Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC/2016_0789

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2011/96 from Bayer CropScience under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2011/96 was submitted by Bayer CropScience on 7 April 2011 for the marketing of genetically modified cotton GHB119 for food and feed uses, import and processing within the framework of Regulation (EC) No. 1829/2003[1]. Cotton GHB119 contains a single insert expressing the Cry2Ae and the PAT proteins, conferring insect resistance and tolerance to the herbicidal active substance glufosinate ammonium respectively.

The application was declared valid by EFSA on 21 November 2011. On the same date EFSA started the formal three-month consultation period of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Biosafety and Biotechnology Unit (SBB). Four experts answered positively to this request, and formulated a number of comments to the dossier, which were edited by the coordinator. See Annex I for an overview of all the comments and for the list of comments actually placed on the EFSAnet on 21 February 2012.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 21 September 2016 (EFSA Journal 2016;14(10):4586[2]), and published on 21 October 2016 together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 27 October 2016 the opinion of EFSA was forwarded to the two Belgian experts who were still on the common list of experts of the BAC and the SBB. They were invited to give comments and to react if needed to the answers given by the EFSA GMO Panel, in particular in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA. The comments formulated by the experts together with the opinion of EFSA including the answers of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council given below.

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1).
[2] See https://www.efsa.europa.eu/en/efsajournal/pub/4586

Scientific evaluation

1. Environmental risk assessment

The Biosafety Advisory Council is of the opinion that it is unlikely that the accidental release of cotton GHB119 seeds (i.e. during transport and/or processing) into the European environment[3] will lead to any unwanted effects.

2. Molecular characterisation

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

3. Assessment of food/feed safety and nutritional value

3.1. Assessment of compositional analysis

The Biosafety Advisory Council takes note of the fact that the result from field trials performed in all Catalonian sites (Spain) were not considered as the statistical analysis of data doesn't comply with current scientific rules. Assessment was based only on data from field trials performed in the USA and in Andalusia (Spain).
The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM cotton GHB119, in comparison with its conventional counterpart do not raise safety concerns.

3.2. Assessment of toxicity

The Biosafety Advisory Council takes note of the fact that some of the toxicological tests were excluded from the assessment as they are not relevant for risk assessment.
The Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns. The toxicity of Cry2Ae and PAT proteins has been assessed in several applications and no safety concerns were identified.

3.3. Assessment of allergenicity

The potential allergenicity of the newly expressed Cry2Ae and PAT proteins has been assessed in the context of this application but also in the context of several previous applications. No concerns in relation to allergenicity were identified.

With regard to the allergenicity of the whole GM plant, to date cotton is not considered to be a common allergenic food. Based on the available information, the Biosafety Advisory Council considers that there is no evidence that overall allergenicity of cotton GHB119 is changed as a result of the genetic modification.

3.4. Nutritional value

Based on compositional data the Biosafety Advisory Council agrees with the EFSA GMO panel that the nutritional value of food and feed derived from cotton GHB119 is not expected to differ from that of food and feed derived from non-GM cotton varieties.

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

4. Monitoring

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

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the answers of the EFSA GMO Panel to the questions raised by the Belgian experts, the answers of the applicant to the EFSA GMO Panel questions and considering the data presently available, the Biosafety Advisory Council is of the opinion that in the context of its proposed uses, cotton GHB119 is unlikely to pose any risk to human and animal health.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM cotton could pose to the European environment.

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

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

Annex I: Full comments of experts in charge of evaluating application EFSA/GMO/NL/2011/96 and *comments submitted on the EFSAnet (ref. BAC_2012_0253)*

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Secretariaat
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21-02-2012

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2011/96 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 16 December 2011
Coordinator: Prof. Philippe Baret
Experts: Eddy Decuypere (KUL), Jean Jacquemin (CRA-Gembloux), Hadewijch Vanhooren (KUL), Johan Van Waes (ILVO)
Domains of expertise of experts involved: Molecular characterisation, human & animal nutrition, toxicology in vivo & in vitro, agronomy, ecology, herbicide tolerance, impact on bio-diversity, cotton
Domains of expertise of experts involved:
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman, Katia Pauwels

INTRODUCTION

Dossier **EFSA/GMO/NL/2011/96** concerns an application of the company **Bayer CropScience** for the renewal of the marketing authorisation of the genetically modified **cotton GHB119** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 21 November 2011.
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

According to the dossier the scope of application does not include the authorization for the cultivation of cotton GHB 119 seed products in the EU. It can however be worthwhile to give some remarks on the different topics, dealing with cultivation and survivability of seeds, in the case that the applicant should ask in the near future for an extension for the scope of cultivation, especially for cultivation in some southern European countries.
So as agronomical expert I will also give some comments in this questionnaire, related to cultivation and the environmental aspect.

