Bioveiligheidsraad
Conseil de Biosécurité

02-10-2009

Secretariaat
Secrétariat

O./ref.: WIV-ISP/BAC/2009_01366

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2005/15 from Mycogen Seeds, c/o Dow AgroSciences LLC and Pioneer Hi-Bred International under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/NL/2005/15 was submitted by Mycogen Seeds, c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, represented by Pioneer Overseas Corporation on 30 May 2005 for the marketing (import and processing) of the insect resistant and glufosinate-tolerant genetically modified 1507 x 59122 maize for food and feed uses under Regulation (EC) No. 1829/2003[1].

The application was officially acknowledged by EFSA on 13 July 2007. 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 (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 to evaluate the dossier, chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology (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 15 October 2007.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 21 April 2009 (The EFSA Journal, 2009, 1074, 1-28)[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 7 May 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_1211902517596.htm>

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In addition, the scientific evaluations of the single events, namely maize line 1507 (C/ES/01/01) and maize line 59122 (EFSA/GMO/NL/2005/12), are taken into account in this advice[3]. The Biosafety Advisory Council formulated a positive advice for each single event[4]. Both are authorised for food and feed uses[5].

Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council no major risks were identified concerning the environment[6].

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. Food/feed safety assessment

The Biosafety Advisory Council considers that even if the compositional analysis of the GM food/feed was performed according to the OECD consensus document[7], it lacks the analysis on dietary fibre. The Biosafety Advisory Council recommends the analysis on dietary fibre since this concept is widely accepted in human food studies and recommends the adaptation of the OECD consensus documents accordingly.

4. Monitoring

General surveillance is advised to follow-up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested.

Conclusion

Based on the scientific assessment of the dossier done by the Belgian experts, taking into account the opinion of EFSA, the answers of the EFSA GMO Panel to the questions raised by the Belgian experts, the answers of the notifier to the EFSA GMO Panel questions and considering the data presently available, the Biosafety Advisory Council,

Agrees with the GMO panel of EFSA that
a) No major risks concerning the environment were identified.
b) No major risks for human and animal health were identified.

[3] Advice of BAC on maize line 59122: BAC_2007_SC_536; Scientific evaluation of SBB on mandate of BAC of maize line 1507: IPH/1520/GMCROPFF/2006-0839.
[4] Advice of BAC on maize line 59122: BAC_2007_SC_536; Scientific evaluation of SBB on mandate of BAC of maize line NK603: IPH/1520/GMCROPFF/2003-0767; Scientific evaluation of SBB on mandate of BAC of maize line 1507: IPH/1520/GMCROPFF/2006-0839.
[5] See Community Register <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm>
[6] 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.
[7] OECD, 2002. Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites. ENV/JM/MONO(2002)25. http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)5

In addition, the Biosafety Advisory Council recommends:

1) To include the analysis of dietary fibre in the compositional analysis of food and to adapt the OECD consensus documents accordingly;
2) General surveillance to follow up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested;

p.o.

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

Annex: Full comments of experts in charge of evaluating application EFSA/GMO/UK/2005/15 *and comments submitted on the EFSAnet (ref: BAC_2007_PT_589)*

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15/10/2007

Secretariaat
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/UK/2005/15 and Comments submitted on the EFSAnet on mandate of the Biosafety Advisory Council

Mandate for the Group of Experts: mandate of the Biosafety Advisory Council (BAC) of 10 August 2007
Coordinator: Prof. Dirk Reheul
Experts: Pascal Cadot (Consultant), Eddy Decuypere (K.U.Leuven), Rony Geers (K.U.Leuven), Godelieve Gheysen (UG), Peter Smet (Consultant), Frank Van Breusegem (VIB), Johan Van Waes (ILVO).
Domains of expertise of experts involved: agronomy, breeding, molecular characterisation, genetic engineering, genome analysis, ecology, herbicide tolerance, plant-insect relations, animal nutrition, toxicology, allergology, immunology, maize
Secretariat: Didier Breyer, Adinda De Schrijver, Martine Goossens

