SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* ATCC 74444 (Ronozyme® Multigrain) for use in poultry for fattening, poultry for laying and piglets (weaned) (DSM Nutritional Products)

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Abstract

Ronozyme® Multigrain G/L is the trade name of the feed additive under assessment containing endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and endo-1,3(4)-beta-glucanase produced by a non-genetically modified strain of *Trichoderma reesei* (ATCC 74444). It is authorised for use as a zootechnical additive (functional group: digestibility enhancer) in poultry for fattening, poultry for laying and weaned piglets. This scientific opinion concerns the request for the renewal of the authorisation of the additive for the species/categories for which there is an authorisation. The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation. There is no new evidence that would lead the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) to reconsider previous conclusions that the additive is safe for the animal species/categories, the consumer and the environment under the authorised conditions of use. Regarding the safety for the user, the additive should be considered a potential respiratory sensitiser. In absence of data, the Panel could not conclude on the potential of the additive to cause skin and eye irritation or dermal sensitisation. There was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation for poultry for fattening, poultry for laying and weaned piglets.

Keywords: zootechnical additive, digestibility enhancers, Ronozyme® Multigrain, poultry, piglets, safety

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from DSM Nutritional Products Ltd[2] for the authorisation of a new use and the renewal of the authorisation of the additive consisting of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* ATCC 74444 (Ronozyme® Multigrain), when used as a feed additive for poultry for fattening, poultry for laying, weaned piglets and pigs for fattening (category: zootechnical additive, functional group: digestibility enhancer). During the assessment, the applicant expressed the wish to withdraw the request for authorisation for pigs for fattening.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under under Article 14(1) (renewal of the authorisation). T*he dossier was received on 23 March 2021 and the general information and supporting documentation are available at* https://open.efsa.europa.eu/questions/EFSA-Q-2021-00498. The particulars and documents in support of the application were considered valid by EFSA as of 8 December 2021.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* ATCC 74444 (Ronozyme® Multigrain), when used under the proposed conditions of use (see **Section 3.1.2**).

1.2. Additional information

The subject of the assessment is the feed additive consisting of three enzymes – endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and endo-1,3(4)-beta-glucanase produced *by Trichoderma reesei* ATCC 74444 (Ronozyme® Multigrain) intended for use as a zootechnical additive (functional group: digestibility enhancer) in poultry for fattening, poultry for laying and weaned piglets.

The Panel on Additives and Products or Substances in Animal Feed (FEEDAP) adopted one opinion on the safety and efficacy of this product (formerly named ROXAZYME® G2) when used for poultry and piglets (EFSA FEEDAP Panel, 2012a).

The additive is currently authorised for use in feed for poultry for fattening, poultry for laying and weaned piglets (4a1602i).[3]

The applicant is seeking the renewal of the authorisation for Ronozyme® Multigrain for the species/categories for which an authorisation exists, namely poultry for fattening, poultry for laying and weaned piglets.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] DSM Nutritional Products Ltd, Wurmisweg 576, 4303 Kaiseraugst, Switzerland, represented in the EU by DSM Nutritional Products Sp. Z.o.o., Tarczyńska 113, 96–320 Mszczonów, Poland.

[3] Commission Implementing Regulation (EU) No 403/2013 of 2 May 2013 concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by Trichoderma reesei (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products). OJ L 121, 13.5.2013, p. 26.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the authorisation request for the use of the product consisting of endo-1,4-beta-xylanase (xylanase; EC 3.2.1.8), endo-1,4-beta-glucanase (cellulase; EC 3.2.1.4) and endo-1,3(4)-beta-glucanase (glucanase; EC 3.2.1.6) produced by *Trichoderma reesei* ATCC 74444 (Ronozyme® Multigrain) as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 8 December 2021 to 8 March 2022 for which the received comments were considered for the assessment.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substances in animal feed.[5]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the product consisting of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and endo-1,3(4)-beta-glucanase produced by *T. reesei* ATCC 74444 (Ronozyme® Multigrain) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021), and EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA, 2021).

