Bioveiligheidsraad
Conseil de Biosécurité

21/05/2014

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2014_0326

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2009/64 from BASF Plant Science under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2009/64 was submitted by BASF Plant Science on 15 January 2009 for the marketing of herbicide-tolerant genetically modified (GM) soybean BPS-CV127-9 for food and feed uses, import and processing within the framework of Regulation (EC) No. 1829/2003[1]. Soybean BPS-CV127-9 contains a single insertion locus of the csr1-2 gene. The gene expresses a mutant acetohydroxyacid synthase large subunit (ahasl) allele (S653N) from Arabidopsis thaliana (L.) Heynh., which confers tolerance to the imidazolinone class of agricultural herbicides.

The application was officially acknowledged by EFSA on 13 July 2009. 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 in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts to evaluate the dossier, chosen from the common list of experts drawn up by the BAC and the Biosafety and Biotechnology Unit (SBB). Eight experts answered positively to this request, and formulated a number of comments to the dossier, which were edited by the coordinator. See Annex I for an overview of all the comments and for the list of comments actually placed on the EFSAnet on 21 October 2009.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 5 December 2013 (EFSA Journal 2014;12(1):3505[2]), and published together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 29 January 2014 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/en/efsajournal/pub/3505.htm

Scientific evaluation

1. Environmental risk assessment

Soybean BPS-CV-127-9 was shown to have a higher seed weight than its conventional counterpart. The Biosafety Advisory Council agrees with EFSA that it is very unlikely that this higher seed weight would have a significant impact on the overall fitness, invasiveness or weediness of the GM soybean. Accidental release of the soybean will therefore not lead to the establishment of plants, if any, in another way than by conventional soybean plants. The Biosafety Advisory Council is therefore of the opinion that it is very unlikely that the import of this soybean for processing it into food and/or feed presents any risks to the European environment[3].

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 composition of the GM soybean BPS-CV127-9 is equivalent to its conventional counterpart with one exception, namely the level of its δ-tocopherol. Delta-tocopherol is one of the eight constituents of vitamin E, but is not considered to be the most effective or crucial part of vitamin E. The most important and biologically active constituent of vitamin E is α-tocopherol. The level of α-tocopherol in soybean BPS-CV-127-9 has not changed in comparison to its conventional counterpart. The level of δ-tocopherol in soybean BPS-CV127-9 is higher than in the conventional counterpart and also slightly higher than in the non-GM soybean reference varieties (non-sprayed GM: 8.1±1.3 mg/100g; conventional counterpart: 7.2±1.5 mg/100g). It is known from literature that their level can vary up to 3.3 fold. The tocopherol level in soybean BPS-CV127-9 is well within the range reported in literature. According to the Biosafety Advisory Council The slightly raised level of δ-tocopherol in soybean BPS-CV127-9 does not raise safety concerns.

3.2. Assessment of toxicity

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

3.3. Assessment of allergenicity

The Biosafety Advisory Council concluded there are no indications that the genetic modification might significantly change that the overall allergenicity of soybean BPS-CV127-9 when compared with that of its conventional counterpart.

3.4. Nutritional value

With regard to nutritional value the Biosafety Advisory Council is of the opinion that the information provided does not raise safety concerns.

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

3.5. Phenotypical and agronomic properties

In the field trials that were performed to produce the material for the compositional analysis, also a number of phenotypical and agronomical characteristics were measured. This revealed that soybean BPS-CV-127-9 had a higher seed weight than its conventional counterpart. The Biosafety Advisory Council is of the opinion that this higher seed weight does not raise concerns about the food or feed safety of this soybean..

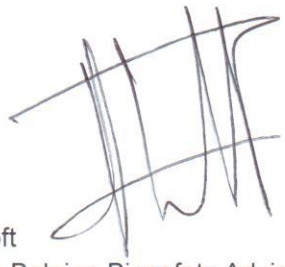
4. Monitoring

With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

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, soybean BPS-CV127-9 is unlikely to pose any risk to human and animal health.

Given the scope of the application of this herbicide tolerant soybean (no cultivation in EU) and the fact that the establishment of volunteer plants would be unlikely (soybean cannot survive without human assistance and is not capable of surviving as a weed in Europe), the potential environmental release of soybean BPS-CV127-9 is unlikely to pose any threat to the European environment.



