REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Feed Additive Consisting of Biotin for All Animal Species for the Modification of Its Authorisation (ADISSEO, DSM Nutritional Products Ltd., NHU Europe GmbH) (RP2227)

Food Standards Agency[1], Food Standards Scotland[2]

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FSA Research and Evidence

An application was submitted to the Food Standards Agency and Food Standards Scotland in May 2024 from saqual GmbH for the renewal of authorisation of the feed additive biotin (3a880) which is submitted on behalf of three applicants: ADISSEO France S.A.S, DSM Nutritional Products Ltd., and NHU Europe GmbH (hereby referred to as "the applicants"). The feed additive is currently authorised for use in feed and water for drinking for all animal species, under the category of 'nutritional additives' and functional group 'vitamins, pro-vitamins, and chemically well-defined substances having a similar effect'. The applicant seeks a modification of the authorisation for a change in the formulation of the additive related to its particle size distribution.

The European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) previously issued two opinions on the safety and efficacy of biotin as a feed additive for all animal species (EFSA, 2012a, b). The FEEDAP Panel concluded that biotin is safe for the target species, consumers and the environment when used under the proposed conditions. Regarding the user/worker, biotin is not irritant to skin, eyes or mucous membranes and is unlikely to cause skin sensitisation. However, the FEEDAP Panel concluded that there is a potential for inhalation exposure from handling biotin due to its high dusting potential and an absence of data on inhalation toxicity.

In 2025 the EFSA FEEDAP Panel published an assessment of the feed additive consisting of biotin for all animal species for the renewal of its authorisation (EFSA, 2025). The FEEDAP Panel concluded there is no new evidence that would lead the Panel to reconsider its previous conclusions regarding the safety of the additive.

The FSA/FSS have reviewed the applicant's authorisation application, supporting documentation, and other regulators' risk assessments, most notably the 2025 EFSA risk assessment opinion, and consider sufficient evidence has been demonstrated to conclude without the need for further questions or risk assessment.

1. Introduction

The FSA and FSS have received a request from saqual GmbH (Kleefeldstrasse 9, 5734 Reinach AG, Switzerland) on behalf of three applicants, ADISSEO France S.A.S, DSM Nutritional Products Ltd., and NHU Europe GmbH and have undertaken an assessment of a feed additive consisting of biotin (3a880) under Assimilated Regulation (EC) No 1831/2003 (EC, 2003) in each nation of Great Britain (GB).

The feed additive was previously authorised under assimilated Implementing Regulation (EU) 2015/723 (EU, 2015) for use in feed and water for drinking for all animal species, under the category of 'nutritional additives' and functional group 'vitamins, pro-vitamins, and chemically well-defined substances having a similar effect'.

The applicant is requesting a modification of the formulation of the additive related to its particle size distribution.

In line with Article 8 of assimilated Regulation (EC) No 1831/2003 (EC, 2003), the assessment has considered and concluded whether the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect; potential impairment of the distinctive features of animal products. This, and the guidance put in place by the European Food Safety Authority (EFSA) for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

To ensure the regulatory systems of FSA/FSS are risk proportionate, and resources are used effectively, FSA and FSS have used the evidence submitted by the applicants and other information in the public domain, including the EFSA risk assessment opinion, to provide a summary assessment of the evidence of safety presented in this report.

In 2025, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) published a scientific opinion on the assessment of the feed additive consisting of biotin for all animal species for the renewal of its authorisation (EFSA, 2025). This opinion has been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion.

The result of the assessment is that there is sufficient evidence of safety and efficacy for the UK to conclude this assessment at this time. This assessment represents the opinion of the FSA and FSS.

2. Assessment

2.1. Details of other regulators opinions and conclusions

2.1.1. Current authorisation

Under assimilated Implementing Regulation (EU) 2015/723 (EU, 2015), following the EFSA 2012 opinions, the additive was authorised in the European Union (EU) and GB for use in feed and water for drinking for all animal species. EFSA released an opinion on the renewal of the use of the feed additive for all species in 2025 (EFSA, 2025).

