EUROPEAN
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Brussels, XXX
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[…](2024) XXX draft

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 as a feed additive for piglets and pigs for fattening of all Suidae species**

(Text with EEA relevance)

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 as a feed additive for piglets and pigs for fattening of all Suidae species**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 as a feed additive for all pigs, requesting that additive to be classified in the category ‘technological additives’ and in the functional group ‘substances for reduction of the contamination of feed by mycotoxins’.

(4) The use of this additive, as indicated in Commission Regulation (EC) No 386/2009 establishing the functional group ‘substances for reduction of the contamination of feed by mycotoxins’, should improve the quality of the feed for animal nutrition which is lawfully on the market, providing additional guarantees for the protection of animal and public health.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 30 January 2024[2] that the preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 is safe up to 60U/kg complete feed for weaned and suckling piglets, pigs for fattening and all minor growing porcine species and that its use in animal nutrition under the proposed conditions of use is safe for the consumers and environment. In the absence of adequate data, the Authority could not conclude on the safety of the additive at the maximum proposed use level (360U/kg) nor on the safety for sows and minor reproductive porcine species. It also concluded that the

[1] OJ L 268, 18.10.2003, p. 29; ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] EFSA Journal, 22(3), e8614.

preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 is considered to be a respiratory sensitiser, although the exposure through inhalation is unlikely, it is neither a skin nor an eye irritant, while no conclusions could be made on its skin sensitisation potential. The Authority further concluded that the substance is efficacious in reducing the fumonisins contamination in feed when added at the minimum use level of 60 U/kg feed for all Suidae. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) Subsequently, the applicant withdrew the application for sows and minor reproductive porcine species.

(7) In view of the above, the Commission considers that the preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised for piglets and pigs for fattening of all Suidae species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*
**Authorisation**

The substance specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘substances for reduction of the contamination of feed by mycotoxins’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*
**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*
*Ursula VON DER LEYEN*

EN

# ANNEX

| Identification number of the feed additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | Units of activity/kg complete feedingstuff with 12 % moisture content | | | |
| **Category: technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: fumonisins** | | | | | | | | |
| 1m04 | Fumonisin esterase EC 3.1.1.87 | **Additive composition**<br>Preparation of fumonisin esterase produced with *Komagataella phaffii* NCAIM (P) Y001485 containing a minimum of 1 200 U[1]/g.<br><br>Solid form<br><br>**Characterisation of the active substance**<br>Fumonisin esterase (EC 3.1.1.87) produced with *Komagataella phaffii* NCAIM (P) Y001485<br><br>**Analytical method**[2]<br>For the determination of fumonisin B1 esterase activity in the feed additive, premixtures and compound feed:<br><br>High Performance Liquid Chromatography coupled to fluorescence detection (HPLC- | Piglets of all Suidae species<br><br>Pigs for fattening of all Suidae species | - | 60 | 60 | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.<br>2. The additive shall only be used to improve the quality of feed which is already compliant with the rules established for mycotoxins in Union law on undesirable substances in animal feed.<br>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those | |

[1] One unit (U) is the amount of enzyme that releases one µmol of HFB1 per minute from 100 µM of FB1 in 50 mM phosphate buffer pH 6.0 at 37°C.

[2] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

| Identi-fication number of the feed additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisa-tion |
|---|---|---|---|---|---|---|---|---|
| | | | | | Units of activity/kg complete feedingstuff with 12 % moisture content | | | |
| **Category: technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: fumonisins** | | | | | | | | |
| | | FLD) based on the quantification of hydrolysed fumonisin B1 released from the action of the enzyme on fumonisin B1 at pH 6.0 and 37 °C. | | | | | risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment. | |

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**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 as a feed additive for all poultry species for fattening, all poultry species reared for laying or breeding and ornamental birds (holder of authorisation: Toa Biopharma Co., Ltd.)**

(Text with EEA relevance)

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 as a feed additive for all poultry species for fattening, all poultry species reared for laying or breeding and ornamental birds (holder of authorisation: Toa Biopharma Co., Ltd.)**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 as a feed additive to be used in feed and water for drinking for chickens for fattening, chickens reared for laying or breeding, turkeys for fattening, turkeys reared for laying or breeding and all minor avian species, including sporting, exotic and all other ornamental birds, to slaughter or point of lay, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 4 May 2022[2] and 27 September 2023[3] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 is safe for the target species, the consumers and the environment. It also concluded that the preparation is not irritant to skin and eyes but is a respiratory sensitiser, while due to the lack of information provided no conclusion could be drawn on its potential to be a skin sensitiser. The Authority further concluded that the preparation is efficacious for the target species under the proposed conditions of use. The Authority concluded that the preparation is

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal 2022;20(6):7342.
[3] EFSA Journal 2023;21(11):8343.

compatible with the coccidiostats diclazuril, decoquinate and halofuginone, while no conclusion could be drawn on the compatibility of that preparation with the coccidiostats monensin sodium, salinomycin sodium, narasin, robenidine hydrochloride and maduramicin ammonium. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed and water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) On 21 June 2024, the applicant withdrew the application as regards the recognition of the compatibility of use of the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 with the following coccidiostats: monensin sodium, salinomycin sodium, narasin, robenidine hydrochloride and maduramicin ammonium.

