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SCIENTIFIC OPINION

Scientific Opinion on applications (EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$) for renewal of the authorisation for continued marketing of existing (1) food and food ingredients produced from oilseed rape GT73; and of (2) feed materials, feed additives and food additives produced from oilseed rape GT73, all 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 a risk assessment for renewal of the authorisation for continued marketing of existing food and feed ingredients, feed materials, feed additives and food additives produced from hybrid oilseed rape GT73. Oilseed rape GT73 has been modified with two genes encoding the CP4 EPSPS and GOX proteins that confer glyphosate tolerance and resistance, respectively. In 2004 the EFSA GMO Panel had issued a scientific opinion on the safety of glyphosate-tolerant oilseed rape GT73 for import and processing uses. In delivering the present opinion, the EFSA GMO Panel considered the information provided in the applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ 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 and toxic proteins.The EFSA GMO Panel reiterates the conclusions of its previous scientific opinion of 2004 that GM oilseed rape GT73 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its proposed uses. This also applies to the products which are the subject of the present application.

KEY WORDS

GMO, oilseed rape, GT73, herbicide tolerant, food and feed safety, environment, risk assessment, renewal, existing product, Regulation (EC) No 1829/2003

1 On request from the European Commission on two applications (reference EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$) submitted by Monsanto under Regulation (EC) No 1829/2003, Question No EFSA-Q-2007-148 and Question No EFSA-Q-2007-149, adopted on 02 December 2009.

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 Panel wishes to thank the members of the Working Group for the preparation of this opinion: Willem Seinen and EFSA's staff member(s) Zoltán Divéki, Antonio Fernandez Dumont and Sylvie Mestdagh for the support provided to this EFSA scientific output.

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SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on two applications submitted by Monsanto under Regulation (EC) No 1829/2003 (reference EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$) for renewal of the authorisation for continued marketing of existing products produced from GM oilseed rape GT73.

The scope of the 2 renewal applications covers the continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives), 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 8(1)(b)/20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed[4].

Oilseed rape GT73 has been modified with two genes encoding the CP4 EPSPS and GOX proteins that confer glyphosate tolerance and resistance, respectively.

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/NL/98/11 for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under part C of Directive 2001/18/EC from Monsanto. In this scientific opinion the EFSA GMO Panel concluded that "*the placing on the market of GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health or, in the context of its proposed use, on the environment*" (EFSA, 2004).

In delivering its opinion the EFSA GMO Panel considered the information provided in the 2 renewal applications (reference EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$), additional information submitted by the applicant on request of the EFSA GMO Panel, Member States comments as well as relevant information published in the scientific literature. In accordance with the Guidance Document for renewal of authorisations of existing 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 GT73, 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 applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$, including updated bioinformatic analyses.

According to the information provided by the applicant, food and feed products produced from oilseed rape GT73 that have been approved in the EU, have been consumed without reports of adverse effects. Scientific publications, which have become available since the previous evaluation of oilseed rape GT73 by the EFSA GMO Panel, did not raise safety issues. In addition, bioinformatic analyses comparing the amino acid sequences of the newly expressed CP4 EPSPS and GOX proteins in oilseed rape GT73 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.

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

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

release or cultivation of oilseed rape GT73. A post-market environmental monitoring plan for oilseed rape GT73 is not required.

The EFSA GMO Panel considers that the information available for oilseed rape GT73 addresses the scientific comments raised by Member States and 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 GT73. Therefore, the EFSA GMO Panel reiterates the previous conclusions that GM oilseed rape GT73 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its proposed uses. 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 two applications (reference EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$) for renewal of the authorisation of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (EC, 2003). The scope of these two renewal applications cover the continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives), 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 8(1)(b)/20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed[5].

The EFSA GMO Panel has previously issued a scientific opinion related to notification C/NL/98/11 for the placing on the market of glyphosate-tolerant GT73 oilseed rape, for import and processing, under part C of Directive 2001/18/EC (EFSA, 2004). In this scientific opinion the EFSA GMO Panel concluded that oilseed rape GT73 is unlikely to have an adverse effect on human or animal health or on the environment, in the context of its proposed use.