3. Assessment

The present assessment regards the renewal of the authorisation of the product containing endo-1,4-beta-xylanase (xylanase; EC IUBMB 3.2.1.8), endo-1,4-beta-glucanase (cellulase; EC IUBMB 3.2.1.4) and endo-1,3(4)-beta-glucanase (glucanase; EC IUBMB 3.2.1.6), produced by *Trichoderma reesei* ATCC 74444 (tradename: Ronozyme® Multigrain, formerly known as ROXAZYME® G2) for use in poultry for fattening, poultry for laying and weaned piglets.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is authorised in two different formulations, a granular form (Ronozyme® MultiGrain (GT), referred to as GT) and a liquid form (Ronozyme® MultiGrain (L), referred to as L), both with a minimum enzymatic activity per gram or ml of additive of 2,700 U[7] xylanase, 800 U cellulase and 700 U glucanase.

[4] FEED dossier reference: FAD-2021-0052.

[5] Evaluation report received on 14/03/2023 and available on the EU Science Hub: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

[6] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[7] One U is the amount of enzyme (xylanase, cellulase or glucanase) that releases 1 μmol of reducing sugar (xylose or glucose) equivalent from wheat arabinoxylan, carboxymethylcellulose or barley beta-glucan, respectively, per minute at pH 5 and 40°C.

As regards the manufacturing process, the enzymes contained in the additive are produced by fermentation with the production strain; [redacted].[8] The applicant declares that no antibiotics are used during the manufacturing process.[9]

The applicant has declared changes in the composition of the additive since the last authorisation. The original composition of the additive was: [redacted][10][11][12] The changes made to the composition of the additive are not expected to introduce safety concerns.

Eight batches of each form of the additive were tested for the enzyme activities.[13] The GT form showed per gram of product: 3,354 U xylanase (range: 2,930–3,630 U), 1,318 U cellulase (range: 1,220–1,450 U) and 1,003 U glucanase (range: 886–1,160 U). The L form showed per ml of product: 3,384 U xylanase (range: 3,290–3,420 U xylanase), 1,233 U cellulase (range: 1,170–1,410 U cellulase) and 941 U glucanase (range: 895–1,070 U glucanase). The measured enzyme activities are in compliance with the specifications set in the authorisation.

The same batches of the two forms of the additive were also analysed for chemical impurities (eight batches of the GT form, five of the L form) and microbiological contamination (eight batches of both forms).

In the GT form, mercury and cadmium values were below the limit of quantification (LOQ) of the analytical method, while levels of arsenic were < 0.3–0.51 mg/kg, and lead were < 0.5–0.92 mg/kg. In the L form, mercury, arsenic, cadmium and lead concentrations showed levels below the LOQ or LOD of the analytical methods.[14] *Escherichia coli* or *Salmonella* spp. were not detected in 25 g of product, *Bacillus cereus* counts were ≤ 10 CFU/g, total viable counts were ≤ 200 CFU/g, counts of coliforms were < 4 CFU/g (L form) or < 10 CFU/g (GT form), counts of yeasts and filamentous fungi were < 10 CFU/g, and counts of Enterobacteriaceae (only done in three batches of each form) were < 10 CFU/g.[15]

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

The applicant provided data on the physico-chemical properties, stability, and homogeneity of the additive based on the new formulations.

The bulk density of the GT form is 1,070 kg/m^3. The dusting potential of three batches of the GT form measured by Stauber–Heubach method showed a mean value of 3.3 mg/m^3 (range: 0–10 mg/m^3). Particle size distribution of the same batch of the additive tested by laser diffraction showed that the mean particle size is 539 μm and no particles below 250 μm were found.[16]

Three batches of the GT form were kept in glass vials sealed with metal caps at a range of temperatures of 10–50°C for up to 24 months, or in glass vials at 40°C/60% relative humidity (RH) for 1 month. Samples kept at −18°C were used as baseline.[17] At 10–35°C after 24 months, average enzyme activities were in the range of 66–98% xylanase, 74–103% cellulase and 81–99% glucanase compared to the initial; at 40°C after 12 months, average enzyme activities were 63% xylanase, 90% cellulase and 80% glucanase compared to the initial; at 50°C after 3 months, average residual activities were 72% xylanase, 91% cellulase and 82% glucanase; and in glass vials after 1 month at 40°C/60 RH% average residual activities were 96% xylanase, 98% cellulase and 84% glucanase.