23-05-2014

Maurice De Proft
President of the Belgian Biosafety Advisory Council

Annex I: Full comments of experts in charge of evaluating application EFSA/GMO/NL/2009/64 and comments submitted on the EFSAnet (ref. BAC_2009_01423)

Bioveiligheidsraad
Conseil de Biosécurité

21-10-2009

Secretariaat
Secrétariat

N./réf. : WIV-ISP/15/BAC_2009_01423
Email. : bac@sbb.ihe.be

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2009/64
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 31 August 2009
Coordinator: René Custers
Experts: Pascal Cadot (Consultant), Armand Christophe (UGent), Johan Claes (KH Kempen), Rony Geers (KUL), Peter Smet (Consultant), Frank Van Breusegem (VIB), Michel Van Koninckxloo (HEPHO), Johan Van Waes (ILVO)
Domains of expertise of experts involved:
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman

INTRODUCTION

Dossier **EFSA/GMO/NL/2009/64** concerns an application of the company **BASF Plant Science** for the renewal of the marketing authorisation of the genetically modified **BPS-CV 127-9 Soybean** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 21 July 2009.
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

GENERAL COMMENTS

Comments/Questions of the expert(s)

Comment 1

It would make the evaluation process somewhat easier if the applicant would adhere to the same subdivisions as given in the evaluation sheet (e.g. Toxicology is 7.2 in the application and D 7.8 in the evaluation sheet a.s.o.)

Comment 2

The dossier is well established and discusses the safety (toxicological, allergenicity, food/feed nutrition) with a number of own experiments. The data are sufficient for the statement that this GMO soybean can be used safely as food or feed. Some minor comments can be made (see further), but these are not strong enough to give an overall negative evaluation.

Comment 3

No comments.

Comment 4

According to the dossier the scope of application does not include the authorization for the cultivation of BPS-CV 127-9 Soybean 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.

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

No comments.

Comment 3

No comments.

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

Comments/Questions of the expert(s)

Comment 1

Under "3. Survivability- specific factors affecting survivability" it is mentioned that soybean plants are not frost-tolerant. Furthermore it is mentioned that no biologically significant differences in survivability compared to the isogenic control were observed.
My question is : are there data available of overwintering of seed of soybean in regions of Southern Europe (Spain, Portugal)? And if yes could the seedlings be controlled by the use of herbicides, such as glufosinate?

Additional comment from the coordinator: In the light of the fact that GM soybeans have already been imported in large quantities over many years, I find this a nice to know instead of a need to know.

Comment 2

The information provided in the application is sufficient.

Comment 3

No comments.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

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 provided in the application is sufficient. (The scope of the application does not include authorization for the cultivation of CV127 Soybean in the EU).

Comment 2

No comments.

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

Comments/Questions of the expert(s)

Comment 1

No comments.

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1

It is well illustrated that the insert can not be detected in the grains of CV 127 soybean and in the control. This can be considered as an indication, but not as a proof, of the safety of the GMO soybean.

Additional comment from the coordinator: "..the insert cannot be detected...." must be a mistake here. 'insert' should be 'AHAS protein'.
It is the amount of AHAS PROTEIN in grain that is below the limit of quanitification.

Comment 2

No comments.

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

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

No comments.

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

Comments/Questions of the expert(s)

Comment 2

No comments.

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 information provided in the application is sufficient.

Comment 2

No comments.

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

D.7.1 Comparative assessment

Comments/Questions of the expert(s)

Comment 1

In this chapter it is mentioned that BPS-CV 127-9 Soybean was compared to two commercial conventional soybean varieties. What does it mean? The BPS-CV 127-9 Soybean is tolerant to imidazolinone. So I think it is not possible to compare with commercial conventional varieties, unless they are also tolerant to imidazolinone (= are also genetically modified). My question is : Is BPS-CV 127-9 Soybean compared to other genetically modified varieties or only to conventional varieties and in the last case was the herbicide tolerance taken into account in this comparison?

