Biosafety Advisory Council

11-04-2008

Secretariat

O./ref.: WIV-ISP/BAC/2008_719
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Title: Advice of the Belgian Biosafety Advisory Council on the application **EFSA/GMO/UK/2004/04** of Bayer CropScience under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/UK/2004/04 was submitted by Bayer CropScience on 20 August 2004 for the marketing (import and processing) of the glufosinate tolerant genetically modified rice LLRice62 for food and feed applications under Regulation (EC) No. 1829/2003[1]. It was officially acknowledged by EFSA on 14 January 2005.

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). Five experts answered positively to this request, and formulated a number of comments to the dossier synthesised 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 14 April 2005. The Belgian Biosafety Advisory Council also analysed the additional data provided by the applicant on request of the EFSA Scientific Panel on GMOs.

[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)

The opinion of the EFSA Scientific Panel on GMOs was adopted on 30 October 2007 (The EFSA Journal, 2007, 588, 1-25)[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 3 December 2007 the opinion of EFSA was forwarded to the Belgian experts. They were invited to give comments and to react if needed to the answers given by the EFSA GMO Panel, in particular in case the comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

The comments formulated by the experts together with the opinion of EFSA including the answers of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council given below.

Scientific evaluation

1) According to the Biosafety Advisory Council, no major risks were identified neither concerning the molecular characterisation nor the environment[3].

2) With regard to the compositional analysis and the toxicology, the Biosafety Advisory Council, considering the information present in the technical dossier and in the additional data provided by the applicant, is of the opinion that it is not possible to draw valid conclusions on the food and feed safety of this GMO.

3) Field trials realised to produce grains for the food and feed safety assessment were not done in accordance with the basic requirements for experimental planning and statistical analyses. Firstly, it is not clear whether cultivation was done with or without glufosinate ammonium herbicide application. Secondly, treatments were planned according to a randomised design but it is clearly indicated on page 56 of the technical dossier that due to the harvesting technique used, co-mingling of samples were expected. This means that grains from transgenic and non transgenic plots were mixed before the biochemical analyses. Proportions of expected co-mingling are not indicated. Moreover, 10% of adventitious plants are also expected in the samples, prior to biochemical analyses. These two points introduced a major bias in the compositional analyses, preventing the possibility of valid conclusions. In the response to EFSA sent by the applicant, additional field trials are presented. They were however realized in the same conditions as those presented in the initial dossier and present therefore the same bias.

[2] <http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178665910099.htm>

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

4) Concerning the composition in key elements, a 95% confidence interval is claimed. These data are not compared to the control of the experiment but to literature data where equivalence boundaries were set to ± 20% of the mean. The choice of a plus or minus 20% difference from the mean is scientifically not a correct choice, as for some component which can be present in very different amounts 20% may be only little, where as for other components 20% difference may be a lot. Moreover, the literature data refer to experiments done under very diverse conditions and thus does not reflect the range of composition variation in that rice variety but are also function of the range of experimental conditions under which they were realized. In the tables 6 to 10 provided by the applicant, these reference literature ranges are not given for all components. In consequence, most of the analyses on the composition in key elements are very difficult to assess.

5) The applicant considered that significant interactions in the ANOVA analyses means that component measured was more influenced by the environment than by treatment. This statement is difficult to accept as interactions never mean a hierarchisation of the effects.

6) Concerning the response to the statistical concern of the EFSA GMO Panel, the applicant persists in his previous position. The applicant claims that type 1 error are inversely correlated to type 2 error. This is not in accordance with the basics of statistical theory. Indeed, as "type 1 error" is false positive on the number of negative instances and "type 2 error" is false negative on the number of positive instances, they are not correlated.

7) Another major drawback of the statistical analysis is that there is no discussion on the statistical power either ex ante or ex post. Sentences such as "Bayer asserts the data set of grain analysis from 14 locations over the environmental backgrounds representing the range of intended commercial production is sufficient." cannot be accepted from a scientific point of view. Science is based on facts and not on assertions. The relevance of the size of the design should have been assessed by a power analysis and not asserted without any justification.

