Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2009_01570

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/RX-MS8-RF3 from Bayer BioScience under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/RX-MS8-RF3 was submitted by Bayer BioScience on 29 June 2007 for renewal of authorisation of the glufosinate tolerant genetically modified (GM) oilseed rape Ms8, Rf3 and Ms8 x Rf3 for food and feed applications (food ingredients and feed materials produced from this GM oilseed rape) according to Articles 8 and 20 of Regulation (EC) No. 1829/2003[1].

Oilseed rape Ms8, Rf3 and Ms8 x Rf3 were lawfully placed on the market as foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and as feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 before the date of application of Regulation (EC) No. 1829/2003.

Oilseed rape Ms8, Rf3 and Ms8 x Rf3 were also subject previously to a notification for the placing on the market as feed containing or consisting of MS8, RF3, MS8xRF3 oilseed rape (notification C/BE/96/01 submitted under Directive 2001/18/EC); approved by Commission Decision 2007/232/EC of 26 March 2007[2]; Belgium has previously issued 2 scientific opinions related to this notification:
- advice of the Biosafety Advisory Council of 26 January 2004[3];
- advice of the Biosafety Advisory Council regarding additional information on molecular characterisation of 24 March 2009[4].

Additionally, oilseed rape Ms8, Rf3 and Ms8 x Rf3 have been entered on the community register of GM food and feed[5].

The application EFSA/GMO/RX-MS8-RF3 was officially acknowledged by EFSA on 28 March 2008. On the same date EFSA started the formal three-month consultation of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. (OJ L 268, 18.10.2003, p.1)
[2] Commission Decision (2006/197/EC) of 26 March 2007 authorizing the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (Brassica napus L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium
[3] Ref. of document : BAC_2004_SC_084
[4] Ref. of document: BAC_2009_914
[5] see: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

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

Within the framework of this consultation, the Belgian Biosafety Advisory Council, under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology to evaluate the dossier. Five experts answered positively to this request and formulated a number of comments on 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 27 June 2008.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 9 September 2009 (The EFSA Journal, 2009, 7 (9):1318[6]), and published together with the responses of the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 23 September 2009, 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.

Scientific evaluation

1. Environmental risk assessment

The scope of this application is for food and feed materials which are produced from GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 and only includes products which contain no viable plant parts. Therefore, there are no requirements to perform an environmental risk assessment in the context of this specific application. Such an assessment has already been performed in the frame of notification C/BE/96/01 submitted under Directive 2001/18/EC.

2. Molecular characterisation

With regard to the molecular characterisation, the Belgian experts are of the opinion that information received is sufficient.

3. Food and feed safety assessment and nutritional value

3.1. Assessment of compositional analysis
The Biosafety Advisory Council is of the opinion that the information provided on the composition of the genetically modified oilseed rape does not raise any safety concerns.

3.2. Assessment of toxicity
According to the Biosafety Advisory Council no major risks were identified concerning toxicity.

3.3. Assessment of allergenicity
Oilseed rape is not a major allergen. The potential allergenicity of the newly introduced proteins has been assessed. No allergenicity assessment was performed on the whole GM

[6] See: <http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902900464.htm>

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

3.4. Nutritional value
According to the Biosafety Advisory Council oilseed rape Ms8 x Rf3 is as nutritious as its non-GM counterpart and a conventional oilseed rape variety.

4. Monitoring

As the allergenicity of the whole GM oilseed has not been assessed this aspect is recommended to be 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 notifier to the EFSA GMO Panel questions and considering the data presently available, the Biosafety Advisory Council,

Agrees with the GMO panel of EFSA that it is unlikely that the Ms8, Rf3 and Ms8 x Rf3 oilseed rapes:
a) in the context of their proposed uses, would have any adverse effects on the environment.
b) would have any adverse effects on human or animal health.

In addition, the Biosafety Advisory Council recommends to follow up any unanticipated allergenicity aspects of the GM oilseed rape in the existing allergenicity monitoring systems.

p.o.

