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SCIENTIFIC OPINION

Scientific Opinion on an application (EFSA-GMO-RX-MON863) for renewal of the authorisation for continued marketing of existing feed materials, feed additives and food additives produced from maize MON863, under Regulation (EC) No 1829/2003 from Monsanto[1]

EFSA Panel on Genetically Modified Organisms (GMO Panel)[2, 3]

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ABSTRACT

This scientific opinion reports on an evaluation of an application (reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$) for renewal of the authorisation for continued marketing of existing feed materials, feed additives and food additives produced from genetically modified (GM) insect resistant maize MON863. Maize MON863 has been modified with a gene encoding the Cry3Bb1 protein which confers protection against coleopteran pests, principally the corn rootworm (*Diabrotica* spp.). In addition, a selectable marker gene *npt*II encoding neomycin phosphotransferase II has been introduced. In 2004 the EFSA GMO Panel issued scientific opinions on a Notification for the placing on the market of GM maize MON863 for import and processing and on a request from the European Commission for the placing on the market of foods and food ingredients derived from GM maize MON863. In delivering the present opinion, the EFSA GMO Panel considered the information provided in the application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$ as well as additional information provided by the applicant and information published in the scientific literature. The new data in the application included bioinformatic analyses using updated databases which confirmed that no relevant similarities exist between the newly expressed proteins and known allergens or proteins toxic to mammals. The EFSA GMO Panel has evaluated the new information provided by the applicant and the scientific literature and concluded that there was no new information that would require changes of its previous scientific opinions on maize MON863 (EFSA, 2004a,b). Therefore, the EFSA GMO Panel reiterates its previous conclusions that GM maize MON863 and its products which are the subject of this application are unlikely to have an adverse effect on human and animal health or the environment in the context of its intended uses (EFSA, 2004a,b).

1 On request from the European Commission on an application submitted by Monsanto under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-MON863), Question No EFSA-Q-2007-163, adopted on 10 March 2010.

2 Panel members: Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Gerhard Flachowsky, Lieve Herman, Huw Jones, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Harry Kuiper, Antoine Messéan, Kaare Magne Nielsen, Joe Perry, Annette Pöting, Jeremy Sweet, Christoph Tebbe, Atte Johannes von Wright, and Jean-Michel Wal. Opinion is shared by all members of the Panel. 0 Panel member(s) with minority opinion. 0 members of the Panel did not participate in [part of] the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: gmo@efsa.europa.eu

3 Acknowledgement: The EFSA GMO Panel wishes to thank the members of the Working Groups Molecular Characterisation, Food and Feed and Environment for the preparation of this opinion and EFSA's staff member(s) Jaime Aguilera, Antonio Fernandez Dumont and Karine Lheureux for the support provided to this EFSA scientific output.

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Key words

GMO, maize, *Zea mays*, MON863, insect resistance, food and feed safety, environment, risk assessment, renewal, existing product, Regulation (EC) No 1829/2003

SUMMARY

Following a request from the European Commission, the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on an application submitted by Monsanto under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$) for renewal of the authorisation of existing feed materials, feed additives and food additives produced from genetically modified maize MON863.

The scope of this application covers the continued marketing of existing feed materials, feed additives and food additives produced from maize MON863 which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of entry into force of Regulation (EC) 1829/2003 these products were notified to the European Commission according to Articles 8(1)(b) and 20(1)(b) of this Regulation and subsequently included in the Community Register of genetically modified food and feed[4]. The scope of this application excludes import of viable plant material and cultivation.

Maize MON863 expresses a variant *Bacillus thuringiensis cry3Bb1* gene which confers protection against coleopteran pests, principally the corn rootworm (*Diabrotica* spp.). In addition, a selectable marker gene *npt*II encoding neomycin phosphotransferase II has been introduced.

The EFSA GMO Panel has previously issued opinions related to a Notification (reference C/DE/02/09) for the placing on the market of maize MON863 for import and processing under Part C of Directive 2001/18/EC and to a request under Article 4 of the Novel Food Regulation (EC) No 258/97 for the placing on the market of foods and food ingredients derived from maize MON863. In these opinions the Panel concluded that MON863 will not have an adverse effect on human and animal health or the environment in the context of its intended use. In addition, several applications related to stacked events including maize MON863 have been evaluated and the GMO Panel concluded that these stacked events are unlikely to have an adverse effect on human and animal health and on the environment, in the context of their intended uses.

