Bioveiligheidsraad
Conseil de Biosécurité

21-04-2009

Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2009_924

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2008/51 from Bayer CropScience under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2008/51 was submitted by Bayer CropScience on 25 January 2008 for the marketing (import and processing) of the herbicide tolerant genetically modified (GM) cotton GHB614 for food and feed uses under Regulation (EC) No. 1829/2003[1].

The application was officially acknowledged by EFSA on 11 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 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 (SBB) to evaluate the dossier. Five 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 12 June 2008.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 5 March 2009 (The EFSA Journal, 2009, 985, 1-24)[2], and published together with the responses of the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 11 March 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.

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. (OJ L 268, 18.10.2003, p.1)
[2] See: <http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902368331.htm>

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Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council the main potential risks concerning the environment[3] relates to unintentional release into the environment of GM cotton seeds during transportation and processing. In that respect, several comments were submitted to EFSA concerning the survivability and germination power of the GM cotton seeds in relationship with the potential establishment of feral populations in case of unintentional release.

In answer to these comments, the EFSA GMO Panel confirmed that the general characteristics of cotton GHB614 are unchanged relative to its conventional counterpart and that consequently no increased fecundity, persistence, ferality, invasiveness or survival capacity are expected in the absence of glyphosate-based herbicides. Moreover, cotton GHB614 will be imported as mostly non-viable seed which makes the likelihood that some imported seed could escape and germinate very low.

The Biosafety Advisory Council therefore agrees with the conclusions of the EFSA GMO Panel that the cotton GHB614 will have no additional agronomic or environmental impact as compared to existing cotton populations.

The Biosafety Advisory Council nevertheless 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 Biosafety Advisory Council fully shares the EFSA's recommendation 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).

2. Molecular characterisation

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

3. Food/feed safety assessment

The Biosafety Advisory Council observes that the potential allergenicity of the whole GM cotton has not been evaluated. Although the Council acknowledges that cotton is not considered to be a common allergenic food and that the main cottonseed product in human food, cottonseed oil, is highly purified and contains very low levels of proteins, the Council is of the opinion that the introduction of the transforming DNA might interfere with the expression levels of other cotton proteins, including allergens. Therefore, it might be relevant to analyze whether the expression levels of allergens is increased and to carry out IgE binding studies.

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

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 supports the conclusion of the GMO panel of EFSA that:

a) No major risks concerning the environment were identified.
b) No major risks for human and animal health were identified.

In addition, the Biosafety Advisory Council:

1) Supports the views 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 and that, within general surveillance, specific measures should be introduced to actively monitor the occurrence of feral cotton plants in areas where seed spillage and plant establishment are likely to occur.
2) Recommends considering introducing assessment of allergenicity of the whole GM cotton in the frame of the revision of the EFSA guidance document on Food/Feed safety assessment.

p.o.

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

Annex: Full comments of experts in charge of evaluating application EFSA/GMO/NL/2008/51 *and comments submitted on the EFSAnet (ref: BAC_2008_769)*

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Secretariaat
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12 June 2008

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2008/51
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: Prof. Philippe Baret
Experts: Dr. Pascal Cadot (Consultant), Eddy Decuypere (KUL), Jean-Luc Hofs (FUSAGx), Peter Smet (Consultant), Johan Van Waes (ILVO)
Domains of expertise of experts involved: Animal nutrition, biochemistry of food/feed, toxicology, immunology, alimentary allergology, agronomy, breeding, improvement of plants, ecology, bio-diversity, herbicide tolerance, biosafety research, cotton
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman

INTRODUCTION

Dossier **EFSA/GMO/NL/2008/51** concerns an application of the company **Bayer CropScience** for the marketing of the genetically modified **cotton GHB614** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 11 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) 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).
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)

Comment 1

According to the dossier the scope of application does not include the authorization for the cultivation of **GHB614** cotton 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 2

No comments for this section.