Additional comment from the coordinator: For the compositional analysis it was not only compared to two commercial conventional varieties (Monsoy 8001 and Coodetec 217), but also to its non-gm comparator, being the isogenic control (either F5 null, F6 null or F7 null). It is not compared to other GM (imidazolinone tolerant)varieties, and this is also not required (see EFSA revised guidance III D 7).

Comment 2

Analytes determined in grain:

Proximates		**Minerals**	
moisture	X	calcium	X
protein	X	copper	
fat	X	iron	X
ash	X	magnesium	X
carbohydrates	X	manganese	
acid detergent fiber (ADF)	X	phosphorus	X
neutral detergent fiber (NDF)	X	potassium	X
total detergent fiber (TDF)	X	selenium	
starch		sodium	
		zinc	
		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)	X	arginine	X	15:0 pentadecanoic				Stachyose	X
B2 (riboflavin)		Asparagine		16:0 palmitic	X	furfural		raffinose	X
B3 (niacin)		aspartic acid	X	16:1 palmitoleic		inositol		trypsin inhibitor	
B6 (pyridoxine)		Cysteine	X	18:0 stearic	X	*p*-coumaric acid		Gossypol	
B9 (folic acid)	X	glutamic acid	X	18:1 oleic	X			malvalic acid	
C (ascorbic acid)		Glycine	X	18:2 linoleic	X			sterculic acid	
E (α-tocopherol)	X	Histidine	X	18:3 linolenic	X			dihydrosterculic acid	
		Isoleucine	X	20:0 arachidic	X				
		Leucine	X	20:1 gadoleic					
		Lysine	X	22:0 behenic	X				
		Methionine	X	24:0 lignoceric					
		phenylalanine	X						
		Proline	X						
		Serine	X						
		Threonine	X						
		Tryptophan	X						
		Tyrosine	X						
		Valine	X						

Although the level of AHAS protein expressed in CV127 soybean is higher than that in the isogenic control, this seems to have no consequences on the amounts of leucine, isoleucine and valine.

Comment 3

Comment 1. It appears that for the calculation of the energy content of soybeans (Part I, table 12, page 65), it is assumed that dietary fiber does not contribute. Yet, it has been recommended that specific energy factors should be applied for dietary fiber for novel foods (FAO Corporate Document Repository, 2001). In contrast with what is claimed in table 12, energy values for soybeans have been published (somewhat higher than the reported calculated values: 416kcal/100 g WET weight, thus even higher on a dry weight basis) (source USDA Nutrient Database for Standard Reference, from http://soya.be/nutritional value of soybeans.php). Of course, this is of no importance for the safety of soybean CV127.

Comment 2. Although levels remain in published ranges, consistent deviations in composition in the same direction from the isoline over the growing seasons may point to changes in plant metabolism which were not intended. This is for instance the case for tyrosine, oleic, linoleic and linolenic acids, beta and delta tocopherols, daidzein, genestein and some antinutrients in grain. It would be useful if an explanation for these differences could be given to exclude the possibility that unnoticed changes that could be potentially harmful are not likely to occur.

Comment 3. Soy oil is the major soybean derived product for human consumption. Thus one would expect a more detailed and more correct fatty acid composition.
More detailed: Several minor fatty acids which are known to be present in soy oil (e.g. Baylin et al., 2007) have not been reported
Incorrect:
1) The part that describes the methodology used states for fatty acids that the procedure of "area normalization" (Part I, Annex 11, page 10) was used (This is acceptable). If so, at least some of the reported values seem to be impossible (e.g, if the highest values reported for fatty acids in grain of CBV127, 2006/2007 (part I, page 69) are summed, a value well below 100% is found).
2) All 18:1 in soy oil is not oleic acid as reported, (oleic acid is the cis-isomer of 18:1n-9) but cis-18:1n-7 makes up a non negligible fraction of total 18:1 (e.g. Baylin et al., 2007). Although possible changes in the non reported fatty acids do not pose a nutritional hazard, they may point to unexpected changes in plant metabolism which themselves might pose a nutritional hazard.

Comment 4. It is not indicated (Part I, Annex 11) in what way vitamin E is calculated from the different tocopherols present.