Comment SBB and coordinator

According to what was decided at the Biosafety Council's meeting of 10 February 2012, the environmental aspects will not be assessed anymore for GM cotton applications whose scope does not include cultivation (which is the case for the present dossier).
It should be noted that for the present dossier, the applicant provided information about dormancy, survivability and over wintering of cotton GHB119 in Southern Europe (p. 61 of technical dossier). A General Surveillance will be also undertaken during the authorisation period for import and processing. This monitoring system will involve the authorisation holder and operators handling and using viable GHB119 cotton seed.

The following general comment was sent to EFSA (as for the AP97 dossier) under item D.11:

According to the Biosafety Advisory Council the main potential risk concerning the environment relates to the potential establishment of feral populations in case of unintentional release into the environment of GM cotton seeds during transportation and processing. Establishment of feral populations in case of incidental spillage is very unlikely to occur in Belgium and in Northwest Europe in general because the climate in these regions is not suited for cotton growth. On the other hand, the possibility of seed spillage and seed germination with a further establishment of feral populations exists in Southern Europe. The Biosafety Advisory Council supports the view that appropriate management systems should be in place to minimize accidental loss and spillage of transgenic cotton during transportation, storage and handling in the environment and processing into derived products. In addition, the Council is of the opinion that the general surveillance should include specific measures to actively monitor the occurrence of feral cotton plants in areas where seed spillage and plant establishment are likely to occur where climatically appropriate (such as harbours, transit road-sides and vicinity of processing plants). We are keen to know the results of these plans of surveillance for the previous cotton dossiers.

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

The trypsin-resistant core protein Cry2Ae from *B. thuringiensis* damages gut lining of lepidopteran larvae, leading to its destruction, and the larvae stop feeding. The specificity of action is due to presence of specific binding sites in the target insects. The combined effect of starvation and tissue damage cause death of the larvae.
The *bar* coding sequence encodes a specific enzyme, PAT (phospkinotricin acetyl transferase) that acetylates the herbicide glufosinate ammonium and thereby detoxifies this herbicide. The working mechanism of the insect-resistant and glufosinate-tolerant GHB119 cotton is well explained.

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

Comments/Questions of the expert(s)

Comment 1

B.7. p. 22: Sterculic and malvalic acid are unique fatty acids of the cyclopropenoid fatty acid group and considered natural toxicants; they are responsible for a positive Halphen test, but it is not further explained what this is, or on what basis this test is done. Is it still done? No further mentioning of this test in the text.
Comment SBB
Same kind of comment was sent to EFSA for application 97.

Comment 2

Under "3. Survivability – a) Ability to form structures for survival or dormancy" it is mentioned that "Cultivated cotton does not produce seeds which can persist in the environment for long periods of time, furthermore cotton seed lacks the ability to develop dormancy. My question is: are there data available to prove this?
Comment SBB
Same kind of comment was sent to EFSA for previous applications (41, 42 and 51).

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

Cry2Ae gene from *Bacillus thuringiensis* and *bar* gene have been in use since several years.
Plasmid map is well described and promoters and genes are positioned. Two tables summarize the genetic elements in the vector and those introduced into the plant.

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

P. 27: - Why only 8 locations given whereas 12 sites were used?
I understand that at the time when trials were planned and performed, EFSA guidance on how many sites were required for compositional analysis was not yet available or clear and 12 sites were realized.
But on what basis these 8 sites were selected out of 12?
Comment SBB
Same comment was sent to EFSA for application 97.

- What means “good internal quality control” as a basis of selection of sites for further analysis?

Comment 2

The *cry2Ae* gene was modified in order to optimize the production *in planta* but no explanations on the number and the type of modifications are given in this paragraph.
The vector pTEM 12, the new traits: herbicide resistance (*bar* gene) and insect resistance (*cry2Ae* gene) are described in Table 2, 3 and in the Fig. 3 with the corresponding genetic elements associated (promoter, leader sequence, transit peptide). Meanwhile, the objective and the reason of this type of targeting into the chloroplasts could be explained in this introductive paragraph and the expected efficiency of this construction.