Comment 3

Preliminary question:
If cottonseed mainly are used for making oil, should not the scope of the application also be "Food produced from GM plants or containing ingredients produced from GM plants ", in addition to "GM plant for food use".

Comment 4

GlyTol cotton GHB 614 is tolerant to glyphosate, the active component in Roundup.
The phosphonomethyl-glycine blocks the activity of 5-enolpyruvylshikimate-3-phosphate synthase or EPSPS, which is a key enzyme in the shikimic pathway.
GHB 614 produces the same EPSPS as in all other plants except for two amino acid substitutions, and is named 2mEPSPS resulting in an insentivity of GlyTol cotton to glyphosate.
EPSPS is a key enzyme in the formation of aromatic amino acids (tyrosine, phenylalanine and tryptophane) in plants, bacteria and fungi but not in animals.
It is not mentioned if the enzyme has other known functions besides the shikimic pathway.

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

Comments/Questions of the expert(s)

Comment 1

Under “3. Survivability – 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 2

B3. Survivability: In mild and dry winter conditions the existence of feral perennial populations of *G. hirsutum* along roadsides is highly probable (Hofs et al. 2006; Hofs et al., 2007). Their persistence depends on the national or regional infrastructure maintenance policy; which is highly variable in Southern Europe.

Comment 3

In Table 1 under paragraph 5 (geographical distribution and cultivation of the plant), the area harvested in China is somewhat lower but almost similar to the area harvested in USA; however the quantity produced in metric tons is unusually high (11400.00 in 1000 metric tons): is this figure correct ?

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

The information relating to the genetic modification is clear and complete.

Comment 2

No questions

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

No comments

Comment 2

No questions

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

Comments/Questions of the expert(s)

Comment 1

GHB614 event is sufficiently characterised at the sequence level. Southern blotting hybridization, PCR and the complement of bioinformatics make the assessment complete and confirm the introduction of one (only) copy of the 2mepsps gene cassette.

Comment 2

No questions

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

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 comments

Comment 2

No questions

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

Comments/Questions of the expert(s)

Comment 1

The presented results confirm the phenotypic and genetic stability of the GM plant. The segregation analysis statistically shows no difference with theoretical segregation ratio of BC2F1. Nevertheless, I am a little worried about this 2/3 R and 1/3 S ratio: couldn't the sample size be bigger? It should be discussed in the application.

Comment 2

No questions

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 dispersal trial set-up (Aelvoet & Freyssinnet, 2007) is not accurate enough to detect the "real" impact of pollen dispersal. The "pollen captors" (pollen receiving plants) were harvested only according four directions (SW, NW, SE, NE). To maximize detection, it should have been performed under a 12 x 12 grid experiment set-up, with one plant (pollen captor) at each nod of the grid (see example in Lavigne et al., 1998). Results reported in Van Deynze et al. (2005) are certainly more reliable.

Comment 2

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

According to Oberdörfer, 2007 phytic acid is also analyzed. This is not mentioned in the technical dossier. Why has this been omitted?

Comment 2

No comments

Comment 3

Conventional cotton + conventional herbicide application was compared with GHB 614 cotton + conventional herbicide application and the latter was on its turn compared with GHB 614 cotton + glyphosate application.

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No comment

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

In general, there is no prove of significant alteration of plant (or seed) compounds.

Comment 2

All four primary products coming from cottonseed processing, namely oil, meal, hulls and linters were included in the selection of material.
The sensitive aromatic amino acids were all analyzed as well as the oil composition or lipid profile. The amount of C18:2 (linoleic acid in the GHB 614 cottonseeds are slightly higher than the levels in Coker 312 cottonseeds but no explanation is given.
Also the amount of cyclopropenoid fatty acid are lower in the transgenic samples, and although values are inside the references ranges reported from literature, and the lower levels from this anti-nutritional factor is rather beneficial, a bit more explanation why this is the case should be given.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1

Units of characteristics measurements should be included in the tables (ex: tables 29 and 30).