8) Considering the nutritional experiments, there were also significant differences in total weight gain, feed conversion efficiency and the hot weight at the end of the study between the group of pigs fed LLRICE62 treated with conventional herbicides and group of pigs fed LLRICE62 treated with glufosinate. Differences were found between the herbicides treatments. Significant differences were found in the final weeks of the study in the total weight gain and hot weight between the control groups and the group fed LLRICE62 sprayed with glufosinate. Also 10% lower feed:gain ratio was recorded in pigs fed conventionally sprayed rice compared to the group fed LL62 rice sprayed with glufosinate. According to the EFSA GMO Panel "while some of these differences were established as statistically significant they were not considered as biologically significant and would not detract from the weight of evidence supporting compositional and nutritional equivalence when comparing LLRICE62 and its conventional counterpart. The

differences may have been due solely to natural, physiological variation between the animals."

The Biosafety Advisory Council does not agree with this statement of the EFSA GMO panel. The objective of a statistical analysis is to make a distinction between the natural or background variability in a population and the added variability due to a treatment. The Biosafety Advisory Council is of the meaning that a statistical significant difference means that the treatment effect has a biological meaning instead of a random effect. Therefore, the Biosafety Advisory Council thinks that the observed significant effect cannot be explained by natural physiological differences between individuals instead of a treatment effect.

General conclusions

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 notifyer to the EFSA GMO Panel questions and considering the data presently available,

1) the Belgian Biosafety Advisory Council considers that no conclusion of equivalence can be drawn from the data provided by the applicant. Data are insufficient to establish substantial equivalence.

2) The Belgian Biosafety Advisory Council considers that data were not conclusive and did not allow to draw any sound scientific opinion that rice LLRICE62 will have no adverse effects on human and animal health in the context of its proposed uses.

3) The Belgian Biosafety Advisory Council advices not to approve the LLRICE62 in the context of its proposed use.

p.o.

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

Annex : Full comments of experts in charge of evaluating application EFSA/GMO/UK/2004/04 and comments submitted on the EFSAnet (ref: BAC_2005_PT_232)

Bioveiligheidsraad
Conseil de Biosécurité

April, 14th, 2005

Secretariaat
Secrétariat

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Comments of experts in charge of evaluating the application EFSA/GMO/UK/2004/04
and
Comments submitted on the EFSAnet on mandate of the Biosafety Council

Mandate for the Group of Experts: Mandate of the Biosafety Advisory Council of February 2th, 2005
Coordinator: Dirk Reheul (UGent)
Experts: Philippe Baret (UCL), Marie-Paule Delcour-Firquet (ISP), Rony Geers (KUL), Jean-Pierre Maelfait (Instituut voor Natuurbehoud), Hadewijch Vanhooren (KUL)
Domains of expertise of experts involved: genetics, population genetics, horizontal gene transfer, GMO traceability, biosafety research, ecology, plant-insect relations, nature conservation, sustainable development, agronomy, animal feed, toxicology and immunology.
Secretariat: Martine Goossens, Adinda De Schrijver

INTRODUCTION

Dossier **EFSA/GMO/UK/2004/04** concerns a notification of Bayer CropScience for the marketing (import and processing) of the genetically modified rice LLRICE62 for food and feed applications under Regulation (EC) No. 1829/2003.
The notification has been officially acknowledged by EFSA on 14 January 2005. The deadline for posting comments on the EFSAnet by the Member States is 14 April 2005.

This document gives an overview of all the comments received by the experts involved in the safety evaluation of application EFSA/GMO/UK/2004/04. The experts were asked to structure their comments according to 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. Items are left blank when no comments have been received either because the expert(s) focused on other related aspects, or because for this dossier the panel of experts who accepted to evaluate the dossier didn't have the needed expertise to review this part of the dossier.