2.1.2. Other regulators opinions

EFSA previously published two opinions on the safety and efficacy of biotin as a feed additive for use in all animal species (EFSA, 2012b, 2012a).

In 2025, EFSA published a scientific opinion on the assessment of the application for the renewal of the authorisation of biotin as a feed additive for all animal species (EFSA, 2025).

2.1.3. Methodology applied in the EFSA opinion

The EFSA FEEDAP Panel assessed the safety and the efficacy of the additive, in accordance with guidance documents:

- Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

and principles in assimilated Regulation (EC) No 429/2008.

These guidance documents also apply to the assessment framework of applications submitted to the FSA for authorisation.

2.2. Section II: Identity, characterisation and condition of use

2.2.1. Characterisation of the active agents

The additive biotin (CAS no. 58-85-5) consists mainly of the active substance D-(+)-biotin with at least 97 % purity. It is a white or almost white, crystalline powder or colourless crystals, very slightly soluble in water (220 mg/L (25°C)). The additive and the active substance are identical.

Biotin is produced by chemical synthesis using dibenzylbiotin as a starting material and several solvents. The applicant declared that the manufacturing process remains unchanged since the previous authorisation and as such no changes in the physical properties of the active substance described in the previous EFSA opinions are expected (EFSA, 2012b, 2012a).

The applicants provided new analytical data on the composition and physical state of the active substance summarised in Table 1.

All chemical impurities resulting from the manufacturing process are within the range that was assessed previously by EFSA (EFSA, 2012b, 2012a). The FEEDAP Panel noted that these values comply with the specifications set for biotin in the European Pharmacopoeia (Ph. Eur., 2022). The FEEDAP Panel concluded that the detected impurities do not raise any safety concern. The FSA/FSS agree with the conclusion of the FEEDAP Panel.

2.2.2. Characterisation of the additive

Biotin is marketed as a preparation at concentrations of 2 % or 10 % by mixing the active substance biotin (min. 97 %) with carriers (e.g., dextrose, maltodextrin, starch, calcium carbonate, silica) and technological additives (e.g., silicic acid, precipitated and dried, antioxidants, preservatives).

The applicants provided some new analytical data on the batch-to-batch variation, impurities and physical properties for five preparations of biotin (Table 2). The number of batches analysed is in line with the EFSA Guidance on the identity, characterisation and conditions of use of feed additives (2017).

The FSA/FSS noted that the particle size distribution (PSD) and dusting potential of the active substance (biotin (min. 97 %)) and the 2 % and 10 % preparations of biotin reported in the new data submitted for the current assessment have changed slightly since the previous opinions (EFSA, 2012b, 2012a). The applicants declared that no changes have been made to the manufacturing process of the additive. The changes in PSD and

Table 1. New data on the batch-to-batch variation, impurities and physical properties of the active substance biotin (min. 97 %). The data presented are ranges for all parameters with [number of batches analysed].