In delivering its opinion the EFSA GMO Panel considered the information provided in the renewal application (reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$), additional information submitted by the applicant on request of the EFSA GMO Panel, the scientific comments submitted by Member States as well as relevant information published in the scientific literature. In accordance with the Guidance Document for renewal of authorisations of existing GMO products, the EFSA GMO Panel has taken into account the new information and data which have become available during the authorisation period.

With regard to the molecular data on maize MON863 that have already been evaluated in the context of the previous applications on maize MON863, the EFSA GMO Panel refers to its previous scientific opinions. The scientific assessment included the transformation process, the vectors used and the transgenic constructs in the GM maize MON863. The further assessment presented here is based on the information provided by the applicant in application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$, including updated bioinformatic analyses.

According to the information provided by the applicant, MON863 and GM maize containing event MON863 stacked with other GM events (which have been approved within the EU) have been

[4] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=12

cultivated in the USA. Scientific publications, which have become available since the previous opinions of the EFSA GMO Panel on maize MON863, have been assessed by the GMO Panel and did not raise safety issues. In addition, bioinformatic analyses comparing the amino acid sequences of the newly expressed proteins in maize MON863 with amino acid sequences in updated data bases of toxic and allergenic proteins confirmed the results of the previous studies which identified no relevant similarities between the newly expressed proteins Cry3Bb1 and NptII and known allergens or proteins toxic to mammals.

The scope of this application excludes import of viable plant material, which is covered by the previous opinions, and cultivation. Therefore, there is no requirement for scientific information on environmental safety assessment of accidental release or cultivation of maize MON863. A post-market environmental monitoring plan for maize MON863 is not required.

The EFSA GMO Panel has evaluated the new information provided by the applicant and the scientific literature and concluded that there was no new information that would require changes of its previous scientific opinions on maize MON863 (EFSA, 2004a,b). Therefore, the EFSA GMO Panel reiterates its previous conclusions that GM maize MON863 and its products which are the subject of this application are unlikely to have an adverse effect on human and animal health or the environment in the context of its intended uses (EFSA, 2004a,b).

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BACKGROUND

On 29 June 2007, EFSA received from the European Commission an application for renewal of the authorisation for continued marketing of existing feed materials, feed additives and food additives produced from maize MON863 (reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$)[5], submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003). The scope of this application covers the continued marketing of existing feed (feed materials and feed additives) and food additives produced from maize MON863, which were lawfully placed on the market in the Community before the date of application of Regulation (EC) No 1829/2003. After the date of application of Regulation (EC) No 1829/2003 the products were notified to the European Commission according to Articles 8(1)(b) and 20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed[6].

The EFSA GMO Panel has previously issued opinions (EFSA, 2004a,b) related to a Notification for the placing on the market of maize MON863 for import and processing (reference C/DE/02/9) under Part C of Directive 2001/18/EC (EC, 2001) and to a request under Article 4 of the Novel Food Regulation (EC) No 258/97 (EC, 1997) for the placing on the market of foods and food ingredients derived from maize MON863. The EFSA GMO Panel concluded that maize MON863 will not have an adverse effect on human and animal health or the environment in the context of its intended uses (EFSA, 2004a,b). In addition, the EFSA GMO Panel has evaluated several applications related to GM maize containing stacked transformation events including maize MON863 (EFSA, 2005a,b,c,d).

The EFSA GMO and BIOHAZ Panels have recently published an opinion (EFSA, 2009) on the use of antibiotic resistance marker genes. This opinion reaffirms a previous statement by the GMO Panel (EFSA, 2007), and a former opinion (EFSA, 2004), that adverse effects from the use of *nptII* gene as an antibiotic resistance marker are unlikely.

After receiving the application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$ and in accordance with Articles 5(2)(b) and 17(2)b of Regulation (EC) No 1829/2003, EFSA informed the Member States, and the European Commission and made the summary of the dossier available to the public on the EFSA website. EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 8 and 20 of Regulation (EC) No 1829/2003. On 5 June 2008 EFSA declared the application as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003[7].

EFSA made the valid application available to Member States and the European Commission and consulted nominated risk assessment bodies of the Member States, including the national Competent Authorities within the meaning of Directive 2001/18/EC (EC, 2001) following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. The Member State bodies had three months after the date of receipt of the valid application (until 5 September 2008) within which to make their scientific comments known.