LIST OF COMMENTS

A. GENERAL INFORMATION

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

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

D. INFORMATION RELATING TO THE GM PLANT

D.1 DESCRIPTION OF THE TRAIT(S) AND CHARACTERISTICS WHICH HAVE BEEN INTRODUCED OR MODIFIED

Comment 1:

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In many regions of temperate rice production and, especially in the Americas (Appendix 37: Noldin 1998), severe red rice infestations have removed land from economic rice production. In many cases, high clay soils of rice farm land are not suitable for other crops. In regions of Texas and Louisiana, as well as in the southern Brazil state of Rio Grande do Sul, former rice land is being grazed for the lack of efficacious red rice control. These rural economies would be enhanced if rice cultivation were able to return, especially to small farmers who have no resources to change the cropping system or to rent new land.

According to Noldin's paper alternative methods exists such as zero-tillage and high purity seeds. Noldin's paper doesn't mention "removed land". This paragraph should be rephrased.

In the same paragraph, I consider that the last sentence referring to the rural economies is unproven. Either economic considerations are not part of the assessment and this sentence should be removed from the technical report and from the summary or the economic and social aspects are taken into consideration and the impact on rural economies and more specifically on small farmers should be studied and quantified on the basis of scientific evidences. It is not the case at this stage.

PLACED ON EFSANET AS:

Economic considerations fall out of the scope of the regulatory frame and should not be part of the assessment. The sentence "These rural economies would be enhanced if rice cultivation were able to return, especially to small farmers who have no resources to change the cropping system or to rent new land." should be removed from the technical report and from the summary.

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

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

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

Comment 1:

Probability that the GMHP become more persistent than the parental or recipient plants in rural habitats or disseminate quicker in natural habitats:

Not to be expected.

Selective advantages or disadvantages conferred to the GMHP:

Only selective advantage when glufosinate ammonium herbicide is used.

D.5. GENETIC STABILITY OF THE INSERT AND PHENOTYPIC STABILITY OF THE GM PLANT

D.6. ANY CHANGE TO THE ABILITY OF THE GM PLANT TO TRANSFER GENETIC MATERIAL TO OTHER ORGANISMS

Comment 1:

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Messeguer et al., 2001 *CIRAD project*	*Estació Experimental del Delta del Ebro, Tarragona, Spain* *215,000 seed assessed*	*1 meter distance: 0.091%* *5 meter distance: 0.010%*

Quotation of Messeguer is not fully correct as in one of the circle trials gene-flow of 0.53 % was observed at 1 meter distance and in the wind direction.

Added comment of coordinator: The level of risk may be higher than indicated by averages of a series of results: for the given trial the results varied between 0.007 an 0.526 %.

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A weed resistance management model developed for Brazil (Appendix 30: Lima 2003 #B004397) finds that resistant red rice populations can be managed using currently practiced agronomic techniques.

This affirmation is of critical importance as a major environmental concern is the impossibility of management of the resistant red rice populations. The only reference quoted is Lima (2003) and the quality of Lima (2003) document is very poor : incomplete description of the model used, absence of list of references, no indication of the accuracy of the estimations. This document doesn't meet the minimal standards of a scientific publication and cannot be used to assert the possibility of management of a "resistant red rice population". In consequence, there is a major uncertainty about the management of red rice resistant population and I consider that the authorization cannot be given in absence of peer-reviewed scientific studies on this aspect.

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

D.7.2 Production of material for comparative assessment

D.7.3 Selection of material and compounds for analysis

D.7.4 Agronomic traits

D.7.5 Product specification

D.7.6 Effect of processing

D.7.7 Anticipated intake/extent of use

D.7.8 Toxicology

D. 7.8.1 Safety assessment of newly expressed proteins

Comment 1:

Acute toxicity by IV injection in the mouse

An acute study is performed by following the OECD TG 420 limit test guidance document recommendations (OECD, 2001). Mice of OF1 strain were used. Groups of 5 female mice received 1 or 10 mg/kg b.w. of PAT protein, of negative control aprotinin or of positive control melittin. A control group received only the vehicle. Clinical signs were recorded daily from day 1 through day 15. The animals were weighed on days –6, -1, 1, 8 and 15 or when found dead. All animals were autopsied. Necropsy included macroscopic examination of abdominal and thoracic cavities, major organs and tissues.