Comment 2

No questions

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1

Information provided is correct.

Comment 2

No questions

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

Mean concentrations of:

2mEPSPS protein measured in GHB614 cotton.

Growth stage = 4 (flowering)	**ng/mg Tissue Fresh Weight**		**Standard deviation**
	Mean	**Range**	
Leaf	0.45		0.22
Stem	1.58		0.96
Root	4.04		1.71
Squares	5.35		0.25
Apex	5.47		0.22
Pollen	0.16		0.01

Please provide data based on dry weight. No range is mentioned. Please provide.
A standard deviation of 0.00 for the the pollen content seems to be rather small (data provided in the technical dossier). In Van der Klis and De Pestel, 2006, a SD of 0.01 is given. Please correct.

	ng/mg Tissue Fresh Weight		Standard deviation
	Mean	Range	
seed	19.2	15.8-25.5	3.1

seed fraction	ng/mg Tissue Fresh Weight		Standard deviation
	Mean	Range	
Kernel	36.3	28.7-47.1	7.2
Lint coat	0.08	0.02-0.16	0.06

products	ng/mg Tissue Fresh Weight		Standard deviation
	Mean	Range	
Lint	< 0.188		
Linters	< 0.750		
Hulls	6.93	6.48-7.41	0.40
Meal	0.26	0.16-0.36	0.10
Toasted meal	< 0.188		
Crude oil	< 0.188		
Refined oil	< 0.188		

Comment 2

No comments

Comment 3

No questions

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

Degradation of the 2mEPSPS protein in simulated gastric fluid (Rouquié, 2006a).

This study indicates a **complete digestion of the 2mEPSPS proteins within 30 seconds**.

Degradation of the 2mEPSPS protein in simulated intestinal fluid (Rouquié, 2006b).

This study indicates a **complete digestion of the 2mEPSPS protein with less than 30 seconds.**

2mEPSPS: Acute Oral Toxicity Study in Mice (Rouquié, 2006c).

No mortality was observed during the study in bovine serum albumin or 2mEPSPS protein-treated animals at a dose of 2000 mg/kg body weight.

No clinical signs were observed in bovine serum albumin or 2mEPSPS protein-treated animals throughout the study period.

There is **no adverse effect on body weight gain** following treatment with 2mEPSPS protein.

No 2mEPSPS-treatment related macroscopic findings were observed.

Sequence homology with known toxins

The 2mEPSPS protein is highly homologous to, and shares similar molecular weight and functionalities with other shikimate synthase proteins which have been demonstrated to be non-toxic and non-allergenic over the years through consumption. Its identity with the wild-type EPSPS (wtEPSPS) enzyme is greater than 99.5%.

Comment 2

No comments

Comment 3

Safety assessment of the newly expressed protein was based on:

- coding sequence of 2mepsps-gene is derived from maize, a safe crop widely used for food and feed.
- Metabolic effects of 2mEPSPS in plants are comparable to those of endogenous plant EPSPS enzymes except for the insensitivity to glyphosate.
- 2mEPSPS is present in very low levels and moreover quickly degraded in simulated gastric and intestinal fluids.

- Acute oral toxicity study in mice confirmed that 2mEPSPS is not toxic to mice even at very high doses.

Therefore, cottonseed products from GHB 614 cotton poses no additional concern compared with non-GM cotton.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

The 2mEPSPS protein was found to be the sole "inner" new constituent of the GM plant. However external factors related to the GM plant management should be taken into account (see section 9.9).

Comment 2

No questions

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

42-day poultry feeding study (Stafford, 2007)

Clinical observations: Twenty-nine birds (6 in Group A, 14 in Group B, and 9 in Group C) exhibited clinical signs during the feeding study. Of these, 14 died prior to study termination.
The clinical signs observed in this study have been commonly seen in previous studies involving this strain of chickens when maintained under the feeding regimes employed in this study *(ad libitum* feeding except during 3 overnight fasting periods). **None of these clinical signs were considered to**

be treatment-related. There was no behavioral evidence of an adverse effect related to the dietary treatments.