Prof. D. Reheul
President of the Belgian Biosafety Advisory Council

Annex: Full comments of experts in charge of evaluating application EFSA/GMO/RX-MS8-RF3 *and comments submitted on the EFSAnet (ref: BAC_2008_779)*

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27 June 2008

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/RX-MS8/RF3
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 18 April 2008
Coordinator: René Custers
Experts: Pascal Cadot (Consultant), Armand Christophe (UGent), Jean-Pierre Hernalsteens (VUB), Peter Smet (Consultant), Nancy Terryn (UGent)
Domains of expertise of experts involved: Genetic engineering, genome analysis, transgene expression, nutrition, analysis of food/feed, immunology, alimentary allergology, toxicology, herbicide tolerance
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman

INTRODUCTION

Dossier **EFSA/GMO/RX- MS8/RF3** concerns an application of the company **Bayer BioScience** for the marketing of the genetically modified **oilseed rape MS8/RF3** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 28 March 2008.
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) allergenicity, 3) toxicity and/or 4) 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

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

Comment 1

Complete and accurate description of the biology and ecology of oilseed rape.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

Sufficiently complete and accurate description of the inserted DNA and the transformation method.

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 in the application is accurate. The inserted genes have been used without unexpected effects in several experimental studies and in large scale cultivation of transgenic plants.

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

Comments/Questions of the expert(s)

Comment 1

Appropriate molecular techniques were used to characterize the transformation events leading to the production of Brassica napus lines Ms8 and Rf3.
However a small remark: in figures 10a, b, c and 11a, b some examples of autoradiograms of the different probe-digest combinations are shown, but they don't contain much of a legend about the lanes loaded. You have to go back to the original file (DB 1995, P71 scanned upside down). Then it is clear and the date for both MS8 and RF3 show that the DNA has integrated in a single locus. Also it establishes the absence of unwanted vector sequences.
Analysis of the regions flanking the insert give no indication of insertion of T-DNA in a functional gene.

Comment 2

The structure of both T-DNA inserts was determined with the best possible accuracy.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

The expression was studied using the most appropriate methods. The observed expression patterns correspond to the well-known properties of the PTA29 and PSSu promoters.

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

Except for the expected effect of the barnase / barstar system on fertility and the herbicide resistance, no effect of the transgenes on the behaviour of the plants was observed. This corresponds to the results of several other studies using these genes and to the experience gained by large scale culture of such transgenic plants as crops.

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

Comments/Questions of the expert(s)

Comment 1

The expected genetic stability was confirmed.

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

The transgenes are stably inserted in the plant nuclear DNA. Classical hybridisation is indeed the only mode of gene transfer that should be expected.

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

No problems

Comment 2
Composition analysis of seed.

Proximates		**Minerals**	
moisture	X	calcium	X
protein	X	copper	X
fat	X	iron	X
ash	X	magnesium	X
carbohydrates	X	manganese	X
acid detergent fiber (ADF)	X	phosphorus	X
neutral detergent fiber (NDF)	X	potassium	X
total detergent fiber (TDF)		selenium	
starch		sodium	X
		zinc	X
		total nitrogen	

Vitamins		Amino acids		Fatty acids		Secondary metabolites		Antinutrients	
A (β-carotene)		alanine	X	14:0 myristic	X	ferulic acid		phytic acid	X
B1 (thiamine)		arginine	X	15:0 pentadecanoic	X	furfural		raffinose	
B2 (riboflavin)		asparagine		16:0 palmitic	X	inositol		trypsin inhibitor	
B3 (niacin)		aspartic acid	X	16:1 palmitoleic	X	*p*-coumaric acid		gossypol	
B6 (pyridoxine)		cysteine	X	17:1 heptadecenoic	X			malvalic acid	
B9 (folic acid)		glutamic acid	X	18:0 stearic	X			sterculic acid	
C (ascorbic acid)		glycine	X	18:1 oleic	X			dihydrosterculic acid	
E (tocopherols)	X	histidine	X	18:2 linoleic	X			sinapine	
		isoleucine	X	18:3 alpha-linolenic	X			glucosinolate	X
		leucine	X	20:0 arachidic	X				
		lysine	X	20:1 gadoleic	X				
		methionine	X	20:2 eicosadienoic	X				
		phenylalanine	X	22:0 behenic	X				
		proline	X	22.1 erucic acid	X				
		serine	X	22:5 docosapentaenoic	X				
		threonine	X	22:6 docohexaenoic	X				
		tryptophan	X	24:0 lignoceric	X				
		tyrosine	X	24:1					
		valine	X						