Mortality was observed on day 1 for all positive control animals treated at 10 mg/kg of melittin. No mortality was observed during the study in PAT protein-treated animals at 1 or 10 mg/kg or in other control groups. No clinical signs were noted in PAT protein-treated animals or in control groups throughout the study period. The body weight evolution was unaffected by the treatments. No treatment-related macroscopic abnormalities were detected in animals treated with either PAT protein at 1 and 10 mg/kg or control substances.

Critics, arguments of the notifier and conclusions

Testing of acute IV toxicity with mice of the isolated PAT protein is not a satisfying proof of safety because the protein is destined to be ingested in the same way than novel foods. Moreover, the duration of administration is too short and any microscopic observation isn't done. The PAT protein used in the test is not defined.

In his complementary data, the notifier precises that the protein used is obtain from *Escherichia coli* providing the demonstration of the equivalence between PAT protein produced by LLRICE62 and by *E. coli* (BK04Q015, C044340)

To support the safety of LLRICE62, Bayer provides sequence homology and epitope homology researches. The overall homology search of the LLRICE62 *bar* gene product indicated significant homology only with acetyltransferases, no identity with known toxins or allergens was shown (Appendix 42, C041097). PAT shares very similar two-dimensional structure, immunoreactivity, molecular weight and functional properties with other acetyltransferase enzymes which occur as a natural component of human and animal diet. In addition, bridging studies demonstrated the structural, biochemical and functional equivalence of the PAT protein (encoded by the *bar* gene) as it is produced by *Escherichia coli*.

The data demonstrate that rice containing the genetic locus LLRICE62 has the same nutritional composition as its non-transgenic counterpart and values for nutritional components fall within the range of values reported for rice commodities in commerce.

It was demonstrated that the PAT protein is degraded within 5 minutes in simulated gastric and intestinal fluids. The notifiant continues his argumentation in saying that the rapid degradation by the

components of the mammalian digestive system greatly minimises any potential for a novel protein to be absorbed by the intestinal mucosa, thereby potentially eliciting a toxic reaction. The proteolytic degradation is by-passed by using the IV injection, thus providing the advantage of being able to study the potential intrinsic toxic properties of the novel protein.

An acute study is performed to have a direct assessment of the acute toxicity of a novel protein. For Bayer, this study is considered to be the most appropriate as proteins are known to be toxic via acute mechanisms. The requerant uses the IV route of exposure in mice as a first tier test to examine toxic potential of novel proteins. Recognizing the IV acute study to be a potential over-predictive study, Bayer considers a positive safety assessment in these first tier criteria to be a sufficient indication of safety for a novel protein. The choice of IV exposure route is supported by experience in the testing of bacterial and food protein toxins. If a novel protein shows no potential intrinsic toxic property at a dose of 10 mg/kg body weight, there is no potential direct toxicity and therefore no acute toxicity hazard.

If we can accept the argumentation of the requerant to explain the choice of IV route, it is no explanation on the choice of the duration of the used test. It would be normal that a 28-days test will be done for a novel food. At my sense, the best argument to not do a short-term test is the fact that the PAT protein is well known and has been already tested in longer test than an acute one.

Comment 2:

Screening for structure-activity relationship, *in vitro* digestibility assays, and acute toxicity testing
It is stated that substantial equivalence has been established for LLRICE62.
A battery of tests designed to evaluate the PAT protein for characteristics associated with food allergens and toxins raised no concern. The PAT protein shared no sequence homology with known allergens and toxins (D.7.9) and is not stable in digestive environments (D.7.8.1.i). PAT exposure in mice via the acute intravenous route, 10 mg/kg bw (D.7.8.1.ii), did not affect body weight or induce any sign of toxicity.
According to the applicant, bridging studies demonstrated the structural, biochemical and functional equivalence for the PAT protein (encoded by the *bar* gene) as it is expressed in LLRICE62 and the PAT protein (encoded by the *bar* gene) as it is produced by *E. coli* (D.7.8.1.iii), and homology searches (sequence and epitope) indicated significant homology only with other acetyltransferases (D.7.8.1.iv).