Suggestion 1. As pointed out in previous evaluation reports, it is suggested that saponins are included in the compositional analysis of soybean. Indeed, saponins are present in soy in relatively high quantities (Berhow et al., 2003) and although poorly absorbed in humans (Hu et al., 2004) they can cause bloat in ruminants (Van Haver et al., 2003) and induce enteritis in salmon (Knudsen et al., 2007). Soya sapogenols, obtained by hydrolysis of saponins, clearly have important biological effects (e.g. Zhang et al., 2008).

Suggestion 2. It is suggested that a recommendation is made about the way carbohydrates are best determined. Calculation values "by difference" (as is done in this report) is not the most indicated way from a nutritional point of view. Why not reporting "available carbohydrates" (as is done for instance in the NUBEL food table).

Comment 4

As stated by the applicant, soybean CV127 can be considered as equivalent to the control varieties that were used. Adverse effects, due to differences in composition are unlikely. However, some remarks have to be made.

The very low value of methionine in Table 14) might be a reason for some concern, since methionine is already the limiting amino acid in soy protein. However, the applicant illustrates that this is due to errors in the analysis method. Tryptophan is higher than the Global and Brazilian references (Table 14) and although this poses most probably no problem, some discussion can be devoted to this topic as well.

Additional comment from the coordinator: But there are no statistical differences between the methionine level in the transgenic line and in the non-transgenic isogenic line. It is a character of the genetic background line.

In Table 15, the fatty acid composition of grain is discussed. For the 2006/2007 season, the Isoline and two CV127 treatments have a very low total amount of fatty acids (only approx. 86% is indicated, compared to approx. 95% for the Comm. Stds). Since the analysed fatty acids are the most common fatty acids in plant material, the question rises which fatty acids are missing. It will make the application more convincing if these differences are explained in terms of which fatty acids are present in the soybean grain, but are not summarized in Table 15.

A number of times throughout the technical dossier, reference is made to *"characteristic of soybean varieties adapted for cultivation in Brazil"* (e.g. page 64). It is not clear from the technical dossier whether this is just an assumption, or whether this is motivated based on literature and/or own experiments. Although this is not a fundamental issue for the application, the dossier would be stronger, if this is motivated as well.

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

In this chapter it is mentioned that BPS-CV 127-9 Soybean was compared with the parental variety Conquista and two other commercial soybean varieties. My question is if in these trials the resistance for imidazolinone is also tested, in relation to yield.

Comment 2

No questions.

Comment 3

No comments

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

Including saponins in the compositional analysis is suggested (see above)

Comment 2

No comments.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

In Tables 24 and 25, the agronomic characteristics for two growth seasons are described. At page 81, it is concluded that there exist some differences between CV127 soybean and the isogenic control. As the applicant states, this has no biological significance. However, the applicant also concludes, based on these data, that the cultivation presents no environmental hazard. These data can however not been used for this conclusion, since here only differences in agronomic characteristics are studied, and not the impact on the environment (which is discussed in D.9).

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

No comment

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

Question. One would expect that the fatty acid compositions of the grain and of the refined oil would be very similar. Yet this is not the case (e.g compare linoleic acid values in Part I, table 15 (page 69) with those in Part I, table 32, page 91). **Can an explanation be given?** (analytical problem?).

Comment 3

Lectin is also an important antinutritional factor in soybean. The presence of lectins is studied in the raw grain, but it is not clear from the technical dossier whether this is also analysed for the toasted meal. There are no results for lectin presented in Table 28. Although lectins are to a certain extent heat sensitive, the comparison should include lectins as well, to guarantee that the structural breakdown under processing is the same.

The above paragraph has been rephrased by the coordinator:

Lectin is also an important antinutritional factor in soybean. The presence of lectins is studied in the raw grain, but there are no results for lectin in toasted meal presented in Table 28. Although lectins are to a certain extent heat sensitive, the comparison should include lectins as well, to guarantee that the structural breakdown under processing is the same.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

No questions

Comment 3

No comments.

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

Protein levels measured in CV127 soybean.