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

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

The copy number of the inserted sequence and the integrity of the genes are presented in this section.
Seven Southern blots (Fig 5-11) hybridized to the different parts of the plasmid pTEM12 are shown and discussed.
A detailed map of the putative inserted sequences is shown with the different restriction fragments (Fig. 4). Bands are visible on the different blots and their size correspond to the expected ones. In Fig. 10, lane 5: Hind III digest, the band at 1280 bp is absent but in Habex 2011, a faint band is present.
The inserted genetic material was amplified in 3 fragments by PCR reactions and the different products were sequenced and aligned. Pre-insertion locus was amplified and sequenced. In Table 11, the 5th primer should be listed HVH010 instead of 11.
Bioinformatic analysis were performed on this sequence for ORF, promoter and Start sites. Bioinformatic analysis were conducted in the pre-insertion locus and it was concluded that it is unlikely that new ORF with homology to known allergens or toxins would be expressed or that known genes can be interrupted.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

In the beginning of this paragraph and in Table 15, the technique used to detect and quantify the new protein is not mentioned.
With the plasmid construction and the type of targeting used in this work, consideration about the target tissue and localisation of new proteins should be emphasized. Is the CRY2Ae protein present in the chloroplast, in mitochondria? Why in the roots? Is this protein dual-targeted?

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

No questions

Comment 2

No changes in fertility, floral morphology , pollen fertility and dissemination were observed.

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

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

Genetic stability was extensively tested by conventional crosses over some years (Fig 14).
Genetic stability was demonstrated in 4 Southern blots on different generations issued from crosses with Coker 312 and Fibermax 966.
A digestion of genomic DNA with EcoRV restriction enzyme give the 3 expected fragments (Fig 16-19).
The new phenotype was also investigated by spraying F2 plants with the herbicide.
The Chi square test was significant for Mendelian inheritance.
The event GHB119 behaves as a single allele at one locus.

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 questions

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 questions

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

- In the USA field trials it is mentioned (p. 76) that the samples represented regimens that were sprayed with Ignite 200 SL herbicide and unsprayed for the GHB119 and unsprayed non-transgenic counterpart Coker 312.
In the trial design it is stated that the non-transgenic Coker 312 is treated with conventional herbicide weed control and GHB119 is unsprayed if not treated with Ignite. Does “unsprayed” means sprayed with conventional herbicide? This should be clarified unambiguously.
- In EU field trials (p. 77) it is mentioned here that GHB119 cotton was grown using either conventional weed control practices or use of glufosinate herbicide. Is this similar to the USA field trials? If so, wording should be similar as well to avoid confusion.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

For USA trials, significant differences between GHB119 and its non-transgenic comparator were found, amongst others, for myristic, stearic, arachidic, palmitoleic, oleic and linoleic acid.
On p. 83 it is stated over-all-sites or by site analysis but in table 29 a by-site t-test indicates 6 significant and 0 non-significant differences for comparisons of A vs B as well as A vs C for oleic and linoleic acid while for myristic, stearic and arachidic acid this is 0 significant and 6 non-significant. How is this possible, certainly taking into account differences in means, S.D and overall p-values from Anova?
- Why the differences between EU and USA trials in composition comparisons?
- In EU trials, dihydrosterculic acid is overall different between A as B and A as C and higher on GHB119, but the results of the by-site t-tests give 15 sites significant 1 non-significant for A vs B, and 16 significant and 0 non-significant for A vs C (table 34) for dishydrosterculic acid, while no sites are different for sterculic acid (A vs B as well as A vs C); however when these results are compared with data in table 33, differences between GHB119 and Coker 312 are almost the same (similar magnitude of differences) for their means and a similar S.D for sterculic acid as well as for dihydrosterculic acid. How then the by-site t-tests can be so different then for both acids?
- No attempt to explain the consistent differences between GHB119 and Coker 312; even if all values are within the range given in literature and it concerns relatively small differences of minor fatty acids, without consequences for nutritional equivalence, it would be scientifically of interest to speculate or to explain these discrepancies.

Comment SBB

Same kind of comment was sent to EFSA for application 97. See also similar comment from another expert under D.7.8.3.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1

No questions

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1

No questions

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

No questions

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1

No questions

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

To complete the assessment of toxicology of both proteins (Cry2Ae and PAT) in mice, doses of respectively 2000 mg/Kg BV and 10 mg/Kg BW were given; why was the Cry2Ae protein given orally and PAT parenteral? In the testing of the whole GM food/feed, both proteins are given orally of course, so any indication why PAT should also be administered directly in blood?