Proximates

Most values are in good compliance with the range built from literature data. The fibre contents are found significantly higher compared to the standard range.
There was only one data source available for comparison (OECD, 2001) and the ADF range from this data source is very small, compared to the low sensibility of this analytical method and a much broader ADF range given for solvent extracted meal. However, for these two components the equivalence between the transgenic and non-transgenic OSR seeds was stated in the statistical analysis over-all-sites.

Minerals and tocopherols

Values are comparable to the control.

Anti-nutrients

The SL OSR event MS8xRF3 might have statistically higher alkenyl and total glucosinolate values compared to its non-transgenic counterpart, but not, if compared to other commercial OSR varieties (CO-OP recommendation data).
For the twelve stations of data there were significant differences observed between transgenic and non-transgenic counterparts for total glucosinolates. However, after review of the data EFSA concluded that "*These altered glucosinolate levels are considered to be a consequence of genetic variation between the GM and comparator line, rather than a result of the genetic modification. The average glucosinolate levels remained well below the maximum glucosinolate content set by the EC (1999) and at normal dietary inclusion rates this glucosinolate content will not affect the performance of livestock and poultry*"

Amino acids

The measured total amino acid values are in compliance with the reported ranges. Larger differences can only be found for aspartic and glutaminc acid. Reference data for these two amino acids were only found for rapeseed meal. This commodity has a total protein content that is twice as large as the raw seeds (seeds 18,7-26,0%dm protein; meal 32,0-40,4%dm protein). Consequently the reference values for the two amino acids are also two times higher than the determined contents in the seed matrix.

Total fatty acids

Values for the following fatty acids are found to be below the limit of detection in all sites and all samples: C8:0 Octanoic (Caprylic), C10:0 Decanoic (Capric), C12:0 Dodecanoic (Lauric), C14:0 Tetradecanoic (Myristic), C14:1 Tetradecenoic (Myristoleic), C15:0 Pentadecanoic, C15:1 Pentadecenoic, C17:0 Heptadecanoic (Margaric), gamma C18:3 Octadecatrienoic (gamma Linolenic), C20:2 Eicosadienoic, C20:3 Eicosatrienoic, C20:4 Eicosatetraenoic (Arachidonic), C20:5 Eicosapentaenoic, and C22:1 Docosenoic (Erucic). The data from these components are not analysed further. For these fatty acids equivalence can be assumed between the non-transgenic and transgenic samples. This is especially important for the fatty acid erucic acid (C22:1), which belongs to the components with anti-nutritional features in rapeseeds.

The %relative fatty acid values correspond very well to the data reported from literature. Slight differences are only found for the sum of saturated, sum of mono-unsaturated and sum of polyunsaturated fatty acids.

Sinapine is commonly present in oilseed rape. The question is raised why this alcaloid has not been determined.

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

No problems

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

Compounds for analysis: see 7.8.2

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

D.7.5 Product specification

Comments/Questions of the expert(s)

D.7.6 Effect of processing

Comments/Questions of the expert(s)

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

Mean concentrations of:

For reasons of comparison with other oilseed rape dossiers the question has been raised whether the applicant could provide data concerning the protein contents in all lines (MS8, RF3 and their hybrid), expressed as ng/mg Tissue Dry Weight per relevant tissue / growth stage.

a) Barnase protein measured in MS8.

Growth stage/ Tissue	**ng/mg Tissue Dry Weight**		**Standard deviation**
	Mean	**Range**	
Leaf	-	-	-
Flower bud	-	-	-
Root	-	-	-
Immature seed	-	-	-
Dry seed	-	-	-
Pollen	not viable		

Barnase cannot be detected in tissues of MS8 plants including flower buds. This is most likely due to the highly specific expression limited both temporally and spatially to the tapetal cell layer and in addition the expression of the protein in this cell layer leads to the disruption of the tapetal cells.

b) Bar protein measured in MS8.