Growth stage = V2

Part	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Whole plant	314	241 - 381	Not provided
Leaves	714	524 - 1283	Not provided
Roots	<LOQ		
1st trifoliate	300	267 - 333	Not provided

Growth stage = R2 (full-flowering)

Part	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Whole plant	160	95 - 184	Not provided
Leaves	106	85 - 132	Not provided
Roots	50	38 - 74	Not provided
Flowers	125	93 - 156	Not provided

Growth stage = R8

Part	ng/mg Tissue Dry Weight		Standard deviation
	Mean	Range	
Whole plant	<LOQ		
Pods	30	27 - 33	Not provided
Roots	48	<37 - 88	Not provided
Grain	<LOQ		

The expression levels of the enzyme were determined in leaves, roots, flowers, grain, and whole plants. Highest levels of AHAS protein were detected in young leaves (highest in young and growing plant tissues where the need for branched chain and other amino acids is greatest due to the higher level of *de novo* protein synthesis and declines as tissues mature (Stidham and Singh, 1991).

Comment 2

No questions.

Comment 3

The number of animals in the experiment with mice is too small in order to be able to find a statistically significant difference between treatments.

Comment 4

Reference is made to the use of *A. thaliana* as an organism that has been handled extensively in research with no known toxicity issues. This is however only a minor argument to support the safety of CV127 soybean, since *A. thalinana* is not consumed during the former research.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

a) Degradation of the AHAS protein in simulated gastric fluid (Privalle, 2009).

The protein is rapidly degraded in SGF.

b) Degradation of the AHAS protein in simulated intestinal fluid (Privalle, 2009).

The protein is rapidly degraded in SIF.

c) AHAS: Acute Oral Toxicity Study inMice (Kamp *et al*., 2008).

The protein was administered by gavage to groups of 5 male and 5 female CD®-1 mice at a dose of 5000 mg/kg body weight/day.
After the test substance administration, the animals were maintained over a post observation period of 14 days.
As no animal died during the study period due to the test substance, a median lethal dose (LD50) was not achieved. Thus, the LD50 can be considered as being higher than 5000 mg/kg bw (or higher than 2620 mg AHAS/kg bw) for male and female CD®-1 mice. In addition, no test substance-related findings were noted. As such, the no observed effect level (NOEL) was the limit dose of 5000 mg/kg bw (2620 mg AHAS/kg bw) for male and female CD-1 mice.

The animals received E.coli produced AtAHAS at a dose of 5000/mg/kg bwt/day corresponding to 2620 mg AtAHAS protein/kg bwt
Is it correct to say that the other 2380 mg consists of water and some carboxymethyl-cellulose? If not, what other ingredients were used?

d) AHAS: Assessment of Amino Acid Sequence Homology with Known Toxins (McKean, 2008)

The submitted protein sequence did not show significant homology to a toxin or other proteins that may be potentially toxic or anti-nutritional to humans or animals.

Comment 2

It seems unlikely that the newly expressed proteins in the levels that they occur would pose health problems. No questions.

Comment 3

No comments

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1

It seems not likely that new constituents other than proteins would be present in food or feed derived from soy CV127. 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

The information provided in the application is sufficient.

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

a) 42-day feeding study in broiler chickens (Rabenschlag de Brum, 2008).

In the study of Rabenschlag de Brum, 2008 (annex 23) the following statement is made:

"Even though during these periods no differences were detected as to feed intakes, it was determined that numerically the feed consumption of chickens fed with feed containing COODETEC 217 soybean meal was lower than that of those fed with feed containing CV127 soybean meal."

What exactly is meant by this?

Conclusion:
It was determined that the treatment using soybean meal from CV127 soybean did not differ significantly (P>0.05) from treatments that contained the CONQUISTA and MONSOY 8001 soybean meals as regards the feed intake, corporal weight, weight gains or feed conversion during any of the periods studied.

b) 90-Day rat feeding study ().

Not performed. No further testing is needed.

Comment 2

The information provided in the application is sufficient.

Comment 3

No comments.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

There are no indications that the levels of well known soybean allergens would be higher in CV127. Yet, the methodology used can not exclude that this could be the case for some of these allergens (see table 38, Part I, page128).

Comment 2

Assessment of the allergenicity of the newly expressed proteins.
Agreed with the statement that, with the current knowledge, AtAHASL protein is unlikely to be allergenic.