Why the doses used as mentioned above? PAT is present in cotton up to 100 times more than Cry2Ae, so is the higher dose of Cry2Ae in the toxicity study related to the route of administration?
- The title of the paragraph on p. 118 does not fit with what follows, since the title indicates oral gavage in rodents, while PAT is given by parenteral route.
- Also for the 90-day toxicity study, GHB119 toasted meal is inserted in the meal, hence Cry2Ae and PAT are ingested orally (p. 121).

Comment 2

Data is lacking on the levels and fate of the herbicide residues in plant tissues.
Although the effect of herbicides on human and animal health falls under Directive 91/414/EC, it is the duty and responsibility of the toxicologist assessing the risk of the genetic modification to evaluate and discuss the complete picture of the genetic modification.
Rationale: the GM cotton plant is developed to be able to use the herbicide glufonisate ammonium. Data concerning the use of the herbicide in the field trials is available. However, no data is made available concerning the identification and quantification of the herbicide and metabolite residues in the GM plants and seeds used for food/feed. As the use of the herbicide is linked to the genetic modification, the applicant should make the residue data available and make an estimation of the anticipated intake (food/feed).

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

Newly expressed proteins: Cry2Ae protein, PAT protein

The Cry2Ae protein purified from *B. thuringiensis* (2 batches!) and the PAT protein purified from *E. coli* were found equivalent to the proteins expressed in cotton GHB119 (Moens, 2011): agreed.

Cry2Ae protein
The safety of the Cry2Ae protein was demonstrated by biochemical characterisation, by an amino acid sequence homology search with known toxins and allergens, an *in vitro* heat stability test and *in vitro* digestibility testing, acute and sub-acute toxicity testing in mice.
Comment:
- 28-day toxicity study in mice (Kennel, 2011), 111 mg Cry2Ae/kg bw/d, control group: BSA.

For the 28-day toxicity study in mice (Kennel, 2011) the Cry2Ae *B.t.* batch VMLV1041-1 (Wierckx, 2010; purity 86%) was used. For other studies including the acute toxicity study in mice (Rouquie, 2006) the Cry2Ae *B.t.* batch NB210806P25 (Bautsoens, 2007; purity >93%) was used.
Groups of 5 animals per sex were used (n=5/sex/group). However, to obtain an adequate statistical power, groups of at least 10 animals/sex/group are required (EFSA guidance document, EFSA Journal 2011; 9(5):2150).

- Error in Part I –Technical Dossier p118/144:

ii. Acute toxicity test by oral gavage in rodents: no negative control was used! Only 2000 mg/kg bw was tested as GEM2 protein (Rouquie, 2006). According to OECD test guideline 425, no control group is needed.

- There were no mortalities, clinical signs, systemic effects, or other treatment-related effects observed after the oral administration of Cry2Ae protein in the acute and 28-day toxicity studies in mice: Agreed.

PAT protein

The safety of the PAT protein has been previously assessed in former applications and peer-reviewed (Hérouet et al., 2005).

Conclusion: The assessment of both proteins is adequate and acceptable. No further comments/questions.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

No further comments or questions.

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

Compositional analysis of fuzzy seeds from GHB119 cotton and the non-transgenic isoline Coker 312 USA (Mackie, 2008a; Oberdörfer, 2008 and 2009c; Rattemeyer, 2008)

Statistically significant differences were found between the GHB119 cotton and the control isoline cotton either over-all-sites or by-site for: total carbohydrates, free and total gossypol, dihydrosterculic acid, most amino acids, and the fatty acids myristic acid (C14:0), stearic acid (C18:0), oleic acid (C18:1), linoleic acid (C18:2), and arachidic acid (C20:0).

EU (Oberdörfer, 2009a, 2009b, 2010, 2011a)

Statistically significant differences were found between the GHB119 cotton and the control isoline cotton either over-all-sites or by-site for: proximate and fibre compounds, phosphorus, malvalic acid,

sterculic acid, dihydrosterculic acid, most amino acids and the fatty acids myristic acid (C14:0), palmitoleic acid ω7 (C16:1), oleic acid (C18:1), linoleic acid (C18:2), arachidic acid (C20:0), and lignoceric acid (C24:0).
However, the mean values of the key components from the USA and EU studies were within the reference ranges for the commercial cotton seeds tested and/or the reference ranges from the respective cotton literature.
Furthermore, the observed changes in the metabolism of the GM plant did not have an impact on the nutritional properties and toxicity of cotton-derived feed and food products as tested in the 42-day poultry study and 90-day repeated toxicity test in rats. In the rat study, total cholesterol, triglycerides and prothrombin time were not altered.