Batch-to-batch variation	Range
Biotin	99 - 100.7 % [15]
Loss on drying	0.05 - 0.4 % [10]
Optical rotation	89.1 - 91.5 ° [15]
Sulphated ash	0.04 - 0.1 % [10]
Impurities	
Impurity A	0.18 - 0.28 mg/kg [10]
Impurity C	0.04 - 0.08 mg/kg [10]
Impurity E	0.06 - 0.21 mg/kg [10]
Lead	< 0.05 mg/kg [15]
Cadmium	< 0.01 mg/kg [15]
Arsenic	< 0.04 mg/kg [15]
Mercury	< 0.01 mg/kg [15]
Fluorine	< 40 mg/kg [5]
Nickel	< 0.2 mg/kg [2]
Sum of dioxins and furans (upper bound, 88 % DS)	
PCDD/Fs	0.0769 ng/kg [3]
DL-PCBs	0.059 ng/kg [3]
PCDD/Fs+PCBs	0.136 ng/kg [3]
nDL-PCBs	0.53 µg/kg [3]
Others	
Polyaromatic hydrocarbons	< 0.5 µg/kg [3]
Chloramphenicol (veterinary drug)	< 0.00015 mg/kg [3]
Ethylene oxide (pesticide)	< 0.01 mg/kg [3]
Melamine	< 0.2 mg/kg [3]
Cyanuric acid	< 0.9 mg/kg [3]
Residual solvents	
Ethanol	ND [5]
Methanol	2.2 - 6.3 mg/kg [5]
Toluene	ND [5] - 0.7 mg/kg [5]
Isobutyl acetate	0.9 - 2.8 mg/kg [5]
Dimethylformamide	ND [5]
Tetrahydrofuran	0.025 - 0.028 mg/kg [5]
Physical properties	
Dusting potential	526 - 713 mg/m^3 [3]
Particle size distribution (% of particles below, v/v)	
100 µm	99.3 % [3]
50 µm	91.5 - 91.9 % [3]
10 µm	27.8 - 29.0 % [3]
1 µm	1.4 - 1.5 % [3]
Stability	

Batch-to-batch variation	Range
30°C/60 % RH 36 months	99.4 - 99.9 % recovery [3]

dusting potential are expected to be due to small variations within the existing manufacturing process and signify a change in the specifications, with potential implications that require assessment.

The previous opinions reported higher dusting potential of the active substance (biotin (min. 97%)) at 1340-2100 mg/m^3. The dusting potential was also reported higher in the previous opinions at 6400-17,600 mg/m^3 for 2 % biotin preparations and 21,100-24,300 mg/m^3 for 10 % biotin preparations (EFSA, 2012b, 2012a).

The PSD measured by laser diffraction reported a similar percentage of particles below 50 µm in the active substance between the 2025 and 2012 opinions (92 % and 85 % respectively) however the fraction of particles smaller than 50 µm has reduced substantially in the 2 % and 10 % preparations of biotin compared to the previous opinions. The previous opinions reported 38-74 % of particles (v/v) < 50 µm in the 2 % preparation and 63-78 % of particles (v/v) < 50 µm in the 10 % preparation (EFSA, 2012b, 2012a). The new data reports the fraction of particles smaller than 50 µm (v/v) at 15.2-18.7 % in the 2 % preparation, 24.3-60.5 % in the spray dried 2 % preparation and 37.9–48.3 % in the spray dried 10 % preparation. In general, the new PSD analysis indicates a greater proportion of larger particles in the preparations and a lower dusting potential of the additive under assessment compared to the previous opinions (EFSA, 2012b, 2012a).

Additionally, the FSA and FSS note that the active substance (biotin (min. 97%)) and some batches of the 2 % preparations of the additive contain a relatively high proportion (> 1 %) of particles smaller than 1 µm indicating the possibility of the presence of nanoparticles. According to the EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles, “the characterisation of the fraction of small particles, including the particle size distribution, is needed in all cases unless the applicant demonstrates that the material will be fully dissolved under the intended use conditions and consumers will not be exposed to particles” (EFSA, 2021).

Biotin is an essential nutrient that has been used in human and animal nutrition for several decades and is known to be water soluble up to 220 mg/L and is more soluble in alkaline solutions. Accounting for its solubility and the recommended inclusion rate for biotin in complete feed, the applicant expect biotin will be fully dissolved in those sections of the

Table 2. New data on the batch-to-batch variation, impurities, physical properties, shelf life and homogeneity of two 2 % preparations, two spray-dried (SD) 2 % preparations and one SD 10 % preparation of biotin. The data presented are ranges for all parameters. (Table adapted from (EFSA, 2025)).