[8] Technical dossier/Section II and Supplementary information October 2022/DSM Multigrain SIn 2022x2 – Annex.
[9] Technical dossier/Section II and Supplementary information October 2022.
[10] Currently under re-evaluation.
[11] Technical dossier/Section II and Supplementary information October 2022/Annex.
[12] Technical dossier/Section II.
[13] Technical dossier/Section II/Annex II 2-4 and Supplementary information October 2022/Annex VI.
[14] LOQ in mg/kg were 0.3 for arsenic; 0.05 for cadmium; 0.50 for lead and 0.05 for mercury.
[15] Supplementary information October 2022/Annex IX.
[16] Technical dossier/Section II/Annex II-7 and Supplementary information April 2023/Annex.
[17] Technical dossier/Section II/Annex II 2-18 and Supplementary information November 2022/Annex.

For the L form, three batches were kept in sealed glass vials at a range of temperatures of 10–50°C for up to 24 months. Samples kept at −18°C were used as baseline.[18] Compared to the baseline values, average enzyme activities were: in the range of 84–97% xylanase, 91–99% cellulase and 95–104% glucanase after 24 months at 10–25°C; 75% xylanase, 91% cellulase and 92% glucanase after 18 months at 35°; 76% xylanase, 91% cellulase and 95% glucanase after 6 months at 40°C (based on two batches); and 68% xylanase, 93% cellulase and 97% glucanase after 1 month at 50°C (based on two batches).

The stability of the GT form of the additive (three batches) was tested when mixed with a vitamin-mineral premixture for chickens for fattening and stored in plastic bags at 25°C for 6 months.[19] No losses were observed at the end of the experimental period.

The stability of the GT form (three batches) when added at 150 mg/kg to feedingstuffs was tested in feed for chickens for fattening based on maize and soy.[20] From each batch, a mash feed and two pelleted feeds (pelleting temperatures 80°C and 90°C) were manufactured and stored in plastic bags for 3 months at 25°C. Average enzyme activities after pelleting were higher than 82% in all cases. Storage for 3 months did not modify substantially the post-pelleting enzyme activities.

The stability of the L form (three batches) was studied when sprayed onto pelleted feed for chickens for fattening at the intended inclusion level of 150 mg/kg feed.[21] Feed samples were kept for 3 months in paper bags at 25°C. Average enzyme activities were 97% xylanase, 88% cellulase and 98% glucanase of the initial ones.

The enzyme activities present in the additive are produced by a non-genetically modified strain of *T. reesei*, originally isolated from a cotton duck shelter and subjected to further selection process by exposure to chemical/physical mutagenesis. The production strain has been deposited at the American Type Culture Collection (ATCC) with the accession number ATCC 74444.[22]

The identification of the production strain as *T. reesei* was confirmed by sequencing the Internal Transcribed Spacer (ITS) regions and the 18S rRNA gene and comparing the sequences with those existing in the NCBI RefSeq Targeted Loci Project and UNITE databases, respectively.[23]

The capacity of the production strain to produce substances with antimicrobial activity was not investigated. However, the potential presence of antimicrobial activity was tested in five batches of each formulation using a diffusion test.[24] The reference strains used were: *Staphylococcus aureus* ATCC 6538, *Streptococcus pyogenes* ATCC 12344, *Bacillus cereus* ATCC 2, *Bacillus circulans* ATCC 4516, *Escherichia coli* ATCC 11229 and *Serratia marcescens* ATCC 14041. No antimicrobial activity was detected.

No data were provided regarding the capacity of the production strain to produce secondary metabolites. Some *Trichoderma* species are known to be capable of producing various mycotoxins and antifungal metabolites. *T. reesei* seems to be unable to produce mycotoxins (EFSA, 2007; Frisvad et al., 2018; EFSA BIOHAZ Panel, 2020) but it is known to produce peptaibols (e.g. paracelsin A, C and D (Frisvad et al., 2018)).[25] Peptaibols are peptides with antimicrobial activity (primarily against Gram-positive bacteria), which are mostly produced under stress conditions (Frisvad et al., 2018). The lack of antimicrobial activity in the additive under assessment (described above) would indicate that if peptaibols are produced under the fermentation conditions, their concentration would be of no concern.