The EFSA GMO Panel asked the applicant for additional data on maize MON863 on 11 July 2008, 12 February 2009 and 4 June 2009 for application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$. The applicant provided the requested information on 11 November 2008, 19 March 2009 and 1 October 2009, respectively. After receipt and assessment of the full data package, the EFSA GMO Panel finalised its opinion on maize MON863. The EFSA GMO Panel carried out the scientific assessment of the renewal application on GM maize MON863 according to the Guidance Document for renewal of authorisation of existing products (EFSA, 2006) taking into consideration the scientific comments of the Member States and the additional information provided by the applicant.

[5] The products were notified to the European Commission according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003

[6] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=12

[7] See section Documentation provided to EFSA

In giving its opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of six months from the receipt of the valid application. As additional information was requested by the EFSA GMO Panel, the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, the EFSA opinion shall include an assessment report stating the reasons for its opinion and the information on which the opinion is based, including the comments of the competent authorities when consulted in accordance with Article 6(4) and 18(4) of Regulation (EC) No 1829/2003. This document is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the overall opinion in accordance with Articles 6(5) and 18(5).

TERMS OF REFERENCE

The EFSA GMO Panel was requested to issue an opinion on an application for renewal of the authorisation for continued marketing of existing products, i.e. feed (feed materials and feed additives) and food additives produced from maize MON863 that were previously notified, according to Articles 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed, and that now was submitted under Article(s) 8(4) and 20(4) of Regulation (EC) No 1829/2003. This application fulfils the requirements of Articles 11(2) and 23(2) of Regulation (EC) No 1829/2003.

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the EFSA GMO Panel did also not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

ASSESSMENT

1. Introduction

Regarding the information which has already been evaluated in the context of the previous Notification (reference C/DE/02/9) for the placing on the market of maize MON863 for import and processing under Part C of Directive 2001/18/EC (EC, 2001) and to a request under Article 4 of the Novel Food Regulation (EC) No 258/97 (EC, 1997) for the placing on the market of foods and food ingredients derived from maize MON863, the EFSA GMO Panel refers to its earlier opinions (EFSA, 2004a,b). The scientific assessment included the transformation process, the vectors used and the transgenic constructs in the genetically modified plant. An evaluation of a comparative analysis of agronomic traits and composition was undertaken and the safety of the new proteins and the whole food/feed was evaluated with respect to toxicology and allergenicity. Evaluation of an environmental assessment was undertaken. The EFSA GMO Panel concluded that MON863 will not have an adverse effect on human and animal health or the environment in the context of its intended use (EFSA, 2004a,b).

The assessment presented here is based on the information provided by the applicant in application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$ for continued marketing of existing feed materials, feed additives and food additives produced from maize MON863, and additional information submitted by the applicant in response to questions from the EFSA GMO Panel, as well as relevant information published in the scientific literature. Information provided by the applicant includes 1) updated molecular characterisation, including additional sequence data for the flanking regions; 2) an update on peer-reviewed scientific data on maize MON863; 3) a report on import and use of maize MON863 in Europe and an estimation of human and animal exposure; and 4) updated information on allergenicity and toxicology, including new bioinformatic analyses.

The EFSA GMO Panel has assessed the new information available for maize MON863 in relation to the data which have already been evaluated by the EFSA GMO Panel in the context of the previous applications concerning maize MON863 (EFSA, 2004a,b).

2. Issues raised by the Member States

The scientific comments raised by Member States are addressed in details in Annex G of the EFSA overall opinion and have been considered throughout this EFSA GMO Panel scientific opinion[8].

3. Evaluation of relevant new scientific data

3.1. Molecular Characterisation

In response to a request from the EFSA GMO Panel an updated bioinformatic evaluation (2009) was performed using extended flanking sequences to determine if any coding sequences were disrupted by the insertion of the T-DNA present in MON863 or whether coding sequences from the maize genome are present in the flanking genomic DNA adjacent to the T-DNA after transformation. The results of the nucleotide searches showed that the DNA flanking the inserted DNA in MON863 is maize mitochondrial DNA. There is no information to indicate whether the mitochondrial DNA associated with the insert in MON863 occurred as a result of the transformation process or whether it was already present at the insertion locus prior to transformation. Expressed sequence tag (EST) alignments to both the 5' and 3' flanking sequences were obtained, but the databases did not contain any information on the function of these ESTs or their translation products. When combined, the data

[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-163

from the bioinformatic analyses do not provide any evidence that coding sequences are located in the extended regions that flank the T-DNA insertion site in MON863 or that endogenous coding sequences had been disrupted during transformation.