After receiving the applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ 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 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 these applications as valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003[6].

EFSA made the valid applications 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 28 June 2008) within which to make their scientific comments known.

The EFSA GMO Panel asked the applicant for additional data on oilseed rape GT73 on 30 September 2008 and 08 June 2009 for applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$. The applicant provided the requested information on 2 April 2009 and 30 September 2009, respectively. After receipt and assessment of the full data package, the EFSA GMO Panel finalised its opinion on oilseed rape GT73.

The EFSA GMO Panel carried out the scientific assessment of the renewal application on GM oilseed rape GT73 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 GT73 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

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

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 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 two applications for renewal of the authorisation of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives), that were previously notified according to Articles 8(1)(a) and 8(1)(b)/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. These applications fulfil 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 on oilseed rape GT73, the EFSA GMO Panel refers to its earlier opinion (EFSA, 2004). 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, including an assessment of a monitoring plan, was undertaken. The EFSA GMO Panel concluded that "*the placing on the market of GT73 oilseed rape for processing and feed use is unlikely to have an adverse effect on human or animal health or, in the context of its proposed use, on the environment*" (EFSA, 2004).

The assessment presented here is based on the information provided by the applicant in the applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ for continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and feed produced from oilseed rape GT73 (feed materials and feed additives), which includes 1) an update on peer-reviewed scientific data on oilseed rape GT73; 2) a report on import and use of oilseed rape GT73 in Europe and an estimation of human and animal exposure; 3) updated information on allergenicity and toxicology, including new bioinformatic analyses, 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 EFSA GMO Panel in the context of the previous notification for GM oilseed rape GT73 (EFSA, 2004).

2. Issues raised by the Member States

Issues raised by the Member States are addressed in Annex G of the EFSA overall opinion[7].

3. Evaluation of relevant new scientific data

3.1. Molecular Characterisation

In response to a request from the EFSA GMO Panel the applicant provided an updated bioinformatic search for putative open reading frames spanning the GT73 insert – genomic junction (both 5' and 3') which may be created as a result of the genetic modification, in order to assess the potential for production of novel chimeric proteins with homology to known toxins, allergens or other bioactive peptides. The data do not indicate any safety concerns from the potential production of new toxins. No putative peptide met or exceeded the Codex Alimentarius Commission threshold for potential allergenicity of 35% identity over 80 amino acids, or of at least eight consecutive identical amino acids. The bioinformatic analyses thus confirmed the conclusion of the original analysis carried out by the applicant.

In response to a request from the EFSA GMO Panel the applicant provided updated bioinformatic analyses to determine if any endogenous open reading frames and/or regulatory elements were disrupted by the insertion. No evidence for this to have happened was obtained.

The stability of the herbicide tolerance trait is monitored by a seed quality and stewardship program put in place by the applicant to maintain the performance of the product.

3.1.1. Conclusion

The updated bioinformatic analyses provided for the oilseed rape GT73 event do not indicate any safety concerns and the EFSA GMO Panel maintains its previous opinion on 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 opinion (EFSA, 2004), the applicant provided updated information on import and use of oilseed rape GT73 and an estimation of human and animal exposure to oilseed rape GT73 as well as new studies in relation to the allergenicity and toxicity to the newly expressed proteins.

The applicant provided new data on import and use of oilseed rape GT73 in Europe and an estimation of human and animal exposure. The estimated exposure levels of oilseed rape GT73 in both humans and animals were very low.

