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SCIENTIFIC OPINION

Scientific Opinion on an application (EFSA-GMO-RX-MS8-RF3) for renewal of the authorisation for continued marketing of existing (1) food and food ingredients produced from genetically modified glufosinate-tolerant oilseed rape Ms8, Rf3 and Ms8 x Rf3, and (2) feed materials produced from genetically modified glufosinate-tolerant oilseed rape Ms8, Rf3 and Ms8 x Rf3, under Regulation (EC) No 1829/2003 from Bayer CropScience[1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Hybrid oilseed rape Ms8 x Rf3 has been produced by conventional crossing between the genetically modified (GM) parental lines Ms8 and Rf3. The hybrid system is achieved using a pollination control system by insertion and expression of *barnase* and *barstar* genes into two separate oilseed rape lines; each gene is linked to the *bar* gene conferring tolerance to glufosinate-containing herbicides. The scope of this application covers the continued marketing of existing food (processed oil) and feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. In 2005 the EFSA GMO Panel had issued a scientific opinion on the safety of glufosinate-tolerant oilseed rape Ms8 x Rf3 derived from parental lines Ms8 and Rf3 for import and processing for feed and industrial uses. In delivering the present opinion, the EFSA GMO Panel considered the information provided in the application EFSA-GMO-RX-MS8-RF3 as well as additional information submitted by the applicant. The new data included molecular and bioinformatic analyses and a 42-day feeding study on chickens. The animal study showed that the tested material of oilseed rape Ms8 x Rf3 was nutritionally equivalent to its non-GM counterpart. In addition, bioinformatic studies using updated databases confirmed that no relevant similarities exist between the newly expressed proteins and known allergens or toxic proteins. Therefore, the EFSA GMO Panel reiterates the conclusions of its previous scientific opinion of 2005 that GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment. This also applies to the products which are the subject of the present application.

1 On request from the European Commission on an application submitted by Bayer CropScience under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-MS8-RF3), Question No EFSA-Q-2007-159, adopted on 9 September 2009.

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KEY WORDS

oilseed rape, Ms8/Rf3, food, feed, safety, renewal, existing product.

SUMMARY

This document provides the scientific opinion of the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on request from the European Commission an application submitted by Bayer CropScience under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-MS8-RF3) for renewal of the authorisation for continued marketing of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3.

The scope of this application covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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) No 1829/2003 these products were notified to the European Commission according to Articles 8(1) (a) and 20(1) (b) of that Regulation and included in the Community Register of genetically modified food and feed[3].

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/BE/96/01 for the placing on the market of glufosinate-tolerant hybrid oilseed rape Ms8 x Rf3 derived from genetically modified parental lines Ms8 and Rf3 for import and processing for feed and industrial uses under Part C of Directive 2001/18/EC. In this earlier opinion, the EFSA GMO Panel concluded that "*the placing on the market of Ms8, Rf3 and Ms8 x Rf3 oilseed rape for import and processing for feed and industrial purposes is unlikely to have an adverse effect on human or animal health or, in the context of its proposed uses, on the environment. This is in addition to the present uses of oil for food purposes and processed meal for feed purposes, both derived from Ms8 x Rf3 oilseed rape, which are already lawfully placed on the market.*"

In delivering the present opinion, the EFSA GMO Panel considered the information provided in the renewal application (reference EFSA-GMO-RX-MS8-RF3) as well as additional information submitted by the applicant upon request of the EFSA GMO Panel. 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, experience and data, which have become available during the authorisation period.

Regarding the molecular data which have already been evaluated in the context of the previous notification on oilseed rape Ms8, Rf3 and Ms8 x Rf3, the EFSA GMO Panel refers to its previous scientific opinion. The scientific assessment included the transformation process, the vectors used and the transgenic constructs in the GM oilseed rape. The further assessment presented here is based on the information provided by the applicant in application EFSA-GMO-RX-MS8-RF3, including an updated molecular characterization. These updated molecular and bioinformatic analyses provided for oilseed rape Ms8 and Rf3 as well as additional data, provided upon request of the EFSA GMO Panel, do not indicate any concerns.

According to the information provided by the applicant, food and feed products produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 that have been approved in the EU, have been consumed without reports of adverse effects. Bioinformatic studies comparing the amino acid sequences of the newly expressed Barnase, Barstar and PAT proteins in oilseed rape Ms8, Rf3 and Ms8 x Rf3 with amino acid sequences in updated databases of toxic or allergenic proteins confirmed the results of the older studies which identified no relevant similarities to known toxic or allergenic proteins. In addition, a 42-day feeding study in broiler chickens showed that the tested material of oilseed rape Ms8 x Rf3 is nutritionally equivalent to its non-GM counterpart.