Growth stage/ Tissue	**ng/mg Tissue Dry Weight**		**Standard deviation**
	Mean	**Range**	
Leaf			
Flower bud			
Root			
Seed			
Dry seed			
Pollen	not viable		

c) Barstar protein measured in RF3.

Growth stage/ Tissue	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Leaf	-	-	-
Flower bud			
Root	-	-	-
Immature seed	-	-	-
Dry seed	-	-	-
Pollen	-	-	-

d) Bar protein measured in RF3.

Growth stage/ Tissue	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Leaf			
Flower bud			
Root			
Immature seed			
Dry seed			
Pollen			

e) Barnase protein measured in MS8xRF3.

Growth stage/ Tissue	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Leaf			
Flower bud			
Root			
Immature seed			

Dry seed			
Pollen			

f) Barstar protein measured in MS8xRF3.

Growth stage/ Tissue	**ng/mg Tissue Dry Weight**		**Standard deviation**
	Mean	**Range**	
Leaf			
Flower bud			
Root			
Immature seed			
Dry seed			
Pollen			

g) Bar protein measured in MS8xRF3.

Growth stage/ Tissue	**ng/mg Tissue Dry Weight**		**Standard deviation**
	Mean	**Range**	
Leaf			
Flower bud			
Root			
Immature seed			
Dry seed			
Pollen			

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

Safety assessment of newly expressed proteins.

The Barnase and Barstar proteins are not detectable in grain. The PAT protein is the only transgenic protein expressed in the seeds.

a) Degradation of the PAT protein in simulated gastric fluid (Hérouet, 2004d).

The PAT protein was degraded very rapidly in the SGF (pH 2), within 30 seconds of incubation, in then presence of pepsin.
No degradation of the PAT protein occurred if pepsin was omitted from the SGF.

b) Degradation of the PAT protein in simulated intestinal fluid (Hérouet, 2004d).

The PAT protein was degraded very rapidly in the SIF (pH 7.5), within seconds of incubation, in presence of pancreatin. The complete degradation of remaining 7 KDal-fragments was achieved within 5 min.
Slight degradation of the PAT protein occurred if pancreatin was omitted from the SGF.
This finding was not observed with the PAT protein encoded by the *pat* gene. This minor difference in the digestion pattern could be the result of the variation in the position of the restriction sites for pepsin in the *pat* and *bar* encoded proteins.

c) PAT: Acute Oral Toxicity Study in Mice (Hérouet, 2004d).

In this study, the PAT protein encoded by the pat gene was produced in
E. coli and highly purified (>95%).
The acute intravenous toxicity study was conducted in female OF1 mice. Groups of 5 mice
were given intravenous tail injections of the PAT protein, aprotinin (negative control) or melittin (positive control) at dose levels of 1 and 10 mg/kg body weight.
There was no mortality or treatment-related toxic effects in female OF1 mice after acute intravenous administration of the PAT protein at 1 and 1 0 mg/kg body weight.

Hérouet, 2004d appendix 6 mentions: “the PAT protein encoded by the pat gene”.
According to the degradation assay in SIF (Hérouet, 2004d appendix 5) the PAT protein encoded by the *pat* and bar genes are not fully equivalent. Toxicity testing was performed by using the first.

d) Degradation of the barnase/barstar protein in simulated gastric fluid ().

Not performed

e) Degradation of the barnase/barstar protein in simulated intestinal fluid ().

Not performed

f) barnase and barstar: Toxicity (Hérouet, 2004a).