New studies have also been performed with regards to the allergenicity and toxicity of CP4 EPSPS and GOX proteins of GM oilseed rape GT73. In response to a request by the EFSA GMO Panel enquiring for an updated analysis using the most recent version of databases containing sequences of known toxic proteins, the applicant provided an updated bioinformatics-supported comparison of the sequences of the newly expressed CP4 EPSPS and GOXv247 proteins with sequences of toxins collected and stored in a proprietary database of the applicant. CP4 EPSPS and GOXv247 did not bear any similarity with toxins. Moreover, the applicant provided the outcomes of bioinformatics-supported comparisons of the sequences of the newly expressed CP4 EPSPS and GOXv247 proteins with those

[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-148
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-149

of allergens. The allergen sequences had previously been retrieved from the Food Allergy Research and Resource Program Database (FARRP, University of Nebraska) and stored in the applicant's proprietary database. Neither CP4 EPSPS nor GOXv247 showed any significant outcomes when compared to allergens in the overall sequence alignment using the FASTA algorithm according to the criterion of 35% identity within an 80-amino-acid window, and in the search for exactly identical stretches of 8 contiguous amino acids.

A published swine feeding study, in which swine received diets containing 15% meal derived from GM oilseed rape GT73, its control or two commercial reference oilseed rape lines, did not indicate any impact of the genetic modification on animal performance (Caine et al., 2007). This study, therefore, provides further confirmation of previous findings of the EFSA GMO Panel on the nutritional equivalence of oilseed rape GT73 to non-GM counterparts (EFSA, 2004).

In conclusion, new information from an updated literature review and from additional studies performed by the applicant confirms the EFSA GMO Panel's previous opinion that oilseed rape GT73 is as safe and nutritious as the non-GM counterparts.

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 GM oilseed rape GT73 (EFSA, 2004).

3.3. Environmental assessment

The scope of these applications 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 GM oilseed rape GT73.

3.3.1. Gene transfer

A prerequisite for any gene transfer is the availability of routes 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 route is limited to horizontal gene transfer from plant material to bacteria.

Current scientific knowledge (see EFSA, 2009 for further details) suggests that the likelihood of gene transfer from GM plants to microorganisms under natural conditions is negligible, and that its establishment would occur primarily through homologous recombination in microorganisms. The unlikelihood of gene transfer was confirmed by studies on horizontal transfer of the CP4 epsps gene from oilseed rape GT73 to microorganisms during digestion in ruminants and during in vitro incubations (Alexander et al., 2006; Reuter et al., 2007; Sharma et al., 2004).

CP4 epsps and gox genes, as expressed in oilseed rape GT73, are of bacterial origin (from Agrobacterium sp. strain CP4 and Ochrobactrum anthropi strain LBAA, 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 CP4 epsps and gox 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 or other selective advantages in microorganisms is very small. For this reason it is very unlikely that genes from oilseed rape GT73 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. Post market environmental monitoring

Considering that the scope of applications EFSA-GMO-RX-GT73[8.1.a] and EFSA-GMO-RX-GT73[8.1.b/20.1.b], excludes import of viable plant material and cultivation, a post market environmental monitoring plan for GM oilseed rape GT73 is not required.

3.3.3. Conclusion

Considering the scope of applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$, there is no requirement for scientific information on environmental risks associated with the accidental release or cultivation of oilseed rape GT73. A post-market environmental monitoring plan for oilseed rape GT73 is not required. The EFSA GMO Panel considers that GM oilseed rape GT73 is unlikely to have an adverse effect on the environment in the context of its proposed uses (EFSA, 2004).

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 GT73 (applications reference EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$) under Regulation (EC) No 1829/2003. The scope of these applications covers the continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives), 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 applications EFSA-GMO-RX-GT73$_{[8.1.a]}$ and EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ in relation to the data which have already been evaluated by the GMO Panel in the context of the previous notification for GM oilseed rape GT73 (EFSA, 2004).

The updated bioinformatic analyses provided by the applicant do not indicate any safety concerns. New information from the scientific literature and from additional studies performed by the applicant confirms the EFSA GMO Panel's previous opinion that GM oilseed rape GT73 is as safe and as nutritious as the non-GM counterparts.

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 oilseed rape GT73. A post market environmental monitoring plan for GM oilseed rape GT73 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 GM oilseed rape GT73. Therefore, the EFSA GMO Panel reiterates the previous conclusions that GM oilseed rape GT73 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its proposed uses (EFSA, 2004). This also applies to the products which are the subject of the present application.

