Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC/2012_0216

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/UK/2008/60 from Syngenta under Regulation (EC) No. 1829/2003

Context

The application EFSA/GMO/UK/2008/60 was submitted by Syngenta on 30 June 2008 for the the marketing of the glyphosate-tolerant genetically modified GA21 maize for import, processing, food and feed uses and cultivation under Regulation (EC) No. 1829/2003[1].

The application was officially acknowledged by EFSA on 21 October 2008. 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 chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology (SBB), to evaluate the dossier. Four experts answered positively to this request and formulated a number of comments on 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 20 January 2009.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 30 November 2011 (The EFSA Journal, 2011, 9 (12):2480)[2], and published on 16 December 2011 together with the responses from the EFSA GMO Panel to comments submitted by the experts during the three-month consultation period.

On 21 December 2011 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. In addition, complementary information regarding toxicity sent by the company to EFSA in December 2010 was provided to the coordinator and the expert who evaluated this aspect of the application..

[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/2480.htm

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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.

In addition, the scientific evaluation of the application EFSA/GMO/UK/2005/19 - maize line GA21 for import and use (except cultivation) - for which food/feed aspects were assessed, is also taken into account in this advice. Due to some shortcomings in the scientific quality of the data the Biosafety Advisory Council could not unanimously conclude on the safety of GA 21 maize[3]. Due to the low power of the statistical analysis and the low sensitivity of animal trials for the toxiciological assessment (presented in surplus to EFSA requirements), some members of the BAC were not convinced of the health safety of GA21.

Since 2008 the market of products containing, consisting of, or produced from maize GA21 is authorised by the European Commission[4].

Scientific evaluation

1. Environmental risk assessment

According to the Biosafety Advisory Council no major risks were identified concerning the environment, provided that the cultivation of GA21 is managed following appropriate agricultural practices.

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

With regard to compositional analysis, the Biosafety Advisory Council is of the opinion that the information provided is sufficient, follows the OECD recommendations and 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

With regard to allergenicity, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.
The Biosafety Advisory Council recommends following up any unanticipated allergenicity aspects of the GM plant in monitoring systems.

[3] Advice of BAC on maize line GA21: BAC_2007_SC_614, available at: <http://www.bio-council.be/bac_advices.html >

[4] Commission Decision 2008/280/EC of 28 March 2008, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:087:0019:0022:EN:PDF>

3.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient and shows the nutritional equivalence of the GM maize with its non-GM counterpart and conventional maize varieties.

4. Monitoring

With regard to the post-market environmental monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.
As the allergenicity of the whole GM maize has not been assessed, it is recommended to take up monitoring of allergenicity as part of the general surveillance of this GM food.

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,

a) The Biosafety Advisory Council, agrees with the GMO panel of EFSA that no major risks concerning the environment were identified.
In line with EFSA opinion, the BAC recommends managing the use of glyphosate on maize GA21 within cropping regimes that have similar or reduced environmental impacts compared with conventional maize cultivation.
The Biosafety Advisory Council also recommends the Competent Authority to check if the actual authorization of the use of glyphosate does cover and allow its use in a transgenic herbicide tolerant crop.

b) The Biosafety Advisory Council is of the opinion that *it is unlikely that maize GA21 will have any adverse effects on human and animal health in the context of its intended uses.*

c) The Biosafety Advisory Council recommends following up any unanticipated allergenicity aspects of the GM maize in the general surveillance.

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

Annex I: Minority declaration Lucette Flandroy
Annex II: Full comments of experts in charge of evaluating application EFSA/GMO/UK/2008/60 and comments submitted on the EFSAnet (ref. BAC_2009_870)

Annex I : Minority declaration Lucette Flandroy

Opinie van Lucette Flandroy

Ambtenaar bij de FOD volksgezondheid, mevr. Lucette Flandroy diende op 13 februari 2012, 3 dagen na de vergadering van de Adviesraad voor Bioveiligheid, een "minderheidsadvies" in over het maïsdossier GA21.

Het advies over GA21, zoals het door de Adviesraad in de vergadering op 10 februari 2012 is opgesteld, werd ter zitting door alle leden aanvaard.