Updated bioinformatic analyses of the insert and flanking sequences also indicated no biologically relevant structural similarities to known allergens. Data did indicate significant alignments between one of the sequences translated from the T-DNA in MON863 and the Cry proteins that are contained in the toxin database. Such alignments are not unexpected and alignments with Cry proteins do not indicate toxicity to humans or animals with the exception of the target insects.

The stability of the trait is assessed by the applicant using a seed quality and stewardship program to maintain the performance of the product. The applicant states that overall, less than 1% of the registered biotechnology products complaints are related to product performance and to date, none of these complaints have revealed trait stability issues.

3.1.1. Conclusion

The updated bioinformatic analyses provided for the event MON863, together with information on seed quality and stewardship, do not indicate any safety concerns and the EFSA GMO Panel maintains its previous opinions on the safety of this event.

3.2. Food and Feed safety assessment

In addition to the information available in the original application that was taken into account by the EFSA GMO Panel in its previous opinions (EFSA, 2004a,b), the applicant provided information on the import and use of maize MON863 in the EU and an estimation of human and animal exposure to maize MON863, new studies in relation to the potential allergenicity and toxicity of the newly expressed proteins as well as information on peer-reviewed scientific data on maize MON863 that have become available since the previous opinions of the EFSA GMO Panel.

The applicant provided data on the import and use of maize MON863 (as well as stacked events containing maize MON863) in Europe and an estimation of the human and animal exposure. Their estimated exposure levels in both humans and animals were very low (i.e. 1,4 10^{-4} g maize flour and 1,1 10^{-3} g oil per person/day and up to 0,63% in livestock diets).

On request of the EFSA GMO Panel the applicant submitted new bioinformatics-supported comparisons of the amino acid sequences of the newly expressed proteins Cry3Bb1 and NptII with sequences of known toxic and general proteins using updated databases. These analyses confirmed the results of the previous studies which showed no similarities between Cry3Bb1 and NptII and known proteins toxic to mammals.

Regarding potential allergenicity, new bioinformatics-supported comparisons of the amino acid sequences of these proteins with sequences of known allergens using updated databases were provided. These analyses, which included searches for overall sequence similarity using the FASTA algorithm and searches for short identical stretches of at least eight contiguous amino acids, confirmed the results of the previous studies showing no similarities of Cry3Bb1 and NptII with known allergens.

In addition, the EFSA GMO Panel evaluated two scientific publications by Nakajima et al. (2009) and Kim et al. (2009), which tested for the presence of Cry3Bb1-specific IgE antibodies in serum samples from patients allergic to maize from the US and Korea, respectively. None of the serum samples studied showed IgE binding to Cry3Bb1.

A compilation of peer-reviewed scientific data on maize MON863 and derived food and feed, which may be relevant for the safety assessment, has been provided by the applicant. Briefly, studies in pigs showed that feeding of maize MON863 in the diet resulted in similar growth performance and carcass quality compared with animals fed non-GM maize (Hyun et al., 2005). In another study, the effects of grazing maize plant residues or feeding grains from maize MON863 was examined using steer calves. Performance was not negatively affected suggesting that plant residues and grains from maize MON863 are similar to plant residues and grains from conventional non-GM maize when utilised by beef cattle (Vander Pol et al., 2005). In addition, molecular characterisation, protein expression levels and field performance of MON863 hybrids were described in the publication by Vaughn et al., (2005). Finally, the *in vivo* digestive fate of the Cry3Bb1 protein was examined in laying hens fed diets containing grains from maize MON863. There were no relevant effects on feed intake, egg production and body weight. The Cry3Bb1 protein was extensively digested, similar to other dietary proteins, and was not detected in hepatic or muscle tissue (Scheideler et al., 2008).

In addition, the applicant made reference to a publication related to a statistical re-analysis of the data obtained in a subchronic (90-day) feeding study in rats using kernels from maize MON863 (Seralini et al., 2007). This study had been already evaluated by the EFSA GMO Panel in its previous opinions and did not raise a safety concern (EFSA, 2004a,b). The EFSA GMO Panel has considered the results of the statistical re-analysis by Seralini et al. (2007) and concluded that there is no reason to revise its previous opinions (EFSA, 2007b). In relation to this, the EFSA GMO Panel has also considered the paper by de Vendômois *et al.* (2009), which provides a statistical re-analysis of data from three 90-day rat feeding studies including the study with maize MON863. The EFSA GMO Panel concluded that the authors' claims are not supported by the data provided in their paper. There is no new information that would lead the EFSA GMO Panel to reconsider its previous opinions on maize MON863 (EFSA, 2010).

