARACTERISATION

Comments/Questions of the expert

Comment 1
No questions.

Comment 2
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
No questions.

Comment 2
The information provided in the application is sufficient.

E. ENVIRONMENTAL RISK ASSESSMENT

E.1. INTRODUCTION

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

E.2. GENERAL APPROACH OF THE ERA

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
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
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

E.3.2. PLANT TO MICRO-ORGANISMS GENE TRANSFER

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
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
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

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

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

E.3.5. IMPACTS OF SPECIFIC CULTIVATION AND MANAGEMENT AND HARVESTING TECHNIQUES

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

E.3.6. EFFECTS ON BIOGEOCHEMICAL PROCESSES

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
Adequate information is provided.

Comment 3
The information provided in the application is sufficient.

E.3.7. EFFECTS ON HUMAN AND ANIMAL HEALTH

Comments/Questions of the experts:

Comment 1
No potential adverse effect as for its changed composition as well as for the new proteins expressed.

Comment 2
EFSA (2012) considered that rapeseed events 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. EFSA (2014) found no indication that event MON 88302 would adversely affect human and animal health. 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. 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.
Therefore, it is assumed that MON 88302 x MS8 x RF3 rapeseed represents negligible risk to human and animal health.

Comment 3
The information provided in the application is sufficient.

E.3.8. OVERALL RISK EVALUATION AND CONCLUSIONS

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
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
No comments.

Comment 2
The information provided in the application is sufficient.

E.4.2. CASE-SPECIFIC GM PLANT MONITORING

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

E.4.3. GENERAL SURVEILLANCE FOR UNANTICIPATED ADVERSE EFFECTS

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

E.4.4. REPORTING THE RESULTS OF MONITORING

Comments/Questions of the expert

Comment 1
No comments.

Comment 2
The information provided in the application is sufficient.

References

EFSA, 2012. Scientific Opinion on application (EFSA-GMO-BE-2010-81) for the placing on the market of genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 × Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape Ms8, Rf3 and Ms8 × Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer. EFSA Journal 10, 2875, 32 pp.

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