In-Life Mortality: A total of 14 fatalities (3% mortality within the test system) occurred during the study, among which 8 birds were males and 6 birds were females. Of the 14 birds that died during the feeding study, 10 died without exhibiting symptoms prior to death. Four birds died in Group A, 6 in Group B, and 4 in Group C. A contingency coefficient cross-tabulation analysis indicated **these differences among groups were not significantly different** (Pearson Chi-square = 3.065, P = 0.547).

Following 42 days of daily exposure to GHB614 cottonseed meal (dietary content of approximately 10%), **there were no negative effects** detected in *feed consumption*, *body weight gain*, or *weight of chilled carcass, leg, thigh, wing or breast* between ROSS #708 broiler chickens fed the genetically modified cottonseed, and two control groups consisting of a non-transgenic commercial variety of cottonseed and a non-transgenic counterpart variety of cottonseed.
Additionally, the differences detected in feed conversion ratios among groups are unrelated to the transgenic trait.

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

Not performed.
Since 1) there are no major compositional differences between GHB614 cotton and its non-transgenic counterpart, 2) the protein has no acute toxicity, 3) is readily degradable in both SGF and SIF and 4) no differences due to the transgenic trait are observed in the feeding study, **no further testing is needed at this moment**.

Comment 2

No comments

Comment 3

An additional poultry feeding study showed no adverse effects on chickens, so there is no problem at all with GHB 614 cottonseed derived products.
However when it is stated that broiler chickens were selected to evaluate the effects of a feed component over an entire life span, this should better be omitted since indeed the “commercial life span” of a broiler is only 6 weeks, but biologically the entire life span of a chicken is a multiple factor of this 6 weeks.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

Assessment of allergenicity of the introduced traits
EPSPS protein has been considered as allergy safe by EFSA scientific panel. To the knowledge of the reviewer, there is no new data that could contest this decision.

Assessment of allergenicity of the whole GM plant
The applicant did not evaluate the potential allergenicity of cottonseeds GHB 614, compared to their natural counterpart. The reviewer acknowledges that cottonseed allergy is not a major issue and that no major allergen of cottonseed has been described. In addition, the major destined use of cottonseed is to prepare refined oil that contain very low levels of proteins, hence with very low allergenic impact. However, because the introduction of new traits might influence the expression levels of other proteins of the host plant and because trace amounts of proteins can be found in refined oil, it is requested that the applicant evaluate the content of 2S storage protein and of vicillin, two known common and potent seed allergens, in the GHB614 cottonseed, compared with the natural counterpart.

Comment 2

No questions

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

It is noted that the introduced trait is of agronomic interest and is not intended to change any nutritional aspects of this cotton. Can this be proved by data?

Comment 2

The GHB614 transformation event is not likely to have altered nutritional parameters.

Comment 3

No questions

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

Comments/Questions of the expert(s)

Comment 1

Post-market monitoring should be linked with herbicide contaminant analysis.

Comment 2

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 comments

Comment 2

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

Feral GM *G. hirsutum* populations may survive over several years but there is no obvious evidence of invasiveness.

Comment 2

No questions

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

In this chapter it is mentioned that the agronomic performance of **GHB614** shows no disadvantage. Furthermore we note 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?

Comment 2

Feral populations can grow along roadsides for several years (see section B.3). Populations in Hofs et al (2006 and 2007) were all GM (RR and Bt) cultivars. Similar cases might occur in Southern Europe. Selective advantage can occur if glyphosate is used in roadside vegetation control.

Comment 3

No questions

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

The risk of seed spillage and seed germination with a further set-up of a feral population exists in Souther Europe. At this stage, there is no evidence that it constitutes an important risk of gene flow. It should be, however, included in a monitoring plan.
Cotton doesn't need an arable surface to grow. in te case of seed spillage some seeds can germinate on the top of decomposing seeds, which act as a growth substrate (see picure in annex). When the cotton root system developping in that cotton compost is strong enough it can pass through a harder surface (road coating).