(6) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation should be authorised. It is appropriate to indicate that the preparation may be used simultaneously with the coccidiostats diclazuril, decoquinate and halofuginone. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*
*Ursula VON DER LEYEN*

**EN**

# ANNEX

| Identification number of the feed additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | CFU/kg of complete feedingstuff with a moisture content of 12% | | CFU/l of water for drinking | | | |
| **Category: zootechnical additives. Functional groups: gut flora stabilisers** | | | | | | | | | | | |
| 4b1895 | Toa Biopharma Co., Ltd., Japan, represented by Toa Biopharma Co., Ltd., Europe Representative Office | *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 | ***Additive composition*** Preparation of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 containing a minimum of 12 × $10^8$ CFU/g additive (1:10:1 ratio) Solid form<br><br>***Characterisation of the active substance*** Viable spores of *Bacillus subtilis* FERM BP-07462, *Enterococcus lactis* FERM BP-10867 and *Clostridium butyricum* FERM BP-10866 | All poultry species for fattening<br><br>All poultry species reared for laying<br><br>All poultry species reared for breeding | – | 2,4 x $10^8$ | - | 1,2 x $10^8$ | - | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.<br>2. The additive may be used via water for drinking.<br>3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: diclazuril, decoquinate and halofuginone.<br>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be | *[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]* |
| | | | | Ornamental birds | Point of lay | 2,4 x $10^8$ | - | 1,2 x $10^8$ | - | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | ***Analytical method*** **(1)**<br>Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697.<br><br>Enumeration in the feed additive, premixtures, compound feed and water of:<br>*Bacillus subtilis* FERM BP-07462: Spread plate method on tryptone soya agar (EN 15784)<br>*Enterococcus lactis* FERM BP-10867: Spread plate method using bile esculin azide agar (EN 15788)<br>*Clostridium butyricum* FERM BP-10866: Pour plate method using iron sulfite agar (ISO 15213) | | | | | | | eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment. | |

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

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**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of endo-1,4-β-xylanase, endo-1,4-β-glucanase and xyloglucan-specific-endo-β-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 as a feed additive for sows of all *Suidae* species (holder of authorisation: Huvepharma EOOD)**

(Text with EEA relevance)

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of endo-1,4-β-xylanase, endo-1,4-β-glucanase and xyloglucan-specific-endo-β-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 as a feed additive for sows of all *Suidae* species (holder of authorisation: Huvepharma EOOD)**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 as a feed additive for all reproductive *Suidae* and all *Suidae* for fattening, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 February 2024[2] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 does not have adverse effects on animal health, consumer safety or the environment. The Authority also concluded that the preparation in granulated formulation is not an irritant to the skin and eyes but should be considered a skin sensitiser. It further concluded that the liquid formulation of the preparation is considered not to be an irritant to the skin and eyes, and not a skin sensitiser. However, both formulations of the preparation are considered respiratory sensitisers. The Authority further concluded that the preparation has the potential to be efficacious in all reproductive *Suidae* at the use level of 1500

[1] OJ L 268, 18.10.2003, p. 29. ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal. 2024;22:e8643.

EPU, 100 CU and 100 XGU/kg complete feed. Due to the lack of sufficient data, the Authority was not able to conclude on the efficacy for *Suidae* for fattening. It did not consider that there is a need for specific requirements of post-market monitoring.

(5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005([3]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application.

(6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for sows of all *Suidae* species. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Regarding the target species for which the Authority's opinion was inconclusive, the applicant committed to providing supplementary information.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*
**Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*
**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*

[3] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives. OJ L 59, 5.3.2005, p. 8. ELI: http://data.europa.eu/eli/reg/2005/378/oj.

Ursula VON DER LEYEN

# ANNEX

| Identification number of the feed additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Units of activity/kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category: zootechnical additives. Functional group: digestibility enhancers.** | | | | | | | | | |
| 4a39 | Huvepharma EOOD | Endo-1,4-beta-xylanase (EC 3.2.1.8)<br>Endo-1,4-beta-glucanase (EC 3.2.1.4)<br>Xyloglucan-specific-endo-beta-1,4-glucanase (EC 3.2.1.151) | ***Additive composition***<br>Preparation of endo-1,4-beta-xylanase, endo-1,4-beta-glucanase and xyloglucan-specific-endo-beta-1,4-glucanase produced with *Trichoderma citrinoviride* DSM 33578 having a minimum activity of:<br>endo-1,4-beta-xylanase: 15 000EPU ([1])/g,<br>endo-1, 4-beta-glucanase: 1 000CU ([2])/g,<br>xyloglucan-specific endo- beta-1,4-glucanase: 1 000XGU ([3])/g.<br>Granulated or liquid form.<br><br>***Characterisation of the active substance***<br>Endo-1,4-beta-xylanase (EC 3.2.1.8), endo-1,4-beta-glucanase (EC 3.2.1.4) and xyloglucan-specific-endo-beta-1,4-glucanase (EC 3.2.1.151) produced with *Trichoderma citrinoviride* DSM 33578<br><br>***Analytical method ([4])*** | Sows of all *Suidae* species | - | Endo-1,4-beta-xylanase 1 500 EPU<br><br>Endo-1, 4-beta-glucanase 100 CU<br><br>Xyloglucan-specific endo-beta-1,4-glucanase 100 XGU | - | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment. | *[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication-tion]* |