Mevrouw Flandroy heeft ter zitting, na de redactie van het advies, wat commentaar geleverd. Deze commentaar is door een hoogleraar in de Adviesraad als fillibusteren omschreven; de inhoud van haar tussenkomst is als irrelevant afgewezen.

Het minderheidsadvies van mevrouw Flandroy is daarom geen minderheidsadvies maar een persoonlijke opinie; het heeft van niemand uit de Adviesraad enige steun.

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

Minority advice of L. Flandroy, member of the Belgian Biosafety Consultative Council, on the application EFSA/GMO/UK/2008/60 concerning the genetically modified GA21 maize.

To justify a **negative advice** for this application on the GM maize GA21, I want to add some elements to those already mentioned in the official advice of the BAC, that gives a negative advice as long as specific appropriate management measures for the cultivation of this GMO have not been legally established in order to avoid medium/long term environmental safety risks linked to the use of the herbicide glyphosate on this GMO.

Firstly, one may have doubts about the sufficiency **of fields trials** made **only** in some places of **Spain, Romania and Czech Republic**, during **only one season in each location**, to conclude in the absence of short/medium term important negative impacts of this GMO in all the climatic conditions and ecosystems of the European Union where this GMO could be cultivated (NB: more than one season of field trials are required for new conventional seeds to be agreed on Member States or EU catalogues of seeds, and the new guidelines of EFSA for the ERA of GM plants also requires at least 2 seasons of field trials). Field trials were also made in the **USA and** in **Brazil**, the results of which can be informative but not sufficient to conclude for potential risks in the EU.

Linked to this first remark: agronomic and phenotypic traits of this GMO were studied in field trials in the USA, in Brazil, and in the 3 concerned above mentioned EU member States , as explicited in the EFSA opinion on this file (p. 16). Statistically significant **differences in grain yields** between maize GA21 and the corresponding comparator were observed during these field trials, that were however **not consistently detected at each individual location** (and thus considered as not biologically important by EFSA), **suggesting, anyway** and precisely, possible unintended modifications in the **GM variety** that makes it **differently adapted to different ecosystems and climatic conditions**, and thus possibly differently susceptible to diseases in different ecosystems.
Only one disease susceptibility (to maize rough dwarf virus) has been **tested in the EU**. During trials on other continents, one made **in Brazil** in 2003 revealed a high phytotoxicity of the studied plants in some place in this study. Whereas the GMO panel of EFSA agrees with the explanation of the notifier, saying that the observed phytotoxicity results from a high incidence of fungi at this location, this study reveals in any case a **difference in phytotoxicity between GA21 plants treated with glyphosate** (phytotoxicity in up to 30% of plants) **and non-GM control plants** (phytotoxicity in up to 50% of plants); supposing that the right non-GM comparator was used, this different phytotoxicity **suggests a difference in disease susceptibility** between GA21 and its non-GM comparator, in some situation of high disease incidence.

Potential differences in disease susceptibility between GA21 and its non-GM comparator should have been studied more accurately, and in particular in EU ecosystems. Indeed, **reduction in resistance towards infections in GA21 could be problematic** not only economically for the farmers cultivating this GMO, but also more generally **in case of contamination and crossing of non-GM maize with GA21**; **the genetic pool of non-GM maize could so indeed be affected**. (It is presently recognized, including in the EFSA opinion on this file, that, even if major at short distance, cross-pollination can, with maize pollen, happen over distances up to kilometers, and that seed spillage can happen during import, transportation, storage, handling and processing.)

In addition, **doubts persist about the food/feed safety of this GMO**, from the results of tests on animals, as already raised by several members of the BAC in its advice of 07/12/2007 on the file of this GMO that was then introduced only for food/feed purpose but not for cultivation (and, at least part of the data reported in the present file are taken from **studies** performed **on nutritional and food/feed safety** aspects in this previous file). An expert associated with the BAC raises concerns on this safety aspect in the present file (p. 6 of the compilation of the compilation of the comments of experts). As already mentioned in

the conclusions of the BAC advice of 2007, the power of the statistical analysis and/or the sensitivity of the **tests performed do not comply with standards of good statistics**, thus making it **impossible to draw sensible conclusions** on differences (or lack of differences) observed in physiological parameters , between animals fed with the purified proteins or with the whole GM food/feed and their controls (cf. top and bottom of p. 7 of the comments of experts made on 5/07/2006). Neglecting this problem of statistical power (not enough experimental animals to take due account of natural biological variability), EFSA anyway considers that several differences with the controls in blood parameters and organ weights are statistically significant, but not toxicologically relevant because no dose related, or limited only to one sex; this justification for irrelevancy does not sound as scientific.