Appendix 27, C025883: only first 2 pages received.

The PAT protein (encoded by the *bar* gene) used for the *in vitro* digestibility (simulated gastric and intestinal fluids) and the acute i.v. toxicity test in mice is produced by *E.coli*. The PAT protein (encoded by the *bar* gene) in *E. coli* is equivalent to the PAT protein (encoded by the *bar* gene) expressed in LLRICE62 considering the structural and functional properties. However, the sequences of the PAT proteins are not completely the same: there is one amino acid difference within the starter region of the protein (aspartic acid in *E. coli* vs. serine in LLRICE62).
In my opinion, the PAT protein (encoded by the *bar* gene) produced by *E. coli* is not equivalent to the PAT protein (encoded by the *bar* gene) expressed in LLRICE62. Although this can been seen as 'redundant', the *in vitro* digestibility and acute toxicity testing in mice should be reproduced with a PAT protein (encoded by the *bar* gene), demonstrated to be absolutely equivalent (i.e. identical) to the PAT protein (encoded by the *bar* gene) expressed in LLRICE62.

Genotoxicity

Genotoxicity testing, whether it is performed or not, should always be well motivated. A motivation is requested why genotoxicity testing was not performed.

Repeated dose toxicity

The 28-day oral toxicity test should be performed as a minimum requirement with a diet that properly nourishes the test animal (rodent), yet contains sufficient amounts of the protein. The study should include a Tier I immunotoxicity screen according to the modified OECD guideline 407 to establish dose-response characteristics and provide an indication for a Tier II screen.

The motivation for not performing the 28-day oral toxicity test because of the performed 14-week swine whole food feeding study, cannot be accepted as no complete endpoints (including biochemical, haematological, histological endpoints) were incorporated in the swine feeding study.

Screening for the possible occurrence of additional expressed products as a consequence of unintended effects of the genetic modification

Provided.

D.7.8.2 Testing of new constituents other than proteins

Comment 1:

No constituents other than the PAT protein is novel. OK

D.7.8.3 Information on natural food and feed constituents

Comment 1:

Appendix 17, report C011512: Substantial equivalence was demonstrated for the antinutrients. The dietary intake for PAT protein was estimated.

D.7.8.4 Testing of the whole GM food/feed

Comment 1:

Poultry (broiler chicken 42-day feeding) and pig (swine 96-day feeding) studies were conducted to demonstrate the safety of LLRICE62 as animal feed (poultry study) and human food (pig study). According to the applicant, no differences were identified for nutritive value of the grain and no indications of toxic or adverse effects were associated with any of the sources of rice in either of the tested animal species.

Poultry broilers feeding study

No significant differences were found between birds receiving the diet containing normal rice or LLRICE62. During the entire period, feed intake, weight gain and feed conversion were similar in all pens. The carcass quality of all birds was similar. It was concluded that LLRICE62 was nutritionally equivalent to non-GM rice.

What is the rationale for a 30% rice containing diet?

Complete characterisation of the rice batches used was done. Were the LLRICE62 and conventional rice grown with/without herbicide treatment? This is unclear to me. What is the average PAT content in the rice meal? What about herbicide residues and metabolites in the rice meal? These questions were partially answered in document 'C/GB/03/M5/3 Response to member state comments'. But have the relevant reports been transmitted to the competent authorities?

Swine feeding study

No data were provided on the PAT-protein, and glufosinate-ammonium residues and its metabolites in the diet and in the carcass. Data provided by the applicant in document 'C/GB/03/M5/3 Response to member state comments', only refers to animal metabolism studies done with the herbicide and estimations made for the PAT protein.