The EFSA GMO and BIOHAZ Panels have recently published an opinion (EFSA, 2009) on the use of antibiotic resistance marker genes. This opinion reaffirms a previous statement by the GMO Panel (EFSA, 2007), and a former opinion (EFSA, 2004), that adverse effects from the use of *nptII* gene as an antibiotic resistance marker are unlikely.

3.2.1. Conclusion

The EFSA GMO Panel has evaluated the new information provided by the applicant and in the scientific literature and concluded that there was no new information that would require changes of its previous scientific opinions on maize MON863 (EFSA, 2004a,b).

3.3. Environmental assessment

The scope of the application excludes import of viable plant material and cultivation. Considering the intended uses of maize MON863, the environmental risk assessment is concerned with the exposure through manure and faeces from gastrointestinal tracts of animals consuming maize MON863.

Therefore, there is no requirement for scientific information on environmental safety assessment of accidental release or cultivation of GM maize MON863.

3.3.1. Gene transfer

Genomic DNA is a component of many food and feed products derived from maize. It is well documented that DNA present in food and feed becomes substantially degraded in the process of digestion in the human or animal gastrointestinal tract. However, a low level of exposure of fragments of ingested DNA, including the recombinant fraction of such DNA, to microorganisms in the

digestive tract of humans, domesticated animals, and other animals feeding on maize MON863 is expected.

Current scientific knowledge indicates that horizontal gene transfer of non-mobile DNA fragments between unrelated organisms (such as plants to microorganisms) is extremely unlikely to occur under natural conditions (see EFSA, 2009 for further details). In addition to the low concentration of DNA in the gastrointestinal tract and the lack of competence of most bacteria to take up foreign DNA, the major barrier to such horizontal transfer is the lack of sufficient DNA sequence similarity for homologous recombination to occur in bacteria.

Maize line MON863 contains a modified *cry3Bb1* gene and an intact *npt*II gene (encoding neomycin phosphotransferase II). The *npt*II gene was used as a selection marker during the construction of event MON863. The EFSA GMO Panel recently formulated an Opinion (EFSA, 2009) on the use of antibiotic resistance genes in GM plants and concluded that the use of *nptII* as a selection marker is unlikely to have an adverse effect on human and animal health or on the environment, in the context of its intended uses.

The *cry3Bb1* gene is of bacterial origin. Thus, in theory, the *cry3Bb1* gene of the recombinant DNA insert could provide sufficient DNA similarity for homologous recombination with genes from environmental bacteria. However, as discussed in more detail below, such hypothesized horizontal gene transfer event is not likely to be maintained in bacterial populations due to a predicted lack of efficient expression and, in the unlikely case of their expression, no identified selective advantage conferred to gene transfer recipients.

In case of illegitimate recombination into genomes of bacteria in the environment, it is unlikely that recombinant genes regulated by eukaryotic plant promoters in maize MON863 would be expressed. The *cry3Bb1* gene is regulated by plant virus promoters. The activity of these plant virus promoters in unrelated organisms such as bacteria can not be excluded but in the unlikely event that the *cry3Bb1* gene and associated regulatory elements are taken up by bacteria, no selective advantage is anticipated because *cry* genes are distributed in various natural bacterial species in the environment.

The hypothesised low level exposure of bacterial communities in the environment to the maize *cry3Bb1* and *nptII* genes must be seen in the context of the natural occurrence and level of exposure to alternative sources of genetically diverse *cry* genes and kanamycin resistance genes to which bacterial communities are naturally exposed.

The wide environmental presence of genetically diverse natural variants of the recombinant DNA coding sequences, the use of regulatory sequences optimised for expression in eukaryotes, and the absence of an identified plausible selective advantage, suggest it is highly unlikely that the recombinant DNA will transfer and establish in the genome of bacteria in the environment or human and animal digestive tract.

3.3.2. Interactions between the GM plant material and non-target organisms

The EFSA GMO Panel evaluated whether the Cry3Bb1 protein might potentially affect non-target organisms by entering the environment through manure and faeces from the gastrointestinal tracts of animals fed maize MON863. Due to the selectivity of the Cry protein, non-target organisms most likely to be affected by the Cry3Bb1 protein belongs to the same or related taxonomic groups as those of the target organisms.