Last general observation concerning allergenicity.
Maize is not considered as a common allergenic source in the concerned document of OECD (dated from 2002), the source for risk assessments made by EFSA.
Anyway, **maize allergens have inbetween been described**, some of them being able to induce anaphylaxis reactions in patients, with very little doses (cf. p. 9 of Compilation of comments of Belgian experts of 20/01/2009). This lead the BAC to request the evaluation of the potential allergenicity of the whole GM plant or kernels in its advice of 07/12/2007 (for the preceding GA21 file introduced for food/feed use only), and in its comments to EFSA (during the consultation period) on this new GA21 file introduced in addition for cultivation. (Thus, in the case of cultivation, necessity to take also into account potential **respiratory allergens, maize pollen being one of these**, causing “real allergy problems in children living near maize fields” following the experience of clinicians and independent allergologists, as stated in p.9 of the Compilation of comments of Belgian experts of 20/01/2009 on this file).
However, in absence of perfectly adequate methods able to foresee the potential allergenic power of a product (and since, in particular, dose/effect relationship is not always straight in the case of allergenicity), **the BAC decided in 2010 not to require the evaluation of the allergenicity of GM maize plants as long as maize is not listed as an allergenic source by OECD**. I consider that competent authorities and responsible ministers have to be aware of this BAC decision.
The BAC anyway **recommends** following up unanticipated allergenicity aspects of the GM plant in **monitoring** systems. This implies, of course, to have adequate monitoring systems in place and functioning.

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20-01-2009

Compilation of comments of experts in charge of evaluating the application EFSA/GMO/UK/2008/60
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 October 2008
Coordinator: Prof. dr. ir. Dirk Reheul
Experts: Pascal Cadot (Consultant), Rony Geers (KUL), Peter Smet (Consultant), Michel Van Koninckxloo (HEPHO)
Domains of expertise of experts involved: Toxicology in vitro, general biochemistry, immunology, alimentary allergology, animal nutrition, traceability of alimentary chain, agronomy, agro-ecology
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman

INTRODUCTION

Dossier **EFSA/GMO/UK/2008/60** concerns an application of the company **Syngenta** for the renewal of the marketing authorisation of the genetically modified **maize GA21** for food and feed applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 21 October 2008.
The scope of the application is:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☒ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

Depending on their expertise, the experts were asked to evaluate the genetically modified plant considered in the application on its 1) environmental, 2) allergenicity, 3) toxicity and/or 4) food and feed aspects[1]. It was expected that the expert should evaluate if the information provided in the

[1] The data related to the molecular characterisation have already been assessed in the frame of application EFSA/GMO/UK/2005/19. Concerning this aspect no new information has been provided in dossier UK/2008/60.

application is sufficient in order to state that the marketing of the genetically modified plant for its intended uses, will not raise any problems for the environment or human or animal health. If information is lacking, the expert was asked to indicate which information should be provided and what the scientifically reasoning is behind this demand.

The comments are structured as in the "Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed" (EFSA Journal (2004), 99, 1-94). Items are left blank when no comments have been received either because the expert(s) focused on other related aspects, or because for this dossier the panel of experts who accepted to evaluate the dossier didn't have the needed expertise to review this part of the dossier.
It should be noted that all the comments received from the experts are considered in the evaluation of this dossier and in formulating the final advice of the Biosafety Advisory Council. Comments placed on the EFSAnet are indicated in grey.