In terms of toxicity testing:

The pig is considered as a reliable indicator of toxic potential, nutritional and metabolic value. As such, a 14 week study was performed to investigate the effect of feed type on weight gain, feed conversion efficiency, dressing percentage, 10th rib backfat thickness, 10th rib longissimus area thickness and estimated carcass lean percentage. As the pig is considered to represent a close approximation to the human food preferences and digestive processes, data on complete endpoints (including biochemical, haematological, histological endpoints) should be provided. However, these data are missing. Moreover, these data become more relevant as feed B and feed C (both LLRICE62) were found to be significantly different compared with the non-GMP controls based on weight gain, hot weight (not feed C), feed:gain ratio, being most pronounced in the last 4 weeks of the study.

In conclusion, substantial equivalence between the tested rice grains cannot be demonstrated based on the outcome of the performed swine feeding study.

Document C/GB/03/M5/3 Response to member state comments: Herbicide residues

Studies are conducted to examine residues of glufosinate-ammonium and its metabolites, plant and animal metabolism studies. Were the relevant reports transmitted to the competent authorities?

D.7.9 Allergenicity

D.7.10 Nutritional assessment of GM food/feed

Comment 1:

Feeding trials should have included more animals per treatment to increase the power of the statistical analysis or sensitivity of the trial.

1. File 4257: trial with pigs
   a. Only mean values are reported so that the sensitivity of the test cannot be calculated.
   b. Body weights at slaughter show a large variability, which seems to be higher than in normal farming conditions, so that one can expect that the number of animals per treatment should have been higher for finding potential treatment effects.

2. File 5148: trial with broilers
   a. The reported variability shows that the threshold difference between treatments is at least 10%, indicating poor sensitivity of the trial.

b. The definition of FCE does not match the calculation result in one table.
c. Wasted feed is not taken into account for calculating FCE.

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

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

D.9.2 Selective advantage or disadvantage
(Possibility of the transfer of genes to the same species, or to other vegetal species sexually compatible, within the plantation conditions of the GMHP and selective advantages or disadvantages conferred to those vegetal species)

Comment 1:

GMHP will not be deliberately planted. If spilled rice seeds germinate near cultivated rice field and produce pollen that arrives on the plantation, a gene transfer may occur.

D.9.3 Potential for gene transfer

D.9.4 Interactions between the GM plant and target organism

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

Comment 1:

Immediate and/or delayed incidence on the environment of the direct or indirect interactions between the GMHP and the target organisms like predators, parasitoids and pathogens:

Not to be expected because a release in the field is not intended.

Immediate and/or delayed incidence on the environment of the direct or indirect interactions between the GMHP and the non-target organisms (taking also into account the interactions of organisms with the target organisms), especially the incidence on the population levels of the competitors, herbivores, symbiotes, parasites and pathogenic agents:

Not to be expected because a release in the field is not intended.

D.9.6 Effects on human health

D.9.7 Effects on animal health

D.9.8 Effects on biogeochemical processes
(Immediate and/or delayed incidence on biogeochemical processes of the potential direct or indirect interactions between the GMO and the target and non-target organisms close by the released GMO(s))

Comment 1:

Not to be expected because a release in the field is not intended.

D.9.9 Impacts of the specific cultivation, management and harvesting techniques
(Immediate and/or delayed, direct or indirect incidence on the environment resulting from the specific techniques for cultivation, management and harvest used for the GMHP when those techniques differ from those used for non-GMHP)

Comment 1:

Not to be expected because a release in the field is not intended.

Magnitude and classification of the as above identified potential risks related to the GMO

Comment 1:

Estimates the magnitude and classification of the above identified potential risk as very low.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

D.11. ENVIRONMENTAL MONITORING PLAN

D.11.1 General

D.11.2 Interplay between environmental risk assessment and monitoring

Comment 1:

Care should be taken that no feral populations develop from spillages during transit from import zones to mills in areas of rice cultivation. This could be an element of the general surveillance in northern countries. In rice cultivating regions it should perhaps be better to make it an environmental aspect of a case-specific monitoring plan.

D.11.3 Case-specific GM plant monitoring

D.11.3 General surveillance of the impact of the GM plant

D.11.5 Reporting the results of monitoring