The presence of viable cells of the production strain was investigated in triplicate in an intermediate concentrate [redacted][26]. A proper positive control was included in the analysis. A negative control was also considered (0.9% NaCl solution). The controls performed as expected. No viable cells of the production strain were found in an intermediate product representative of the final formulations.

[18] Technical dossier/Section II/Annex II 2-19 and Supplementary information November 2022/Annex.
[19] Technical dossier/Section II/Annex II-7 and Supplementary information November 2022/Annex.
[20] Technical dossier/Section II/Annex II-7 and Supplementary information November 2022/Annex.
[21] Technical dossier/Section II/Annex II-7 and Supplementary information November 2022/Annex.
[22] Technical dossier/Section II/Annex II 2-10.
[23] Technical dossier/Section II/Annex II 2-8.
[24] Technical dossier/Section II/Annexes II 2-4 and II 2-15 and Supplementary information October 2022/Annex VI.
[25] Technical dossier/Section II and Supplementary information October 2022/DSM Multigrain SIn 2022x2 – Annex.
[26] Technical dossier/Section II/Annex 2-16 and Supplementary information November 2022/Annex VIII and IX.

3.1.2. Conditions of use

The additive is currently authorised for use in feed for:

- poultry for fattening other than turkeys for fattening at a minimum inclusion level of 135 U xylanase, 35 U glucanase and 40 U cellulase per kg feed[27];
- poultry for laying at a minimum inclusion level of 216 U xylanase, 56 U glucanase and 64 U cellulase per kg feed[28];
- turkeys for fattening and weaned piglets at a minimum inclusion level of 270 U xylanase, 70 U glucanase and 80 U cellulase per kg feed.[29]

The authorisation under other provisions foresees:

- In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
- For use in feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans).
- For use in weaned piglets up to 35 kg.
- For safety: breathing protection and gloves shall be used during handling.

The applicant wishes to maintain the same conditions of use.

3.2. Safety

The safety of Ronozyme® Multigrain for the target species, consumers, users and the environment, including the safety of the production strain, has been evaluated in a previous opinion (EFSA FEEDAP Panel, 2012a). The Panel concluded that the additive is safe for the target species evaluated, and the use of the product as a feed additive would be of no concern for the consumers of products derived from animals fed with the additive, or for the environment. The Panel also concluded that the additive is not irritant to skin and eyes or a dermal sensitiser but should be considered a potential respiratory sensitiser. However, the Panel notes that the conclusions on user safety are based on tests conducted with an intermediate product described as a stabilised concentrate.

For the present dossier the applicant (i) stated that no adverse events on the target animals, consumers or the environment have been recorded in the company or have been reported by customers or other operators as a result of the use of the product since its introduction to the market in 2013[30] (ii) performed a literature search in order to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users and the environment, and (iii) provided new tests to support consumer safety.

3.2.1. Literature search

In line with the requirements established in the EFSA guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021), the applicant performed a literature search to provide evidence that the additive remains safe under the approved conditions of use for target species, consumers, users and the environment. The literature search was conducted in January 2021 without time restrictions, and the search terms and search strategy were provided. The applicant searched in a total of three relevant databases (Web of Science Core Collection, BIOSIS Citation Index and Medline) and the main search terms included the commercial name and the production organism in combination with the enzyme or terms relevant for safety of consumers, users, target animals and the environment.[31] After removing the duplications, 10 hits were considered. However, six were not further assessed because they either referred to a previous EFSA opinion (one), to the industrial use of *T. reesei* (two, Annex 3-9 and 3-16), to gene transcription mechanisms and biochemistry of *T. reesei* (two, Annex 3-13, 3-14) or to other products (one, Annex 3-12). The remaining four publications were reviews of the safety of enzymes produced from microbial fermentation, including *T. reesei*. Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead the Panel to reconsider its previous conclusions on the safety of the product for the target species evaluated, consumers and the environment under the authorised conditions of use.