(Applicant) and brand name if available	(ADISSEO)MICROVIT® H PROMIX	(NHU EUROPE GmbH)	(NHU EUROPE GmbH)	(DSM) ROVIMIX® Biotin 2% SD	(DSM) ROVIMIX® Biotin HP
Biotin preparation	**2 %**	**2 %**	**2 % SD**	**2 % SD**	**10 % SD**
Batch-batch variation					
Biotin (%)	2.03 - 2.28	2.05 - 3.01	2.02 - 2.04	2.0	10.2 - 10.4
Loss on drying (%)	-	0.2	5.6 - 5.8	-	-
Impurities (mg/kg)					
Lead	< 2	4.21 - 4.31	< 0.2	-	-
Cadmium	< 0.5	0.10 - 0.13	< 0.1	-	-
Arsenic	< 2	0.53 - 0.95	< 0.2	-	-
Mercury	< 0.01	< 0.01	< 0.1	-	-
Fluoride	< 20 - 22	51 - 92	-	-	-
Sum of dioxins and furans (upper bound, 88% DS)					
PCDD/Fs (ng/kg)	0.0519 -0.0595	0.05683	-	-	-
DL-PCBs (ng/kg)	0.0277 -0.0318	0.05922	-	-	-
PCDD/Fs+PCBs (ng/kg)	0.0796 -0.0912	0.11605	-	-	-
nDL-PCBs (µg/kg)	0.0493 -0.0563	0.53	< 1	-	-
Mycotoxins (µg/kg)					
Aflatoxins B1, B2, G1, G2	< 0.1	-	< 0.2	-	-
Aflatoxin G2	< 0.2	-	< 0.2	-	-
Deoxynivalenol	< 50	< 40	< 10	-	-
Zearalenone	< 20	< 10	< 5	-	-
HT-2 toxin	< 20	< 20	< 2	-	-
T-2 toxin	< 20	< 2	< 2	-	-
Fumonisins B1+B2	-	< 40	< 50	-	-
Ochratoxin A	-	< 5	< 0.5	-	-
Microbial contamination					
Yeast and moulds (CFU/g)	-	-	< 100	-	-
Enterobacteriaceae (CFU/g)	-	-	< 10	-	-
Salmonella spp. (in 25g)	-	-	ND	-	-
Physical properties					
Bulk density (kg/m^3)	1425 - 1472	-	-	-	-
Dusting potential (mg/m^3)	1533 - 1750	-	2098 - 3069	5360 - 9940	3750 - 8830
Particle size distribution (% of particles below, v/v)					
100 µm	31.2 - 32.6	-	56.7 - 58.3	66.3 - 92.0	74.4 - 83.4
50 µm	15.2 - 18.7	-	24.3 - 26.5	32.4 - 60.5	37.9 - 48.3
10 µm	8.6 - 10.7	-	2.1 - 2.3	1.8 - 5.1	2.4 - 4.4

(Applicant) and brand name if available	(ADISSEO)MICROVIT® H PROMIX	(NHU EUROPE GmbH)	(NHU EUROPE GmbH)	(DSM) ROVIMIX® Biotin 2% SD	(DSM) ROVIMIX® Biotin HP
1 µm	1.9 - 2.4	-	0.3	0	0
Stability in feed (% recovery)					
25°C at 60% RH for 24 months	-	98	-	-	-
40°C at 75% RH for 6 months	-	98	-	-	-
Homogeneity (coefficient of variation, %)					
Pelleted feed, 0.4 mg biotin/kg feed	-	-	-	5	3

gastrointestinal tract where resorption takes place. Considering its solubility and as biotin is a widely used, authorised human food, veterinary drug, pharmaceutical, cosmetic and feed additive, the FSA/FSS are satisfied that biotin particles smaller than 1 µm would be fully dissolved and absorbed efficiently. The FSA/FSS conclude that further risk assessment relating to the small particle fraction of the additive is not required.

The FEEDAP Panel raised no issues regarding the updated PSD or possibility of nanoparticles in their opinion (EFSA, 2025).

