TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on application (EFSA-GMO-FR-2008-59) for placing on the market of a dried killed genetically modified bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) in accordance with Article 18 of Regulation (EC) No 1829/2003

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-FR-2008-59 for the placing on the market of a dried killed genetically modified bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]

Alongside with the scientific opinion of its Scientific Panel on Additives and Products and substances used in Animal Feed (FEEDAP Panel) on the safety and nutritional value of a dried killed bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) as a feed material for pigs, ruminants and salmonids, EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The reference material for PT73 (TM) can be accessed at the Institut Pasteur. The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan. The FEEDAP Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars regarding labelling and detection are not considered by EFSA since they fall outside its remit.

Key words: heat inactivated biomass, *Escherichia coli,* safety, nutritional value, genetically modified microorganism, Regulation (EC) No 1829/2003

Requestor: Competent Authority of France

Question number: EFSA-Q-2017-00562

Correspondence: FEEDAP@efsa.europa.eu

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

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1. Introduction

On 7 August 2008, the European Food Safety Authority received from the French Competent Authority an application for authorisation of a dried killed genetically modified (GM) bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) submitted by Ajinomoto Eurolysine SAS within the framework of Regulation (EC) No 1829/2003 on GM food and feed.

The scope of application EFSA-GMO-FR-2008-59 is for the placing on the market of a dried killed genetically modified bacterial biomass from *Escherichia coli* (FERM BP-10942) to be used a feed material in feeds for ruminants, pigs and salmonids. EFSA first checked the completeness of the application in accordance with the requirements laid down in Article 17(3) of the above mentioned Regulation. On 6 June 2008, EURL–GMFF received samples and control samples in accordance with the same Articles.

According to Article 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available.[2]

At the end of a thorough completeness check, EFSA declared the application valid on 24 July 2008.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-FR-2008-59. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Article 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC,[3] of all EU Member States on each request for placing on the market of products consisting of or containing GMOs. The Member States were therefore given three months to comment the valid application from the date of its receipt.

1.1. Terms of Reference

According to Article 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-FR-2008-59 including: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the GMO Panel, iv) the labelling proposal, v) the method for detection, validated by the European Union Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed and vii) the post-market monitoring plan.

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2008-412b

[3] 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. OJ L 106, 12.3.2001, p. 1–38.

2. Considerations

2.1. Name and address of the Applicant

Application EFSA-GMO-FR-2008-59 was submitted by Ajinomoto Eurolysine S.A.S. 153 rue de Courcelles, 75817, Paris Cedex 17. France.

2.2. Designation and specification of the product

The scope of application EFSA-GMO-FR-2008-59 is for the placing on the market of a dried killed genetically modified bacterial biomass from *Escherichia coli* (FERM BP-10942) to be used a feed material in feeds for ruminants, pigs and salmonids.

2.3. Scientific opinion of the FEEDAP Panel

On 5 July 2017 the FEEDAP Panel adopted a scientific opinion on the safety and nutritional value of a dried killed bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) as a feed material for pigs, ruminants and salmonids (Annex A). During its evaluation, the FEEDAP Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

The FEEDAP Panel concluded that the molecular characterization of the strain does not indicate a safety concern. No DNA sequences of concern including those conferring antibiotic resistances are present in the production strain.

The maximum safe level for dairy cows would be 7 % PT73 (TM) of feed dry matter (≈6 % in complete feed). This value could be extended to other ruminants (from the beginning of rumination). Complete feed for pigs for fattening may contain up to 10 % PT73 (TM). PT73 (TM) is safe for salmonids up to a dietary concentration of 13 %.

The toxicological data indicate effects of PT73 (TM) on blood coagulation and liver, which are considered to be adverse. Since the causative agent and mechanism of these effects is unknown there is no way of determining whether residues exist in animal products sufficient to cause similar effects in consumers. As a consequence, the FEEDAP Panel is unable to conclude on the safety for the consumer of products derived from animals receiving feed containing PT73 (TM).

PT73 (TM) is not considered a skin/eye irritant but should be considered as a potential skin and respiratory sensitiser. The FEEDAP Panel considers that due to the endotoxin content any exposure of users to dust from the product via the inhalation route should be considered a serious risk.

PT73 (TM) does not contain viable recombinant cells but contains trace amounts of recombinant DNA. No risks associated with a theoretically possible horizontal gene transfer of this recombinant DNA to environmental bacteria have been identified. The FEEDAP Panel considers that substitution of PT73 (TM) for other protein-rich feed materials will not adversely affect the environment.

2.4. Labelling

The FEEDAP Panel did 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 (Annex B).

2.5. Method for detection

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify AG3139 transformation event in bacterial biomass derived from *Escherichia coli* K-12 DNA. The reports were issued on 24 June 2009. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2 to Commission Regulation (EC) No 641/2004[4] (Annexes C1, C2, C3).

[4] Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

2.6. Certified reference materials

The reference material for PT73 (TM) can be accessed at the Collection de l'Institut Pasteur, under the accession denomination pUC-TMDA.

2.7. Post-market monitoring plan

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation and Good Manufacturing Practice.

2.8. Member States Comments

The FEEDAP Panel has addressed the comments submitted by the Member States during the three-month consultation period.

3. Conclusions

According to Article 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-FR-2008-59 for the placing on the market of a dried killed genetically modified bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)).

List of Annexes[5]

Annex A:	Scientific opinion of the FEEDAP Panel on safety and nutritional value of a dried killed bacterial biomass from *Escherichia coli* (FERM BP-10942) (PT73 (TM)) as a feed material for pigs, ruminants and salmonids
Annex B:	Labelling
Annex C1:	Validation report
Annex C2:	Validated method
Annex C3:	Sampling/DNA extraction

[5] The annexes of the EFSA Overall opinion can be found in the Register of Questions (tab "Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2008-412b