List of comments received from the experts

GENERAL COMMENTS

Comments/Questions of the expert(s)

A. GENERAL INFORMATION

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient in order to state that the marketing of the Maize Event GA21 for its intended uses, will not raise any problems for the environment or human or animal health.
Weeding maize was very simple as long as the use of Atrazine (herbicide total which maize is resistant) was authorized, it is no longer the case in the European Union. The event GA21 would restore, for some time, the practice of weeding through another single molecule: glyphosate.
To be grown in Europe, hybrids derived from GA21 Maize Event will be submitted to the registration process in national catalogs of varieties of agricultural plant species, this procedure will determine the interest of their culture, from an agronomical point of view, in the areas where it is supposed to be grown.

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

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

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.

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

Comments/Questions of the expert(s)

Note from the SBB :
See advice of the Belgian Biosafety Advisory Council on dossier EFSA/GMO/UK/2005/19 (ref. BAC_2007_SC_614) : "no risks identified concerning the molecular characterisation".

D.3. INFORMATION ON THE EXPRESSION OF THE INSERT

Comments/Questions of the expert(s)

Note from the SBB :
See advice of the Belgian Biosafety Advisory Council on dossier EFSA/GMO/UK/2005/19 (ref. BAC_2007_SC_614) : "no risks identified concerning the molecular characterisation".

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.

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

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

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.

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)

D.7.2 Production of material for comparative assessment

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.3 Selection of material and compounds for analysis

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.4 Agronomic traits

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.5 Product specification

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.6 Effect of processing

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.7.7 Anticipated intake/extent of use

Comments/Questions of the expert(s)

D.7.8 Toxicology

Comments/Questions of the expert(s)

Comment 1

mEPSPS protein measured in GA21 maize

Referring to table 2 of appendix 9: data provided in this table do not correspond very well with similar data found in earlier notifications containing the event GA21.

Comment 2

Two studies were carried out, one with mice and another with rats. In both cases the number of replicates per group, and hence the statistical power, seem to be too low to detect potential statistical differences with respect to body weight. A remarkable fact in the mouse study is a larger value of the s.d. in the treatment group for the blood values, while the opposite is the case for body weight.

D. 7.8.1 Safety assessment of newly expressed proteins

Comments/Questions of the expert(s)

Comment 1

a) Degradation of the mEPSPS protein in simulated gastric fluid (Graser, 2005 (appendix 19)).

No intact mEPSPS (*ca*. 47.4 kDa molecular weight) was detected following digestion of the microbially and plant-derived mEPSPS in SGF for 1 minute as assessed by SDS-PAGE.
Faint, diffuse bands of lower molecular weight (*ca*. 4 -5 kDa) were visible on SDS-PAGE of the microbial test substance over the time course. These bands did not cross-react with the corresponding anti-mEPSPS antibody as shown on the corresponding Western blot.
The plant-derived enzyme preparation showed a minor, additional band with slightly higher mobility (i.e., lower molecular weight) than mEPSPS by SDS-PAGE. This band also cross-reacted with the anti-EPSPS antibody and most likely represents a degradation product of mEPSPS. However, the additional protein band was also degraded completely after 1 min. The plant-derived protein sample also contained interfering material in the lower molecular ranges (resulting in a diffuse smear between *ca*. 9 to 2 kDa) that made it impossible to visualize distinct lower molecular weight bands on the SDS gel. This interfering material was not visible on the corresponding Western blot as evidenced by the presence of only a single, defined visible band in the 1 min sample in the range of the 6kDa marker band. This immunoreactive protein fragment most likely represents a breakdown product of mEPSPS due to pepsin action and was no longer detectable after 5 min.

b) Degradation of the mEPSPS protein in simulated intestinal fluid (author).

The technical dossier refers to appendix 19 for the digestibility assays. This document contains only information for the assay under gastric conditions.

c) mEPSPS: Acute Oral Toxicity Study in Mice (Barnes, 2005 (appendix 21)).