Most Cry proteins are degraded by enzymatic activity in the gastrointestinal tract of animals receiving GM or their derived products (*e.g.* silage), meaning that only low amounts of these proteins would remain intact to pass out in faeces. This has been demonstrated for Cry1Ab (*e.g.* Einspanier et al.,

2004; Lutz et al., 2005, 2006; Wiedemann et al., 2006; Guertler et al., 2008; Paul et al., 2010). It is expected that there would subsequently, be further degradation of the Cry proteins in the manure and faeces due to microbial proteolytic activity. Therefore, exposure of soil and aquatic environments to the Cry3Bb1 protein from disposal of animal wastes is likely to be very low and localised. While Cry proteins can bind to a certain degree to clay minerals or humic substances in soil, thereby reducing their availability to microorganisms for degradation, there are no indications of persistence and accumulation of Cry proteins from GM crops in soil (reviewed by Icoz and Stotzky, 2008). More specifically, Cry3Bb1 of GM maize was found to be more rapidly degraded in soil compared to Cry1Ab under similar conditions (Baumgarte and Tebbe, 2005; Miethling-Graff et al., 2010).

Considering the scope of the application and the intended uses of maize MON863, it can be concluded that the exposure of potentially sensitive non-target organisms to the Cry3Bb1 protein is likely to be very low and of no ecological relevance.

3.3.3. Post market environmental monitoring

Considering that the scope of application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$ excludes import of viable plant material and cultivation, a post-market environmental monitoring plan for GM maize MON863 is not required.

3.3.4. Conclusion

Considering the scope of application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$, there is no requirement for scientific information on environmental risks associated with the accidental release or cultivation of maize MON863. A post-market environmental monitoring plan for maize MON863 is not required. The EFSA GMO Panel considers that GM maize MON863 is unlikely to have an adverse effect on the environment in the context of its intended uses.

CONCLUSIONS AND RECOMMENDATIONS

The EFSA GMO Panel was requested to deliver a scientific opinion on an application for renewal of the authorisation for continued marketing of existing products produced from GM maize MON863 (application reference EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$) under Regulation (EC) No 1829/2003. The scope of this application covers the continued marketing of existing feed materials, feed additives and food additives produced from maize MON863, which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003 and included in the Community Register of genetically modified food and feed.

The EFSA GMO Panel has assessed the information provided by the applicant in the application EFSA-GMO-RX-MON863$_{[8.1.b/20.1.b]}$ in relation to the data which have already been evaluated by the GMO Panel in the context of the previous applications for GM maize MON863 (EFSA, 2004a,b).

New information provided by the applicant and from the scientific literature confirms the EFSA GMO Panel's previous opinion that GM maize MON863 is unlikely to have an adverse effect on human and animal health or the environment in the context of its intended use.

The scope of these applications excludes import of viable plant material and cultivation. Therefore, there is no requirement for scientific information on environmental risks associated with the accidental release or cultivation of maize MON863. A post market environmental monitoring plan for GM maize MON863 is not required.

The EFSA GMO Panel has evaluated the new information provided by the applicant and the scientific literature and concluded that there was no new information that would require changes of its previous scientific opinions on maize MON863 (EFSA, 2004a,b). Therefore, the EFSA GMO Panel reiterates its previous conclusions that GM maize MON863 and its products which are the subject of this application are unlikely to have an adverse effect on human and animal health or the environment in the context of its intended uses (EFSA, 2004a,b).

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, received 29 June 2007, concerning a request for placing on the market of genetically modified event MON863 in accordance with Regulation (EC) No 1829/2003.

2. Acknowledgement letter, dated 20 July 2007, from EFSA to the European Commission.

3. Letter from EFSA to applicant, dated 05 June 2008, delivering the 'Statement of Validity' for application EFSA-GMO-RX-MON863, event MON863, submitted by Monsanto under Regulation (EC) No 1829/2003.

4. Letter from EFSA to applicant, dated 11 July 2008, requesting additional information and stopping the clock.

5. Letter from applicant to EFSA, dated 22 August 2008, providing the timeline for submission of response.

6. Letter from applicant to EFSA, dated 11 November 2008, providing additional information.

7. Letter from EFSA to applicant, dated 21 January 2009, restarting the clock.

8. Letter from EFSA to applicant, dated 12 February 2009, requesting additional information and stopping the clock.

9. Letter from applicant to EFSA, dated 19 March 2008, providing additional information.

10. Letter from EFSA to applicant, dated 04 June 2009, requesting additional information and maintaining the clock stopped.

11. Letter from applicant to EFSA, dated 21 July 2009, providing the timeline for submission of response.

12. Letter from applicant to EFSA, dated 01 October 2009, providing additional information.

13. Letter from EFSA to applicant, dated 16 November 2009, restarting the clock.

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