Comment related to seed germination at page 93 of the report:
There is no need to treat fuzzy seeds to make it germinate. Fuzzy seeds can reach a germination rate of 80-85% and healthy seed germination rates are generally up 60% (Lançon and Klassou, 1988). Delinted seeds do need less moisture (or water) to start germination but need other additional moisture to achieve the process and reach the seedling stage. In contrast, in the case of fuzzy seeds, the seed doesn't germinate below a certain cumulated moisture level. If this level is attained, germination process goes on until seedling development. It means that delinted seeds are more susceptible to drought periods during the germination process. Fuzzy seeds CAN germinate and present a risk as well.

Comment 2

No questions

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

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

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No questions

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

See section 9.9

Comment 2

No questions

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

See section 9.9

Comment 2

No questions

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

See section 9.9

Comment 2

No questions

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

Comments/Questions of the expert(s)

Comment 1

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 glyphosate, for which the variety is tolerant, is used?

Comment 2

The advantage of the GHB614 event relies upon the use of glyphosate herbicide. The present application foresees up to three glyphosate treatment over the cropping season. Over-the-top applications imply a direct absorption of the glyphosate within the plant.
In the scope of the comparative assessment (as agronomic treatments include glyphosate over-the-top sprays) it would be relevant to intend to analyse herbicide residues and metabolite (AMPA) in the event GHB614 and also conventional cultivar (with its herbicide active ingredient).

The applicant should report on the presence of the glyphosate, their metabolites and related surfactant residues in seed products. Their (medium or long term) impacts on animal and human health should be discussed. Reference of pesticide (glyphosate) risk assessment and EU regulatory measures would be valuable.

Finally, as the scope of the present application is not for cultivation in Europe, weed resistance to glyphosate will not be highlighted in these comments (only as a matter of interest).

Comment 3

No questions

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

It is said that GHB614 varieties showed the same susceptibility as the conventional counterparts to abiotic stress (Freyssinet & Trolinder-Wright, 2006). But what is the reaction of GHB614 2mEPSPS protein concentration in the plant to environmental stress? In other words, is the GHB614 cultivar less tolerant to glyphosate under abiotic stress? The 2004-2005 field experimentation was obviously not designed to answer these questions.

Comment 2

No potential impact of GHB 614 on biotic or abiotic environment is expected to result from import, processing or use of this product for food and feed in the EU.
If an impact has to be expected or hypothesized, then it could be the effect of glyphosate used when GHB 614 is cultivated.
The widespread use of glyphosate will be made possible and promoted by the use of GM-cotton GHB 614.
However, since this application is for consent to import GHB 614 cottonseed in EU to use it as any other cottonseed, excluding the cultivation of GHB 614, it also excludes the usage of glyphosate.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

Comment 1

The proposed environmental monitoring plan is OK.

Comment 2

No comments

Comment 3

No comment

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 GHB 614.

Comment 2

As mentioned in section 9.9 of the comments, e.r.a. should be carried out to assess the concentration of herbicide residues and its metabolite(s) in the plant.
Herbicide management shouldn't be separated from the GM herbicide tolerant product.

Comment 3

No comment

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

Comment 1

Comments of section 11.2 should be taken into account.

Comment 2

No comment

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

Comments/Questions of the expert(s)

Comment 1

Baselines must consider the strengthening of the control of herbicide residues in seeds and other processed products.

The GS plan is not clear and there is confusion between monitoring plan and general information to the agribusiness sector. The detailed GS protocols (to detect potential unanticipated adverse effects) should be presented. These protocols are not provided through the mentioned websites (Europabio etc.).

Comment 2

No comment

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

Comment 1

No comments

Comment 2

No comment

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