INTRODUCTION

Dossier **EFSA/GMO/UK/2005/15** concerns an application of the company **Mycogen Seeds, c/o Dow AgroSciences and Pioneer Hi-Bred International** for the marketing of the genetically modified **1507x59122 maize** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 13 July 2007.
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). 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
No questions. For the labelling, I refer to comments on EFSA dossier UK/2005/20 on Maize 59122xNK603
Again, under f) the sentence is found that the genetic modification in 1507x59122 maize does not give rise to any ethical or religious concerns.
It is proposed to omit "to any ethical concern" for the following reason: it is not because inserts in 1507x59122 maize do not contain human or animal genes, or because of no differences in composition, food or feed value, absence of toxicity or allergenicity… that there may be no ethical concerns. Ethical concerns may arise from a certain view on nature and human impact on it, based on subjective reasons originating from such a view, and not only based on objective arguments of safety.
Even if these arguments giving rise to ethical concerns are completely subjective, the ethical concerns are nevertheless real and have to be taken into consideration in a democracy if they arise in a substantial part of the population.

Comment 2
No comments

Comment 3
No comments/questions

Comment 4
According to the dossier the scope of application does not include the authorization for the cultivation of 1507 x 59122 maize seed products in the EU. It can however be worthful 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.
So as agronomical expert I will also give some comments in this questionnaire, related to cultivation and the agronomical value.

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

Comments/Questions of the expert(s)

Comment 1
No comments

Comment 2
No comments

Comment 3
No comments/questions

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1
No questions

Comment 2
No comments

Comment 3
No comments/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 questions

Comment 2
No comments

Comment 3
The equivalence between the stacked event and the single events concerning the presence, copy number and maintenance of the flanking regions is done with Southern blot analysis using selected gene probes. These analyses confirmed the presence of similar sized hybridising fragments in the single and stacked events, thereby confirming the expected equivalence between the different events.

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

Comments/Questions of the expert(s)

Comment 1
No questions

Comment 2
No comments

Comment 3
No comments/questions

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Comment 1
Cry34Ab1 is present at 23.5 to 69.1 ng/mg dry weight, and Cry35Ab1 at 0.82 to 3.35ng/mg dry weight, which is comparable to the expression in 59122 maize.
Cry1F is present at 0.56 to 3.81 ng/mg dry weight which is comparable to the expression in 1507 maize
Molecular equivalence and identical copy number in 59122x1507 maize and those present in 59122 and 1507 maize respectively could be expected as no new genetic modification has been introduced in 1507x59122 maize which was obtained from traditional breeding methods between progeny of the single genetic modified maize strains.
It also indicates that no fusion proteins are formed

Comment 2
No comments

Comment 3
Comment p18 – line 6 Technical dossier. For sake of completeness it would be better to write "for the authorisation of 1507x59122 maize GRAINS for import and processing for all food and feed uses,..." This to avoid any confusion with the use of maize silage as feed. This specification for maize grains might be considered to be implemented also at other relevant positions in the dossier.

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 differences in agricultural characteristics found

Comment 2
No comments/questions

Comment 3
Remarks concerning the survivability of seeds of maize. In the dossier it is mentioned that seed of commercial maize varieties cannot survive without human assistance outside managed agricultural conditions. Furthermore it is mentioned that freezing temperatures have an adverse effect on germination. The minimum temperature for germination of 8 to 10°C restricts maize survival and reproduction capabilities mainly to the Southern European geographical zones. This is correct but from our experience maize seeds can survive in the soil during a not so severe winter. It can happen that out of full ears, fallen on the ground at harvest and after labouring of the land, covered with soil,

some seeds survive and give plantlets during the next season. So here in the case of GMO-plants it will be necessary to have a follow up of the fields in the next year to detect for surviving plants. This information is only relevant if at a certain moment the scope would be extended to cultivation in Northern and Western Europe with moderate to cold winter conditions.

Comment 4
Table 5 claims in the title to give data on the stacked transgene event and the two parent lines. I only find data from the stacked transgene event and a hybrid control.
Additional comment from the coordinator
The table does not give information on the parental lines !

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
No comments/questions

Comment 3
Figure 7 in annex 1 is un-readable.
Why is one of the transgene inserts (59122) segregating and the other not in the seeds of the hybrid with stacked events? If these are hybrid seeds, shouldn't all samples have both parents' contribution? If these plants are progeny from the selfed hybrid with the stacked events shouldn't both transgene inserts be segregating? I would like the applicants to be more clear on this point.

Additional comment from the coordinator (clarifying above comment)
On p 11 of Annex 1 the following paragraph is written:
"The 1507 inbred line was created by several rounds of backcrossing to the 3KP inbred background and the 59122 inbred line was created by two rounds of backcrossing to the 1W2 inbred background. The stacked hybrid represents a cross of the two inbred lines and contains the 3KPx1W2 hybrid background. Both the 59122 line and the stacked hybrid were expected to segregate for the event DAS-59122-7 insertion."