DOCUMENTATION PROVIDED TO EFSA

Application EFSA-GMO-RX-GT73$_{[8.1.a]}$

1. Letter from the European Commission, dated 18 June 2007, concerning a request for renewal of the authorisation for continued marketing of existing food and food ingredients produced from GT73 oilseed rape that were previously notified, according to Article 8(1)(a) of Regulation (EC) No 1829/2003 on genetically modified food and feed.

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 19 February 2008, providing EFSA with an updated version of the application EFSA-GMO-RX-GT73$_{[8.1.a]}$ submitted by Monsanto under Regulation (EC) No 1829/2003.

5. Letter from EFSA to applicant, dated 28 March 2008, delivering the "Statement of Validity" for the application EFSA-GMO-RX-GT73$_{[8.1.a]}$ submitted by Monsanto under Regulation (EC) No 1829/2003.

6. Letter from EFSA to applicant, dated 30 September 2008, requesting additional information and stopping the clock.

7. Letter from applicant to EFSA, dated 2 April 2009, providing the additional information upon EFSA request.

8. Letter from EFSA to applicant, dated 8 June 2009, requesting additional information.

9. Letter from applicant to EFSA, dated 30 September 2009, providing additional information upon EFSA request.

10. Letter form EFSA to applicant, dated 27 October 2009, restarting the clock.

Application EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$

1. Letter from the European Commission, dated 18 June 2007, concerning a request for renewal of the authorisation for continued marketing of existing feed materials, feed additives and food additives produced from GT73 oilseed rape 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.

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 19 February 2008, providing EFSA with an updated version of the application EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ submitted by Monsanto under Regulation (EC) No 1829/2003.

5. Letter from EFSA to applicant, dated 28 March 2008, delivering the "Statement of Validity" for the application EFSA-GMO-RX-GT73$_{[8.1.b/20.1.b]}$ submitted by Monsanto under Regulation (EC) No 1829/2003.

6. Letter from EFSA to applicant, dated 30 September 2008, requesting additional information and stopping the clock.

7. Letter from applicant to EFSA, dated 2 April 2009, providing the additional information upon EFSA request.

8. Letter from EFSA to applicant, dated 8 June 2009, requesting additional information.

9. Letter from applicant to EFSA, dated 30 September 2009, providing additional information upon EFSA request.

10. Letter form EFSA to applicant, dated 27 October 2009, restarting the clock.

REFERENCES

Alexander TW, Reuter T, Okine E, Sharma R and McAllister TA, 2006. Conventional and real-time polymerase chain reaction assessment of the fate of transgenic DNA in sheep fed Roundup Ready rapeseed meal. British Journal of Nutrition, 96: 997-1005.

Caine W R, Aalhus JL, Dugan M E R, Lien KA, Larsen IL, Costello F, McAllister TA, Stanford K and Sharma R, 2007. Growth performance, carcass characteristics and pork quality of pigs fed diets containing meal from conventional or glyphosate-tolerant canola. Canadian Journal of Animal Science, 87: 517-526.

EC, 2001. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities, L106, 1-39.

http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf

EC, 2003. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Communities, L268, 1-23.

EFSA, 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto. The EFSA Journal 29, 1-19.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/opinion_gmo05_ej29_gt73_en1.pdf?ssbinary=true

EFSA, 2006. Guidance document for the renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. The EFSA Journal 435**,** 1-14.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599871.htm

EFSA, 2009. Statement of EFSA on the consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants" and the Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants". The EFSA Journal 1108, 1-8.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902604575.htm

Reuter T, Alexander TW, Martinez TF and McAllister TA, 2007. The effect of glyphosate on digestion and horizontal gene transfer during in vitro ruminal fermentation of genetically modified canola. Journal of the Science of Food and Agriculture, 87: 2837-2843.

Sharma R, Alexander TW, John SJ, Forster RJ and McAllister TA, 2004. Relative stability of transgene DNA fragments from GM rapeseed in mixed ruminal cultures. British Journal of Nutrition, 91: 673-681.