There were no effects on clinical condition, bodyweight, food consumption, clinical pathology, organ weights, macroscopic or microscopic pathology that were considered to be related to the administration of 2000 mg mEPSPS protein/kg bodyweight to male and female mice. No further testing is needed.

d) mEPSPS: Assessment of Amino Acid Sequence Homology with Known Toxins (Harper, 2008 (appendix 17))

The NCBI Entrez protein database was searched using the BLASTP program to determine if the double mutated maize 5-enol pyruvylshikimate-3-phosphate synthase protein (mEPSPS) has any significant amino acid sequence homology to known toxins. It was concluded that the mEPSPS query sequence showed no significant sequence homology to any proteins identified as, or known to be, toxins.

D.7.8.2 Testing of new constituents other than proteins

Comments/Questions of the expert(s)

D.7.8.3 Information on natural food and feed constituents

Comments/Questions of the expert(s)

D.7.8.4 Testing of the whole GM food/feed

Comments/Questions of the expert(s)

Comment 1

a) 49-day feeding study in broiler chickens (Brake, 2005 (appendix 26)).

Poultry diets prepared with transgenic Event GA21 maize grain from plants that were either treated or untreated with glyphosate herbicide both supported rapid broiler chicken growth at very low mortality rates and very good feed conversion ratios without any substantial differences in overall carcass yield. It was clear that there were no obvious deleterious effects associated with consumption of Event GA21 transgenic maize grain when compared to control (non-transgenic) maize grain.

f) 90-Day rat feeding study (Barnes, 2005 (appendix 25)).

There were no differences in bodyweight, food consumption, clinical condition (including ophthalmoscopy and functional observation battery), clinical pathology, organ weights or histopathology that were considered to be attributable to the inclusion of Event GA21 positive transgenic maize grain in CT1 diet.
No further testing is needed.

D.7.9 Allergenicity

Comments/Questions of the expert(s)

Comment 1

Assessment of the allergenicity of the newly expressed proteins.
According to currently available data and to data presented in the dossier, mEPSPS is unlikely to be allergenic.

Assessment of the allergenicity of the whole GM plant or crop.

The applicant did not assess the allergenicity of the whole GM plant. Conversely to what is stated in the application, maize allergy is documented, although it is not recognized as a major allergy concern. Some maize allergens have been described in the literature (Pastorello et al. 2003; Pasini et al. 2002, Weichel et al. 2006). Recently, patients showed maize-induced anaphylaxis, and some reacted to as little as 100 mg of maize (Scibilia et al. 2008). This reinforces the need to evaluate the allergenicity of the whole GM plant.

It is relevant to analyze whether the expression levels of known maize allergens is increased in the genetically modified maize grains or to analyze whether the overall allergenicity of the modified maize has increased, compared to a natural counterpart. This is relevant as, theoretically, the introduction of the new trait might have modified the expression level of some endogenous maize proteins. Patient IgE binding to maize grain extract or titration of known major allergens of maize should be carried out.

In addition, because the application deals with cultivation, respiratory maize allergens should be taken into account. Although literature on that subject is scarce, allergy to maize pollen is well known in the allergy outpatient departments of the clinics and of the independent allergologists. It results from cross-reactivity with grass pollen, and is a real allergy problem in children living near maize fields. The most known cross-reacting allergens are Zea m 1 and Zea m 13, that cross-react with the group 1 and 13 allergens of grasses (Petersen et al. 2006). Therefore, the expression level of those major allergens should be determined in the pollen of genetically modified maize GA21, compared to a traditional counterpart.

D.7.10 Nutritional assessment of GM food/feed

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

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

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

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.

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

NOT Applicable

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)

D.9.7 Effects on animal health

Comments/Questions of the expert(s)

Comment 1

The statistical design and number of replicates were right for inferring conclusions in the reported trial with broiler chickens.

D.9.8 Effects on biogeochemical processes

Comments/Questions of the expert(s)

Comment 1

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

The information provided in the application is sufficient.

D.10. POTENTIAL INTERACTIONS WITH THE ABIOTIC ENVIRONMENT

Comments/Questions of the expert(s)

Comment 1

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

The information provided in the application is sufficient.

D.11.2 Interplay between environmental risk assessment and monitoring

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.11.3 Case-specific GM plant monitoring

Comments/Questions of the expert(s)

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

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

D.11.5 Reporting the results of monitoring

Comments/Questions of the expert(s)

Comment 1

The information provided in the application is sufficient.

References

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