Assessment of the allergenicity of the whole GM plant or crop.
The applicant did assess the allergenicity of the whole GM plant by comparing 2D protein patterns of parent plant cultivated in Brazil, parent plant cultivated in US and CV127 plant. The data are supportive of no difference in allergenicity between parental and modified crops. However, the evaluation could be improved to ascertain the absence of increased allergenic potential in the modified crop. As mentioned by the applicant (annex 24), the major allergens are also the major proteins in soybean extract, and the corresponding silver-stained bands may be overstained, leading to misquantification of these bands. The experiments may be reproduced by applying less protein in the gels, in order to focus on these particular bands and to avoid overstaining and allow more quantitative comparison.

Comment 3

No comments

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

A feeding study with broiler chickens was performed. No differences were found when CV127 or control soybean was incorporated in the diet. No questions.

Comment 3

See D.7.1 on the comparative assessment.

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

Comments/Questions of the expert(s)

Comment 1

Proposal by applicant is OK.

Comment 2

The information provided in the application is sufficient.

Comment 3

No comments

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

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

The information provided in the application is sufficient.

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

The information provided in the application is sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient. (The scope of the application does not include authorization for the cultivation of CV127 Soybean in the EU).

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1

Not applicable and the information provided in the application is sufficient.

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

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.9.6 Effects on human health

Comments/Questions of the expert(s)

Comment 1

No questions.

Comment 2

No comments.

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

Comment 2

No questions

Comment 3

The information on the environmental temperature during the trials with poultry is too thin in order to know if the level of temperature whether or not did influence the transit rate of the feed through the intestinal tract, i.e. modifying digestibility through experimental groups.
The number of animals in the growth trial is sufficient for finding differences with respect to growth rate, but the number of pens is too small for finding differences with respect to feed conversion ratio.
Comment from coordinator: the above comment will be given under D.7.10

Comment 4

No comments.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

Not applicable. The information provided in the application is sufficient.

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

Comments/Questions of the expert(s)

Comment 1

Information given by applicant is OK.

Comment 2

Not applicable. The information provided in the application is sufficient. (The scope of the application does not include authorization for the cultivation of CV127 Soybean in the EU).

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

Not applicable and the information provided in the application is sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

Comment 1

Risk assessment proposed by applicant is OK; here in this case not applicable since no demand for cultivation.

Comment 2

The information provided in the application is sufficient.

Comment 3

Not applicable.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

Not applicable.

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

The information provided in the application is sufficient.

Comment 3

Not applicable.

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

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

The information provided in the application is sufficient.

Comment 3

Not applicable.

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

Comment 1

Not applicable

Comment 2

The information provided in the application is sufficient.

Comment 3

Not applicable.

References

Baylin A, Siles X, Donovan-Palmer A, Fernandez X, Campos H (2007) Fatty acid composition of Costa Rican foods including trans fatty acid content. J Food Comp Anal 20: 182-192.

Berhow MA, Kong SB, Vermillon KE, Duval SM (2006). Complete quantification of group A and group B soyasaponins in soybeans. J Agric Food Chem 54:2035-2044.

FAO Corporate Document Repository (2001). http://www.fao.org/DOCREP/006/y5022e/y5022e07/htm

Hu J, Reddy MB, Hendrich S, Murphy PA (2004). Soyasaponin I and sapongenol B have limited absorption by Caco-2 intestinal cells and limited bioavailability in women. J Nutr 134: 1867-1873.

Knudsen D, Jutfelt F, Sundh H, Sundell K, Koppe W, Fokiar H (2008). Dietary soya saponins increase gut permeability and play a key role in the onset of soyabean-induced enteritis in Atlantic salmon (Salmo salar L.). Br J Nutr. 2008 Jul;100(1):120-129.

Van Haver E, De Schrijver A, Devos Y et al. (2003). Guidance notes for the safety assessment of genetically modified crops for food and feed use. Royal Library of Belgium, Deposit No D/2003/2505/16 page 30.

Zhang W, Popovich DG. (2008). Effect of soyasapogenol A and soyasapogenol B concentrated extracts on HEP-G2 cellproliferation and apoptosis. J Agric Food Chem 56:2603-2608.