In addition, another study on processed cottonseed products (cotton grown in Argentina) was provided by the applicant (Kowite, 2009).
Not the non-transgenic parental isoline Coker 312 but the similar conventional counterpart variety Coker 315 was used as the control group. The results were in line with what was observed in the un-processed cottonseeds (USA and EU data) and were within the reference ranges.

No particular natural constituents of GHB119 cotton are considered to be of significant concern to require additional information or further risk assessment. The higher mean values of the anti-nutrients were within the reference ranges of commercial cotton. The applicant argued that the observed differences were possibly caused by somaclonal variations that can occur during plant transformation, and that may have led to minor changes in the metabolism of the plant.
Nevertheless, the differences found in the fatty acid composition of GHB119 cottonseed (USA, EU, Processed cottonseed studies) are also observed in the EFSA/GMO/NL/2011/97 dossier, T304-40 cotton (USA and EU studies). A scientific argumentation on this is encouraged/designated.
Comment SBB
Same kind of comment was sent to EFSA for application 97. See also similar comment from another expert under D.7.3.

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

No questions

Comment 2

Poultry study (Stafford, 2009)
- Non-transgenic control: similar conventional counterpart Coker 315. GHB119, Coker 315, and the commercial variety FM 958 were grown in Argentina. Question: why not the Coker 312?
- Cottonseed toasted meal in the diet: 5%. Question: why only 5%? 10% is feasible.

I agree with the applicant that no negative impacts of the nutritional quality of GHB119 cottonseed meal were observed on poultry when fed as 5% of the daily diet.

Northern Bobwhite dietary toxicity study (Stafford, 2010): supporting data

90-day toxicity study in the rat (Totis, 2010)

- Non-transgenic control: parental isoline Coker 312, commercial variety FM 958.
- Cottonseed toasted meal in the diet: 10%.

The assessment is adequate and acceptable. I agree with the applicant that the transgenic GHB119 cottonseed meal when fed 13 weeks as 10% of the daily diet of rats did not cause any biologically relevant health effects.

In conclusion, no potential health and food/feed safety concerns have been identified.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

No questions

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

No questions

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

Comments/Questions of the expert(s)

Comment 1

No questions

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

Comments/Questions of the expert(s)

Comment 1

No questions

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

No questions

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

In this chapter it is mentioned that “the likelihood that some escaped seed would germinate is very low because most of the imported seed is non-viable". My question is: Is the germination power of the imported seed analysed?
Additional comment sent to EFSA
What is the process used to make the seed "non-viable" and what is the real proportion of viable and non-viable imported seed?

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

No questions

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

No questions

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

No questions

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

No questions

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

Not applicable

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

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

In this paragraph it is mentioned that the scope of the present application does not include cultivation of cotton plants in the EU and is limited to import and processing. Nevertheless I give here some

remarks in the case that the applicant should ask in the near future for an extension for the scope of cultivation. In the framework of the EU- regulation 2002/53 a new variety has to be submitted to DUS (Distinctness, Uniformity, Stability) and VCU (Value for Cultivation and Use) tests before the variety can be commercialised. The new variety has to be compared with the best existing standard varieties. So my question here is : can the GM- cotton be incorporated in normal VCU trials, for example treated with specific herbicides for cotton and will the agronomical value be the same as tested in trials, where the herbicide glufosinate ammonium, for which the variety is tolerant, is used?

Comment SBB and coordinator

Same comment was made for applications 51 and 97 and was NOT sent to EFSA (see previous remark on environmental issues).

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

Not applicable

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

Comment 1

In summary: under 7.8.4. it would be better to use the term “economic life span” for poultry instead of entire life span when considering the 6 week growing period for broilers.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

Comment 1

Based on the scope of application (no cultivation) I can agree with the remark that the overall environmental risk posed by this genetically modified plant is negligible in the context of the intended uses of cotton GHB119.

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

References

Peeters N. and Small I. (2001) Dual targeting to mitochondria and chloroplasts Biochimica et Biophysica Acta 1541, 54-63