Inbred lines are not expected to segregate; yet it is written that line 59122 is expected to segregate for the event……". How do the applicants explain this ?

Although the applicants mention that the pedigree of the hybrid is available, no production scheme is given in the dossier. Hence we do not know with which (segregating ????? see comment here above) material trials and tests are conducted. We would like to see a clear history of the pedigree of the final hybrid and of the material used in all trials and tests.

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
It is explained that there are few to no possibilities for transfer of genetic material to other plants in case of unintended release of 1507x59122 maize e.g. via spillage during transportation of grain since the scope of this application does not include authorization for the cultivation of 1507x59122 maize seed products in EU

Comment 2
No comments/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
Although some statistically significant differences in compositional parameters between 1507x59122 maize and the non-GM control maize were observed, on a per location basis these differences were not consistently observed.
All values for 1507x59122 maize and non-GM control maize were within reported literature ranges.
Therefore , it is correctly concluded as for equivalency of GM and non-GM control maize and of grain from commercial maize

Comment 2
In this chapter it is mentioned that 1507 x 59122 maize was compared to non-GM maize with comparable background. Wherever possible publicly available data on commercial maize has also been used in the comparisons. What does it mean? The 1507 x 59122 is tolerant to glufosinate-ammonium. So I think it is not possible to compare with commercial varieties, unless they are also tolerant to glufosinate-ammonium (= are also genetically modified).

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1
No questions

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1
No comments

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1
No comments

Comment 2
The 1507 x 59122 maize was tested in North America and Canada. The results obtained confirmed that it is comparable to non-GM control maize, regardless of herbicide treatment.
So my remark: The results are only based on 1 year trials and the year effect can be given significant effects. And furthermore: what does it mean: regardless of herbicide treatment?

Additional comment from the coordinator (clarifying above comment)
The 1507 x 59122 maize was tested in North America and Canada during 2003. The results obtained confirmed that it is comparable to non- GM control maize, regardless of herbicide treatment. European agronomists never lean on results from trials conducted during 1 single year to compare varieties. Variety trials are always conducted during several years in several locations in order to be able to calculate genotype*environment interactions and to study overyears variability.

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1
No comments

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1
No comments

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

Comment 1
No questions

The anticipated intake of the expressed proteins is several orders of magnitude below levels shown to have NO effects in laboratory toxicology testing

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1
-No homology with known toxins for Cry1F, Cry34Ab1,Cry35Ab1,PAT-proteins expressed in 1507x59122 maize
-No indication for any toxicity in vivo in acute toxicity tests with doses many times higher than normal uptake by man in the highest possible ("worst") scenario

Comment 2
1507x59122 maize is derived from traditional breeding methods between progeny of genetically modified 1507 maize and 59122 maize. So no new genetic modifications have been introduced in 1507x59122 maize.

- 1507 maize has been genetically modified to express the Cry1F and PAT proteins. Expression of the Cry1F protein confers season-long resistance against certain lepidopteran pests, such as the European corn borer *Ostrinia nubilalis* and the pink borer *Sesamia* spp. It is expressed constitutively and provides control against insect pest damage when cultivated. Expression of the PAT protein confers tolerance to the application of glufosinate-ammonium herbicide.

- 59122 maize has been genetically modified to express Cry34Ab1, Cry35Ab1 and PAT proteins. The expression of the Cry34Ab1 and Cry35Ab1 proteins confers resistance against certain coleopteran insect pests such as *Diabrotica virgifera virgifera, Diabrotica barberi* and *Diabrotica undecimpunctata howardi* commonly known respectively as Western Corn Rootworm, Northern Corn Rootworm and Southern Corn Rootworm.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1
Safety assessment of the newly expressed proteins was based on:
-protein specificity
-no homology with known protein toxins
-very quickly digested in vitro and therefore very little chance that the intestine would be exposed to possible feed allergens,if any present
-no acute toxicity

Comment 2
Since the safety of the Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins for animal and human health has already been demonstrated as part of the safety evaluation of 1507 and 59122 maize, further testing for acute toxicity of these proteins, all of which being present in 1507x59122 maize, is **not required**.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

Comment 1
Not applicable

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

Comment 1
No questions

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 was performed by using **1507x59122 maize**.