The scope of this application excludes import of viable plant material and cultivation. Therefore, there is no requirement for scientific information on environmental safety assessment of accidental

[3] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=15

release or cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3. A post-market environmental monitoring plan for oilseed rape Ms8, Rf3 and Ms8 x Rf3 is not required.

The EFSA GMO Panel concludes that there is no new information provided by the applicant or in the scientific literature that would require changes of its previous scientific opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3. Therefore, the EFSA GMO Panel reiterates the previous conclusions that GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment. This also applies to the products which are the subject of the present application.

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BACKGROUND

On 29 June 2007, EFSA received on request from the European Commission on an application for renewal of the authorisation for continued marketing of existing products derived from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (EFSA-GMO-RX-MS8-RF3) submitted by Bayer CropScience 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 (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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 Commission according to Articles 8(1) (a) and 20(1) (b) of that Regulation and included in the Community Register of genetically modified food and feed[4].

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/BE/96/01 for the placing on the market of glufosinate-tolerant hybrid oilseed rape Ms8 x Rf3 derived from GM parental lines Ms8 and Rf3 for import and processing for feed and industrial uses under Part C of Directive 2001/18/EC (EFSA, 2005). In this opinion the EFSA GMO Panel concluded that oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human or animal health or, in the context of its proposed uses, on the environment.

After receiving the application EFSA-GMO-RX-MS8-RF3 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 application 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 11 and 23 of Regulation (EC) No 1829/2003. On 28 March 2008, EFSA declared the application as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003[5].

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 27 June 2008) within which to make their scientific comments known.

On 29 September 2008 and 12 March 2009, the EFSA GMO Panel asked the applicant for additional data on oilseed rape Ms8, Rf3 and Ms8 x Rf3. The applicant provided the requested information on 30 January 2009 and 6 May 2009 respectively. After receipt and assessment of the full data package, the EFSA GMO Panel finalised its opinion.

The EFSA GMO Panel carried out the scientific assessment of the renewal application on GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 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.

In giving its opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3 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.

[4] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=15
[5] See section Documentation provided to EFSA

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 opinions 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 a scientific opinion on an application for renewal of the authorisation for continued marketing of existing products produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3, that were previously notified according to Articles 8(1)(a) and 20(1)(b) of Regulation (EC) No 1829/2003 on genetically modified food and feed, and that have now been 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.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Groups on Molecular Characterisation, Food/Feed and Environment for the preparation of this opinion.

ASSESSMENT

1. Introduction

Regarding the information which has already been evaluated in the context of the previous notification on oilseed rape Ms8, Rf3 and Ms8xRf3, the EFSA GMO Panel refers to its earlier opinion (EFSA, 2005). The scientific assessment included the transformation process, the vectors used and the transgenic constructs in the genetically modified plants. 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. An environmental assessment, including an assessment of a monitoring plan, was undertaken. The EFSA GMO Panel concluded that "*oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment. This is in addition to the present uses of oil for food purposes and processed meal for feed purposes, both derived from Ms8 x Rf3 oilseed rape, which are already lawfully placed on the market*" (EFSA, 2005).

The assessment presented here is based on the information provided by the applicant in the application EFSA-GMO-RX-MS8-RF3 for import of processed food and food ingredients and feed materials produced from oilseed rape Ms8, Rf3 and Ms8xRf3, which includes 1) an updated molecular characterisation, including vector description; 2) updated information on the comparative analysis and in particular on the bioequivalence evaluation; and 3) updated information on allergenicity and toxicology, including new homology searches, as well as the additional information submitted by the applicant in response to additional questions from the EFSA GMO Panel.

The EFSA GMO Panel has assessed the new information in relation to the data which have already been evaluated by the GMO Panel in the context of the previous notification for GM oilseed rape Ms8, Rf3 and Ms8xRf3 (EFSA, 2005).

2. Issues raised by the Member States

Issues raised by the Member States are addressed in Annex G of the EFSA overall opinion.

3. Evaluation of relevant new scientific data

3.1. Molecular Characterisation

Updated annotation of the plasmid vectors pTHW107 and pTHW118 based on the determined nucleotide sequence was provided in the renewal application. On further request, the applicant clarified that sequencing of the plasmids revealed some differences compared to the formerly deduced putative sequences. As none of the differences between the deduced sequence and the determined sequence is located in the functional regions subsequently transferred to the recipient oilseed rape, they are not considered relevant to the current as well as previous risk assessments.