[27] Equivalent to 50 mg additive/kg feed.
[28] Equivalent to 75 mg additive/kg feed.
[29] Equivalent to 100 mg additive/kg feed.
[30] Technical dossier/Section III and Supplementary information April 2023/Appendix_No adverse effects statement.
[31] Technical dossier/Section III/Annexes 3-5 to 3-16.

3.2.2. Safety for the consumer

The applicant submitted an *in vitro* micronucleus test performed to evaluate the potential to induce chromosomal damage of one batch of intermediate ultrafiltrate concentrate described above [redacted] TOS: 29%).[32]

The study was conducted in whole blood human lymphocytes according to OECD TG 487 and claimed to be Good Laboratory Practice (GLP) compliant. The product was tested at up to 5,000 ug TOS/ml applying a short treatment (3 + 21 h of recovery) in the absence and presence of metabolic activation, and a continuous treatment (24 + 24 h of recovery) without metabolic activation. The highest concentration tested corresponded to the top dose recommended by OECD TG 487 for the *in vitro* mammalian cell micronucleus test. No cytotoxicity was induced by the test item. The frequency of micronuclei in binucleated cells was comparable between treated and negative control cultures. The Panel concludes that the test item did not induce structural and numerical chromosome aberrations under the experimental conditions applied in this study.

3.2.3. Safety for the user

No experimental data were submitted by the applicant to support the safety of the final formulations of the additive for the users. The applicant sent information on the single constituents of the additives; however, the FEEDAP Panel considered this approach not in compliance with the requirements set in the relevant EFSA Guidance (EFSA FEEDAP Panel, 2012b).

The dusting potential of the GT form of the additive is up to 10 mg/m^3 (see Section 3.1.1). Based on this value the FEEDAP Panel considered that the exposure through inhalation is unlikely. In spite of the low dusting potential, the Panel considered that due to the proteinaceous nature of the active substances, the additive should be considered a potential respiratory sensitiser.

In the absence of adequate data, the Panel cannot conclude on the potential of the additive to cause skin and/or eye irritation and/or dermal sensitisation.

3.2.4. Conclusions on safety

Based on the information provided by the applicant and the fact that the changes in the manufacturing process are not expected to introduce safety concerns, the FEEDAP Panel concludes that there is no evidence to reconsider the conclusions reached in the previous opinion on the safety of the additive for poultry for fattening, poultry for laying and weaned piglets. Therefore, the Panel concludes that the additive remains safe under the approved conditions for these target species, consumers and the environment.

The additive should be considered a potential respiratory sensitiser. No conclusions can be drawn on the skin/eye irritation and dermal sensitisation potential of the additive.

3.3. Efficacy

The additive Ronozyme® Multigrain GT/L is authorised in poultry for fattening other than turkeys for fattening at a minimum inclusion level of 135 U xylanase, 35 U glucanase and 40 U cellulase per kg feed; poultry for laying at a minimum inclusion level of 216 U xylanase, 56 U glucanase and 64 U cellulase per kg feed; turkeys for fattening and weaned piglets at a minimum inclusion level of 270 U xylanase, 70 U glucanase and 80 U cellulase per kg feed.

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisations that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

There is no need for assessing the efficacy of the additive for poultry for fattening, poultry for laying and weaned piglets in the context of the renewal of the authorisation.

3.4. Post-market monitoring

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[33] and Good Manufacturing Practice.

[32] Technical dossier/Section III/Annex 3-2.

[33] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

4. Conclusions

The applicant provided evidence that the additive currently in the market complies with the conditions of authorisation. Ronozyme® Multigrain GT/L remains safe for the target species, the consumers and the environment when used in poultry for fattening, poultry for laying and weaned piglets at the authorised conditions of use.

The additive should be considered a potential respiratory sensitiser. In absence of data, the Panel cannot conclude on the potential of the additives to cause skin and eye irritation or dermal sensitisation.

There is no need for assessing the efficacy of the additive for poultry for fattening, poultry for laying and weaned piglets.

References

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Abbreviations

ATCC	American Type Culture Collection
CFU	colony-forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GLP	Good Laboratory Practice
LOD	limit of detection
LOQ	limit of quantification
RH	relative humidity