The applicant addressed the changes in PSD declaring that these changes are not expected to be relevant. Considering that the manufacturing process and composition remain essentially unchanged, the FSA/FSS agrees that these changes are not expected to have a significant impact on the stability, homogeneity and efficacy of the product. Although the new data suggest the dusting potential has been reduced, the overall level is still high, posing a potential risk to users. The previous authorisation already states that breathing protection shall be worn during handling due to the high dusting potential and likelihood of inhalation by users and the FSA/FSS agrees that this should be maintained in the current assessment. Changes in PSD and dusting potential do not pose additional safety risks.

2.2.3. Manufacturing process

The applicant declared that the manufacturing process remains unchanged since the previous authorisation and EFSA opinions (EFSA, 2012b, 2012a).

All chemical impurities resulting from the manufacturing process are within the range that was assessed previously by EFSA (EFSA, 2012b, 2012a). The FEEDAP Panel concluded that the detected impurities do not raise any safety concern (EFSA, 2025). The FSA/FSS agree with the conclusion of the FEEDAP Panel.

2.2.4. Stability and homogeneity

As the manufacturing process for the additive and its preparations has not been changed, the stability and homogeneity data available to the FEEDAP Panel in 2012 and their conclusions are still applicable to the current assessment.

Previously the shelf-life of the active substance and of the 2 % preparation under normal conditions (25 °C and 60 % relative humidity (RH)) was shown to be 24 months, for the 10 % biotin preparation it was 24-36 months (EFSA, 2012b, 2012a). Under accelerated conditions (40°C) the shelf life of the active substance and 2 % preparation was shown to be 6 months (EFSA, 2012b).

The applicant provided new stability data to confirm the shelf life of the active substance and a 2 % preparation. Three batches of biotin (min. 97 %) were stored at 30°C at 60 % RH for 36 months and the final recovery values were reported between 99.4 and 99.9 %. Three batches of a 2 % biotin preparation were stored at 25°C at 60 % RH for 24 months and another three batches were stored at 40°C at 75 % RH for 6 months. The average recovery was 98 % for all batches of 2 % biotin.

Biotin content was analysed in 10 samples of pelleted broiler feed to which a 2 % biotin preparation and a 10 % biotin preparation had been added to achieve a target level of 0.4 mg/kg. Coefficients of variation were 5 % and 3 %, respectively.

Considering the conclusions of the FEEDAP Panel in the previous opinions (EFSA, 2012b, 2012a) and the new data provided by the applicant the FSA/FSS agree with the shelf-life proposed by the applicant and conclude that the additive is stable and capable of homogenous distribution in feed. The FSA/FSS agree that the changes in PSD of the additive are not expected to have a significant impact on stability or homogeneity.

2.2.5. Conditions of use

Biotin (97 %) is currently authorised for use as nutritional additive in feed for all animal species without a minimum or maximum level. Under other provisions of the authorisation, it is specified that:

1. Biotin may be placed on the market and used as an additive consisting of a preparation.

2. In the directions for use of the additive and premixture, indicate the storage and stability conditions.
3. For safety: breathing protection shall be worn during handling.
4. The additive may be used in water for drinking.

The applicant did not request any change to the current conditions of use of the authorisation.

2.2.6. Conclusions on Section II: Identity, characterisation and conditions of use

The additive was fully characterised, and the identity of the active agent confirmed.

The FEEDAP Panel concluded that the amounts of the detected impurities, as well as microbial contamination, do not raise safety concerns. The information on the shelf-life and manufacturing process was provided.

Considering that the manufacturing process and composition of the active substance are unchanged since the previous dossiers, the FSA/FSS agrees that the changes in PSD are not expected to have a significant impact.

FSA and FSS agree with the conclusions reached by EFSA for the identity and characterisation of the additive and active agent. The FSA and FSS agree with the conditions of use proposed by the applicant.

2.3. Section III: Safety

According to assimilated Regulation (EC) No 429/2008, tolerance, metabolism and residue; and toxicological studies are not required for Nutritional additives (vitamins, pro-vitamins and chemically defined substances having similar effects) which had been authorised as feed additives under Directive 70/524/EEC and which do not have the potential to accumulate, which is the case for biotin.