([1]) One EPU unit is the amount of enzyme which liberates 0.0083 micromoles of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4.7 and 50 °C.
([2]) One CU unit is the amount of enzyme that liberates 0.128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4.5 and 30 °C.
([3]) One XGU unit is the amount of enzyme that releases low-molecular fragments from dyed xyloglucan in amount equal to the amount of such fragments liberated from 1 unit enzyme standard under the conditions of the assay (50 ºC and pH 4.5).

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | For the determination of endo-1,4-beta-xylanase activity in the feed additive, premixtures and compound feed:<br>— colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrate.<br>For the determination of endo-1,4-beta-glucanase activity in the feed additive, premixtures and compound feed:<br>— colorimetric method based on the quantification of water soluble dyed fragments (azurine) produced by the action of endo-1,4-beta-glucanase on azurine-crosslinked cellulose.<br>For the determination of xyloglucan-specific-endo-beta-1,4-glucanase activity in the feed additive, premixtures and compound feed:<br>— colorimetric method based on the quantification of soluble dyed labelled fragments produced by the action of xyloglucan-specific-endo-beta-1,4-glucanase on xyloglucan substrate. | | | | | | |

([4]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

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**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding, sows of all *Suidae* species and all fin fish (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.)**

(Text with EEA relevance)

**COMMISSION IMPLEMENTING REGULATION (EU) …/...**

**of XXX**

**concerning the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding, sows of all *Suidae* species and all fin fish (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.)**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 as a feed additive for all poultry, all *Suidae* and all fin fish, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 February 2024[2] that, under the proposed conditions of use, the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 is safe for all poultry, all *Suidae* and all fin fish. It further stated that the preparation is safe for consumers and the environment. The Authority also concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737, in the final formulations of the additive, is not a skin irritant. The two liquid formulations of the additive are not eye irritants, while the two solid ones are to be considered eye irritants. The Authority was not able to conclude on the skin sensitisation of the final formulations of the additive. Due to the proteinaceous nature of the active substance (6-phytase), the additive is considered a respiratory sensitiser. However, exposure by inhalation was considered unlikely. The Authority further concluded that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 has the potential to be efficacious in all poultry

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal. 2024;22:e8663.

for fattening and reared for laying or breeding and in all reproductive *Suidae* at the minimum proposed use level of 200 FYT/kg complete feed and in all fin fish at the minimum proposed use level of 1000 FYT/kg complete feed. Due to the lack of sufficient data, the Authority was not able to conclude on the efficacy for laying and reproductive poultry, and for *Suidae* for fattening or reared for reproduction. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that the preparation of 6-phytase produced with *Aspergillus oryzae* DSM 33737 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening or reared for laying or reared for breeding, sows of all *Suidae* species and all fin fish. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Regarding the target species for which the Authority's opinion was inconclusive, the applicant committed to providing supplementary information.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*
**Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*
**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*
Ursula VON DER LEYEN

# ANNEX

| Identification number of the feed additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Units of activity/kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category: zootechnical additives. Functional group: digestibility enhancers.** | | | | | | | | | |
| 4a48 | DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o. | 6-phytase (EC 3.1.3.26) | ***Additive composition***<br>Preparation of 6-phytase (EC 3.1.3.26) produced with *Aspergillus oryzae* DSM 33737 having a minimum activity of:<br>Solid form: 10 000 FYT([1])/g.<br>Liquid form: 20 000 FYT/g.<br><br>***Characterisation of the active substance***<br>6-phytase (EC 3.1.3.26) produced with *Aspergillus oryzae* DSM 33737<br><br>***Analytical method ([2])***<br>For the quantification of phytase activity in the feed additive:<br>- colorimetric method based on the enzymatic reaction of phytase on the phytate - VDLUFA 27.1.4.<br>For the quantification of phytase activity in | All poultry species for fattening or reared for laying or reared for breeding | - | 200 FYT | - | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal eye (only for the two solid formulations), breathing and skin protective equipment. | *[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]* |
| | | | | Sows of all *Suidae* species | | 200 FYT | | | |
| | | | | All fin fish | | 1 000 FYT | | | |

([1]) One Phytase Unit (FYT) is defined as the amount of enzyme that releases 1 µmol of inorganic phosphate from phytate per minute (concentration of 5.0 mM) at pH 5.5 and 37°C.

([2]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/publications/feed-2021-2299_en.

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | premixtures:<br>- colorimetric method based on the enzymatic reaction of phytase on the phytate;<br>- VDLUFA 27.1.3.<br>For the quantification of phytase activity in compound feed:<br>- colorimetric method based on the enzymatic reaction of phytase on the phytate;<br>- EN ISO 30024. | | | | | | |