Bioveiligheidsraad
Conseil de Biosécurité

25 January-2013

Secretariaat
Secrétariat

O./ref.: WIV-ISP/41/BAC_2013_0023

Title: Advice of the Belgian Biosafety Advisory Council on the application EFSA/GMO/NL/2012/107 from Monsanto under Regulation (EC) No 1829/2003

Context

The application EFSA/GMO/NL/2012/107 was submitted by Monsanto on 12 March 2012 within the framework of Regulation (EC) No 1829/2003[1] for authorization of the use of insect resistant genetically modified (GM) maize MON 810 pollen as or in food, completing herewith the scope of the application RX-MON 810 (renewal of authorization of maize MON810 for food and feed applications, including cultivation).

The application EFSA/GMO/NL/2012/107 was officially acknowledged by EFSA on 29 May 2012. On the same date EFSA started the formal three-month consultation of the Member States, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms (GMOs) being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted toxicologists chosen from the common list of experts drawn up by the BAC and the Biosafety and Biotechnology Unit (SBB) to evaluate the dossier. Two experts answered positively to this request and formulated two comments to the dossier, which were edited by the coordinator. See Annex I for an overview of the comments, one of which was actually transmitted to EFSA on 29 August 2012.

The opinion of the EFSA Scientific Panel on GMOs was adopted on 6 December 2012 (The EFSA Journal, 2012, 1012, 3022[2]), and published together with the responses of the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

On 4 January 2013 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 comments formulated in their initial assessment of the dossier were not taken into account in the opinion of EFSA.

The advice of the Biosafety Advisory Council given below is based on the comments formulated by the experts, the opinion of the EFSA GMO Panel including answers to these comments, as well as the scientific advice given by the BAC in November 2009 on the

[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/3022.htm

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application EFSA/GMO/RX-MON810[3] which concluded that the food and feed uses of MON 810 present no risks for human or animal health and that no risks for the environment are foreseen from the cultivation of this GM maize.

Scientific evaluation

Assessment of food safety

The safety of the Cry1Ab protein expressed in MON 810 has been previously assessed (notably in the frame of application RX-MON 810) and no concerns regarding potential toxicity or allergenicity have been identified. The same Cry1Ab protein is expressed in pollen of maize MON 810 and therefore no safety issues are expected from the intake of this pollen.

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, and considering the data presently available, the Biosafety Advisory Council is of the opinion that the previous assessment and conclusions of the BAC on safety of the GM maize MON 810 reached for food/feed aspects remain valid. The Biosafety Advisory Council therefore agrees with EFSA *that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen is to replace maize pollen from non-GM maize in or as food.*

p.o. Ph. Herman

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

Annex I: Minority declaration of Lucette Flandroy
Annex II: Full comments of experts in charge of evaluating application EFSA/GMO/NL/2012/107 and comments submitted on the EFSAnet (ref: BAC_2012_0781)

[3] Ref. of document : BAC_2009_01510

Minority declaration of L. Flandroy on the dossier GMO/NL/2012/107
(pollen of MON810 in or as food)

The authorization asked in this dossier is specifically to allow pollen from MON810 maize in or as food.
The analysis and tests made previously for the authorization of MON810 (EFSA/GMO/RX-MON810) for a usual food/feed use were performed with isolated Cry1Ab protein or with GM maize grain, but not with the pollen of this maize. They do not preclude the possibility of unforeseen pleiotropic effects of the transgene presence specifically in the pollen of this strain, leading eventually to negative human health impacts if consuming this pollen. In the present dossier, no specific scientific test has been presented about the nutritional or eventual toxicity or allergenicityof this pollen. While pollen is in small quantity in current honey and the transgene is not expressed abundantly in the pollen, some people eat pure pollen, and I consider it is not reasonable neither legal to allow the specific consumption of this pollen as being safe on science-sound basis without having at least tested its eventual toxicity.

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29-08-2012

Secretariaat
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Compilation of comments of experts in charge of evaluating the application EFSA/GMO/NL/2012/107
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 15 June 2012
Coordinator: Prof. Eddy Decuypere
Experts: Birgit Mertens (WIV-ISP), Peter Smet (Consultant)
Domains of expertise of experts involved:
Secretariat (SBB): Didier Breyer, Adinda De Schrijver, Martine Goossens, Philippe Herman, Katia Pauwels

INTRODUCTION

Dossier **EFSA/GMO/NL/2012/107** concerns an application of the company **Monsanto** for the marketing authorisation of the genetically modified **maize MON810** for food applications under Regulation (EC) 1829/2003.
The application has been officially acknowledged by EFSA on 29 May 2012.
The scope of the application is:
a) GM food
☐ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
b) GM feed
☐ Feed containing or consisting of GM plants
☐ Feed produced from GM plants
c) GM plants for food or feed use
☐ Products other than food and feed containing of consisting of GM plants with the exception of cultivation
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)
The scope of the current application complements the scopes of previous MON 810 renewal applications, and includes the use of MON 810 pollen as or in food. The range of uses of MON 810 will continue to be identical to the full range of equivalent uses of current commercial maize.

Depending on their expertise, the experts were asked to evaluate the genetically modified plant considered in the application on its toxicity 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 human 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.

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

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 (Smet)

No new toxicological data were provided. No new proteins are present in MON 810 pollen, so the same conclusions remain as for the original dossier.

Comment 2 (Mertens)

Ik heb geen belangrijke commentaren.
De enige vraag die ik heb, is waarom er gebruik wordt gemaakt van een NOAEL van een acute orale toxiciteitstest. Meestal wordt een NOAEL-waarde van een (sub)chronische toxiciteitstest gebruikt. Zijn er geen gegevens van sub(chonische) testen beschikbaar (nochtans wordt in het EFSA-rapport EFSA-GMO-RX-MON810 een 28d studie met het Cry1Ab proteïne vermeld)?

English translation:
Why does the applicant use the NOAEL of an acute oral toxicity test? Mostly it is the NOAEL value from a (sub)chronic toxicity test that is used. Are there no data available from sub(chronic) tests (yet the EFSA report on GMO-RX-MON810 mentions a 28d study with Cry1Ab protein)?

Comment SBB:
EFSA (2009) refers to a 28 days toxicity study in rats (Onose et al, 2008).
The question could be why the 'No Adverse Effect level (NOAEL)' has not been derived from this subchronic toxicity study in rats with reduced gastric acid secretion and/or small intestinal damage.

References

EFSA (2009) Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. Scientific Opinion of the Panel on Genetically Modified Organisms. *The EFSA Journal* (2009) 1149, 1-84

Onose J-I et al. (2008) Evaluation of subchronic toxicity of dietary administered Cry1Ab protein from Bacillus thuringiensis var. Kurustaki HD-1 in F344 male rats with chemically induced gastrointestinal impairment. Food and Chemical Toxicology 46 (2008) 2184–2189