The EFSA GMO Panel received an updated description of the insert structure in the Rf3 line. As the original analyses could lead to two different interpretations of the structure of the insert, the applicant performed additional Southern and PCR analyses to distinguish between the two models. The analyses revealed that the inserted DNA consists of one partial copy of the T-DNA, where only part of the Pta29 promoter was inserted, flanked by another partial copy in an inverted orientation, which includes a complete *barstar* gene cassette (Pta29 promoter, *barstar* coding region, *nos* terminator) and a part of the PssuAt promoter. Pairwise alignment of the Rf3 event sequence and the pTHW118 sequence revealed a two base pair insertion in the PssuAt promoter and a single base pair substitution in the 3' *nos* terminator. Compared to the originally reported insert structure the region spanning the complete and the truncated Pta29 promoter elements is inverted. The data were supported by the

analysis of the complete DNA sequence of the Rf3 insert. Southern analysis with identical restriction enzyme and probe combination indicated that the structure of the insert in the plant was not changed since the original notification (reference C/BE/96/01). The EFSA GMO Panel accepts the revised interpretation of the insert structure and considers that it does not indicate instability of the insert in the plant.

At the request of the EFSA GMO Panel, the applicant performed new bioinformatic analyses. These cover all junctions created by the transformation process, including those flanking the genomic sequences as well as the internal junctions in the Rf3 event (revised insert structure). Possible interruptions of endogenous genes were analyzed. Putative new open reading frames (ORFs; from stop to stop codon) were compared to known toxins and allergens. The analyses did not reveal any newly created ORFs with significant identity to known toxins or allergens. The data provided do not indicate any safety concerns with regard to the interruption of known genes or regulatory elements or from the potential production of new toxins or allergens.

There has been a long history of cultivation of oilseed rape Ms8 x Rf3 in North America since 2000. No indications of trait instability have arisen. Furthermore, the PAT protein is considered to be non-toxic and the levels reported for oilseed rape Ms8 x Rf3 do not raise any safety concerns.

3.1.1. Conclusion

The updated molecular and bioinformatic analyses provided for the oilseed rape lines Ms8 and Rf3 do not indicate any safety concerns.

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 scientific opinion (EFSA, 2005), the applicant provided a 42-day feeding study in broiler chickens as well as new studies in relation to the potential allergenicity and toxicity of the newly expressed proteins.

New studies have been performed with regards to the potential allergenicity and toxicity of Barnase, Barstar and PAT proteins expressed in GM oilseed rape Ms8 x Rf3. These bioinformatic studies using updated databases confirmed the results of studies already evaluated by the EFSA GMO Panel, showing that no homologies exist between the newly expressed proteins Barnase, Barstar and PAT and known toxic proteins or allergens.

A 42-day feeding study was carried out on male broiler chickens (420 Ross chickens). Animals were divided in three groups (140 chickens per group). Animals were fed diets containing 10% GM oilseed rape Ms8 x Rf3 that either was treated with the target herbicides or untreated, or fed 10% of a commercial non-GM oilseed rape variety with background genetics similar to Ms8 x Rf3. In all cases, full-fat hammer-milled rapeseed was used. No significant differences in any of the parameters studied (animal health, survival, feed intake, weight gain, feed conversion and carcass and muscle weights) were noted between the groups fed diets containing the Ms8 x Rf3 oilseed rape (sprayed and non-sprayed) and the conventional control oilseed rape. The broiler feeding study shows that GM oilseed rape Ms8 x Rf3 is nutritionally equivalent to its non-GM counterpart.

3.2.1. Conclusion

The EFSA GMO Panel concludes that there is no new information provided by the applicant or in the scientific literature that would require changes of its previous scientific opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3 (EFSA, 2005).

3.3. Environmental assessment

The scope of this application excludes import of viable plant material and cultivation. Therefore, there is no requirement for scientific information on environmental safety assessment of accidental release or cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3.

3.3.1. Gene transfer

A prerequisite for any gene transfer is the availability of pathways for the transfer of genetic material, either through horizontal gene transfer of DNA, or vertical gene flow via seed dispersal and cross-pollination. Considering the scope of the current application, the possible pathway is limited to horizontal gene transfer from plant material to bacteria.