First, it was checked whether protein content in **1507x59122 maize** grains is similar to that in the 1507 and 59122 maize grains respectively. This was indeed the case for the Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins.

	Cry1F (ng/mg dry w.)	Cry34Ab1 (ng/mg dry w.)	Cry35Ab1 (ng/mg dry w.)	PAT (ng/mg dry w.)
1507	1.20-3.10*	-	-	< LLOQ*
59122	-	28.9-84.8**	0.48-1.58**	< LLOQ**
1507x59122	0.56-3.81***	23.5-69.1***	0.64-3.35***	0.00-0.44***
1507x59122	2.61°°°	33.8°°°	1.80°°°	0.06°°°

* Annex 5-II (min/max)
** Essner and Coats, 2003 (min/max)
*** Technical dossier, table 6 (min/max)
°°° Delaney and Smith, 2004 (mean values)

In this study (Delaney and Smith, 2004) 33J56 is a commercially available non-transgenic hybrid maize grain which is used as a reference substance. Table 3 clearly indicates the absence of Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins in this 33J56 maize. In table 14, three out of the four proteins are detected (Cry1F, Cry34Ab1, Cry35Ab1; the fact that the PAT protein is not detected does not surprise me, since its concentration is most of the time below the limit of quantitation) in the starter and finisher phase diet of the 33J56 reference group. In the technical dossier it is mentioned that this is due to contamination during clean-up. To my point of view, any comparison making use of the 33J56 reference group is worthless and incorrect.
Otherwise, no statistically significant differences - concerning growth performance, carcass yields, thighs, breasts, wings, legs, abdominal fat, kidneys and whole liver - were observed between broiler

chickens consuming control (near isoline) or test diets or among all four experimental treatment groups (control, test and 2 references, of which one was contaminated).

A 13-week feeding study in the rat is not included. Why not? Such a study **should be performed** since synergistic effects cannot be excluded beforehand.

Additional comment from the coordinator (clarifying above comment about the results from the Delaney and Smith study)
Annex 3 refers to the study of Delaney and Smith, 2004. 33J56 is a commercially available non-transgenic hybrid maize grain which is used as a reference substance. Table 3 clearly indicates the absence of Cry1F, Cry34Ab1, Cry35Ab1 and PAT proteins in this 33J56 maize. In table 14, three out of the four proteins are detected (Cry1F, Cry34Ab1, Cry35Ab1; the fact that the PAT protein is not detected is not a surprise, since its concentration is most of the time below the limit of quantitation) in the starter and finisher phase diet of the 33J56 reference group. On p 17-18 of annex 3, it is mentioned that this is due to contamination during clean-up. Any comparison making use of the 33J56 reference group is scientifically incorrect.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1
Assessment of the allergenicity of the newly expressed proteins.
The reviewer agrees with the conclusion that, with the current knowledge, Cry34Ab1, Cry35Ab1 and PAT do not have the characteristics of known allergens, and are not likely to behave as allergens.
Cry1f, due to a very low similarity with Der p 7, a mite allergen, has been further investigated in the literature, but does not seem to have allergenic potential (Ladics et al. 2006). It is therefore reasonable to conclude, with the current knowledge, that Cry1f is not likely to be an allergen.

Assessment of the allergenicity of the whole GM plant or crop.
In section 7.9.2, the allergenicity of the genetically modified maize has not been investigated. The rationale of this section is not to take the new traits into consideration, but to evaluate, due to the introduction of the new traits, possible changes in the allergenicity of the recipient plant when this plant is known as an allergenic source.
Although it is rare, food allergy to maize exists and we must be cautious that it does not become more frequent. Major allergens have been determined (Pastorello et al. 2003; Pasini et al. 2002), and new allergens might be described in the near future (Weichel et al. 2006). Besides the fact that the introduced traits are not likely to behave as allergens, their introduction in the plant and the effects thereof might interfere with the expression levels of other maize proteins, including allergens. For that reason, it is relevant to analyze whether the expression levels of known major allergens is increased in genetically modified 1507x59122 maize grains. This can be carried out with Elisa to purified allergens. It can also be determined whether the overall allergenicity of a genetically modified grain maize extract is increased, as compared to that of its traditional counterpart. Again, Elisa can be used, by using maize patients serum to probe.