The Barstar protein has no sequence homology with known toxins.
The Barnase protein has toxic properties at high concentrations. However, this protein is restricted to the tapetum of the anthers and limited to the pollen formation period. Moreover, the co-expression with the Barstar protein neutralizes it by forming an inert and stable Barnase-Barstar complex.
In the hybrid plants, there is no exposure to the Barnase, Barstar and Barnase/Barstar complex to humans and animals under normal conditions.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

1) It is stated that the PAT protein is a highly specific enzyme for the acetylation of L-gluphosinate and does not acylate other L-amino acids (part I, page 86). This does not exclude that other components could be acetylated. Indeed, in the internal paper of Bayer CropScience by Freyssinet, 2002, page 19 (in Part 1, annex 2) it is stated that glutamate and glutamate analogues were enzymatically modified. In the application no information is given concerning potential new acetylated constituents nor were they tested. However, based on the animal experiments and history of safe use in humans, I do not expect that such new constituents, if any, pose a risk to humans and animals.
2) The metabolism of L-phosphinothricin (L-Pt) differs in transgenic L-Pt resistant plants from the pathways in genetically unmodified plants (Dröge-Laser et al, 1994). This poses the general problem whether such “unusual” metabolites of herbicides which may accumulate in the plant have to be considered as residues or rather as new constituents. In case of different plants expressing the PAT protein, 2 different fractions of N-acetyl L-Pt could be isolated which were considered as 2 conformers of the same molecule (Dröge-Laser et al, 1994). However, based on the animal experiments and history of safe use in humans, I do not expect that these metabolites pose a risk to humans and animals.

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1

I am not convinced that the claim that “natural constituents of oilseed rape have not been changed” is correct (see point 1 above).

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

I agree with the conclusion of the applicant.

Comment 2

a) 42-day feeding study with broiler chickens (Stafford, 2005)

There were no significant differences in weight gain, feed consumption, feed conversion or carcass, breast, thigh, leg and wing weight among treatment groups.
Following 42 days of repeated exposure to MS8/RF3 rapeseed (dietary), there were no diet related differences observed among treatment groups of ROSS broiler chickens fed the conventional rapeseed and those fed MS8/RF3 sprayed and non-sprayed rapeseed at a dietary concentration of 10%.

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

Not performed. No further testing is needed.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

Assessment of the allergenicity of the newly expressed proteins.
The newly introduced proteins are not likely to be allergenic.

Assessment of the allergenicity of the whole GM plant or crop.
The applicant did not evaluate the potential allergenicity of oilseed rape MS8/RF3, mainly on the basis that oilseed rape is not an allergen source. However, rapeseed allergy has been recently described and 2S albumin has been demonstrated as being an allergen of oilseed rape (1, 2). The 2S albumins are seed pan-allergens. Of note, the determination of oilseed rape allergenicity in the aforementioned references relied on skin testing with crushed seeds, which is not a form consumed by humans. Therefore, it might be argued that oilseed rape being only used to make refined oils in human diet, and refined oils being claimed to be devoid of proteins, conversely to crude oils, this rules out the possibility of allergic reaction against oilseed rape allergens. However, traces of proteins in quantities enough to induce allergic reactions were found in refined peanut oil (3), which shows that it might be possible to react after ingestion of refined oil.
Therefore, although there is probably no allergy risk in the overwhelming majority of allergic population, it might be relevant to determine the levels of 2S albumin, but also of vicillin (another known seed pan-allergen family) in oilseed rape MS8/RF3, as compared to a natural counterpart. This

is relevant particularly because the introduction of the new traits might have influenced the expression levels of these allergens in the GMO plant.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

The conclusion of the applicant that the genetic transformation has no impact on the nutritional value of the oilseed rape seeds seems warranted by the arguments given.

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

Comments/Questions of the expert(s)

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

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

Not applicable

D.9.2 Selective advantage or disadvantage

Not applicable

D.9.3 Potential for gene transfer

Not applicable

D.9.4 Interactions between the GM plant and target organism

Not applicable

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

Not applicable

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

No negative effects expected.

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

No effects different from those of conventional rapeseed derived feed expected.

D.9.8 Effects on biogeochemical processes

Not applicable

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

Not applicable

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Not applicable

D.11. ENVIRONMENTAL MONITORING PLAN

Not applicable

References

Dröge-Laser W, Siemeling U, Puhler A, Broer I (1994) The Metabolites of the Herbicide L-Phosphinothricin (Glufosinate). Identification, Stability, and Mobility in Transgenic, Herbicide-Resistant, and Untransformed Plants. Plant Physiol 105:159-166.