(a) Plant to bacteria gene transfer

Current scientific knowledge (see EFSA, 2009 for further details) suggests that gene transfer from GM plants to microorganisms under natural conditions is extremely unlikely, and that its establishment would occur primarily through homologous recombination in microorganisms. Barnase, barstar as well as bar genes, as expressed in GM oilseed rape varieties containing Ms8/Rf3 traits, are of bacterial origin (from Bacillus amyloliquefaciens and Streptomyces hygroscopicus, respectively). As the functional genes are already present in microorganisms in the natural environment, homologous recombination and acquisition of these genes by microorganisms will not alter the gene pool of the natural microbial community.

Taking into account the microbial origin and/or nature of the barnase, barstar as well as bar genes and the lack of selective pressure in the intestinal tract and/or the environment, the likelihood that horizontal gene transfer would result in increased fitness on microorganisms or other selective advantages is very small. For this reason it is very unlikely that genes from GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 would become established in the genome of microorganisms in the environment or human and animal digestive tract. In the very unlikely event that such a horizontal gene transfer would take place, no adverse effects on human and animal health or the environment are expected, as no principally new traits would be introduced into or expressed by natural microbial communities.

3.3.2. Monitoring

Considering the scope of application EFSA-GMO-RX-MS8-RF3 excluding import of viable plant material and cultivation, a post-market environmental monitoring plan for oilseed rape Ms8, Rf3 and Ms8 x Rf3 is not required.

3.3.3. Conclusion

Considering the scope of application EFSA-GMO-RX-MS8-RF3, there is no requirement for scientific information on environmental risks associated with the accidental release or cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3. A post-market environmental monitoring plan for oilseed rape Ms8, Rf3 and Ms8 x Rf3 is not required. The EFSA GMO Panel considers that GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on the environment in the context of its proposed uses (EFSA, 2005).

CONCLUSIONS AND RECOMMENDATIONS

The EFSA GMO Panel was requested to deliver a scientific opinion for renewal of the authorisation for continued marketing of existing products produced from GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 (application reference EFSA-GMO-RX-MS8-RF3) under Regulation (EC) No 1829/2003. The scope of this application covers the continued marketing of (1) existing foods produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3 (processed oil) and (2) existing feeds produced from oilseed rape Ms8, Rf3 and Ms8 x Rf3, 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-MS8-RF3 in relation to the data which have already been evaluated by the GMO Panel in the context of the previous notification for GM oilseed rape Ms8, Rf3 and Ms8xRf3 (EFSA, 2005).

The updated molecular and bioinformatic analyses provided by the applicant do not indicate any safety concerns. In addition the broiler feeding study provided by the applicant shows that GM oilseed rape Ms8 x Rf3 is nutritionally equivalent to its non-GM counterpart.

The EFSA GMO Panel considers that there is no requirement for scientific information on environmental risks associated with the accidental release or cultivation of oilseed rape Ms8, Rf3 and Ms8 x Rf3. A post-market environmental monitoring plan for oilseed rape Ms8, Rf3 and Ms8 x Rf3 is not required.

The EFSA GMO Panel concludes that there is no new information provided by the applicant or in the scientific literature that would require changes of its previous scientific opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3. Therefore, the EFSA GMO Panel reiterates the previous conclusions that GM oilseed rape Ms8, Rf3 and Ms8 x Rf3 is unlikely to have an adverse effect on human and animal health or, in the context of its proposed uses, on the environment (EFSA, 2005). This also applies to the products which are the subject of the present application.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 18 June 2007, concerning a request for renewal of authorisation for the placing on the market of oilseed rape MS8/RF3 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 4 December 2007, with request for clarifications under completeness check.
4. Letter from applicant to EFSA, dated 7 February 2008, providing EFSA with an updated version of the application EFSA-GMO-RX- MS8-RF3 submitted by Bayer CropScience under Regulation (EC) No 1829/2003.
5. Letter from EFSA to applicant, dated 28 March 2008, delivering the 'Statement of Validity' for application EFSA-GMO-RX- MS8-RF3 submitted by Bayer CropScience under Regulation (EC) No. 1829/2003.
6. Letter from EFSA to applicant, dated 29 September 2008, with request for additional information.
7. Letter from applicant to EFSA, dated 30 January 2009, providing additional information upon EFSA request.
8. Letter from EFSA to applicant, dated 12 March 2009, with request for clarifications/additional information.

9. Letter from applicant to EFSA, dated 6 May 2009, providing additional information upon EFSA request.

10. Letter from EFSA to applicant, dated 9 July 2009, restarting the clock.

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http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_Statements456.htm