Comment 2
See remarks under 7.8

-No indication of any allergenicity and no characteristics of newly expressed proteins in 1507x59122 maize to known allergens; no sharing of immunologically relevant sequence homology

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

Comment 1
No comment

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

Comments/Questions of the expert(s)

Comment 1
No comment

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

Comments/Questions of the expert(s)

Comment 1
The mechanism of interaction between GM plant and target organism, hence the action mechanism of Cry34Ab1 Cry35Ab1 is very important to understand since it is linked with its specificity. Cry – proteins are activated by proteases and disrupt the insect gut wall via pore formation mediated by binding to specific gut receptors.
Cry35Ab1 alone has no effect while Cry34Ab1 has an effect but this is strengthened by Cry35 in a mixture; however the exact best mixture is not mentioned or known.
For Cry1F the action mechanism is similar to the interactions between B-thuringiensis Cry-proteins and target organisms;
Delta-endotoxins produced as protoxins dissolve in alkaline conditions of insect gut and are processed by proteases to release the active toxin, the aminoterminal part equal to the Cry1F protein. These bind to receptors of apical villi of insect midgut cells, with oligomerization of toxin and pore formation, resulting in lysis and cell death and finally insect death
As the application for the authorization of 1507x59122 maize is for feed and food use , not for seed and plant propagation or cultivation in EU, this aspect is therefore perhaps not so important as if it where for cultivation authorization

Comment 2
Not applicable

D.9. POTENTIAL CHANGES IN THE INTERACTIONS BETWEEN THE GM PLANT WITH THE BIOTIC ENVIRONMENT RESULTING FROM THE GENETIC MODIFICATION

D.9.1. Persistence and invasiveness

Comments/Questions of the expert(s)

Comment 1
Not relevant in scope of this application

Comment 2
Provided information: sufficient.

D.9.2 Selective advantage or disadvantage

Comments/Questions of the expert(s)

Comment 1
Not relevant here

Comment 2
Provided information: sufficient.

Comment 3
It is mentioned that maize is highly domesticated and cannot become established as a feral species outside the agricultural environment. How must we interpret the term "agricultural environment": southern Europe conditions (warm and dry) are more favourable for maize plants compared to northern Europe (cold and wet in spring).

D.9.3 Potential for gene transfer

Comments/Questions of the expert(s)

Comment 1
Not relevant in scope of this application

Comment 2
Provided information: sufficient.

D.9.4 Interactions between the GM plant and target organism

Comments/Questions of the expert(s)

Comment 1
See remarks under D8 as for the Cry-proteins

Comment 2
Provided information: sufficient.

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

Comments/Questions of the expert(s)

Comment 1
No comments

Comment 2
Provided information: sufficient.

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 significant effects on any of the parameters measured in the broiler trials;
See also the remarks for the trials with 59122x1507xNK603 maize compared with non-GM maize with comparable genetic background

Comment 2
A broiler trail was conducted (Annex 3). Mortality rate was rather high taking into account the rather low stocking density. No remarks on the experimental design and conclusions from the trial.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1
No questions

Comment 2
Provided information: sufficient.

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

Comments/Questions of the expert(s)

Comment 1
No questions

Comment 2
Not applicable

Comment 3
In this paragraph it is mentioned again that the scope of application does not include cultivation of maize plants of 1507 x 59122 maize in the EU. 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 have 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- maize be incorporated in normal VCU trials, for example treated with specific herbicides for maize and will the agronomical value be the same as tested in trials, where herbicides for which the variety is tolerant were used?

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1
No questions

Comment 2
Provided information: sufficient.

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

Comments/Questions of the expert(s)

Comment 1
No questions. Hardly relevant here in scope of the application

Comment 2
We support the recommendation of ACRE (2006) that provision of detailed arrangements for general surveillance post-market monitoring plans for the import and processing of grain from GM maize should be made a condition of any consent. These should include which and when information should be provided to EFSA and how the applicant can ensure this to happen.

Although resistance to insect attack is not the only factor preventing maize to grow outside the agricultural environment, the (indeed low) possibility of the establishment of maize protected against insect larvae in the wild in Europe should be a point of particular interest in a more detailed general surveillance plan.

Comment 3
If seeds were imported by train containers for making food and feed, some monitoring has to done to control if there are no maize plants along the railway roads. As already mentioned under a moderate winter seeds of maize can survive and can give plantlets in the next spring; so these plants have to destroyed.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

Comment 1
No questions; see D11.1

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

Comment 1
No questions

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

Comments/Questions of the expert(s)

Comment 1
No comment

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

Comment 1
No comment

References

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