All three applicants provided a post-marketing safety monitoring report and declare that no reports of adverse effects for target animal safety, consumer safety, user/worker safety, or the environment have been received since the authorisation of the additive biotin (3a880).

2.3.1. Safety for the target species, consumers, environment and the user

The 2012 EFSA opinions determined that biotin is safe for the intended animal species, with a margin of safety likely at least tenfold greater than both dietary requirements and typical inclusion levels. The FEEDAP Panel concluded that biotin has low intrinsic toxicity and presents limited retention in edible tissues and animal products. As a result, consumer exposure to biotin through foods derived from biotin-supplemented animals was not considered a health risk. The Panel further concluded that the use of biotin in animal nutrition does not raise concerns for consumers or for the environment. Regarding user safety, biotin was assessed as non-irritant to the skin, eyes, and mucous membranes, and not a dermal sensitiser; however, inhalation exposure during handling may be hazardous (EFSA, 2012b, 2012a).

The applicants provided the results of a literature search that covered the full period since the authorisation (from January 2011 to February 2024). Multiple data bases such as PubMed and Elsevier were searched and a secondary manual search in Google Scholar was also performed.

The literature search identified 15 relevant studies for target animal safety, 11 relevant studies for consumer safety and 3 relevant studies for user safety. No relevant studies were identified regarding the safety of the environment.

The FEEDAP Panel reviewed these publications and found no new evidence that would alter their previous conclusions regarding the safety of the additive. Consequently, the FEEDAP Panel concluded that biotin remains safe for the target species, the consumers and the environment under the authorised conditions of use. Regarding the user safety, biotin is not irritant to skin and eyes and is not a dermal sensitiser but exposure to the additive through inhalation is likely (EFSA, 2025).

The FSA and FSS agree with the conclusions reached on the safety of the additive for target species, the consumer, user and the environment.

2.3.2. Conclusions on Section III: Safety

The FEEDAP Panel concluded that that biotin remains safe for the target species, the consumers and the environment under the authorised conditions of use. Regarding the user safety, the FEEDAP Panel concluded that biotin is not irritant to skin and eyes and is not a dermal sensitiser but exposure to the additive through inhalation is likely.

The FSA and FSS agree that the changes in PSD are not expected to have a significant impact on the safety of the additive for the target species, consumer, environment or user.

2.4. Section IV: Efficacy

The FSA/FSS conclude that the changes to the PSD of the additive are not expected to have an impact in the stability, homogeneity or ADME of the additive, therefore previous efficacy conclusions are still relevant.

3. Analytical method evaluation

The FSA/FSS evaluated the European Union Reference Laboratory (EURL) analytical method evaluation, noting it was carried out in 2011, when the UK was still part of the EU and would have participated in their approval. No concerns are raised at this stage for the validity of the methods for UK/GB use, and therefore the FSA/FSS accept the EURL analytical method evaluation report (EURL, 2011). The FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

4. Other regulators opinions and conclusions

The applicants provided evidence that the additive currently on the market complies with the existing conditions of authorisation.

The FEEDAP Panel concluded that biotin remains safe for all target animal species, consumers and the environment under the authorised conditions of use. Regarding the user safety, the FEEDAP Panel concluded that biotin is not irritant to skin, eyes and is not a dermal sensitiser. Exposure by inhalation is likely.

5. Uncertainties and limitations

No specific uncertainties or limitations were flagged in the assessment by EFSA. The FSA and FSS did not identify further uncertainties or limitations to be considered for this assessment.

6. FSA & FSS conclusions for GB assessment

The application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the Panel, which were also submitted to the FSA and FSS. The 2025 EFSA opinion identified and characterised the hazards present from the proposed use and concluded there is sufficient information to enable an assessment of exposure, which is also relevant to GB. The applicants have made no changes to the currently authorised additive except for the modification to PSD which does not impact the conclusions of the

Abbreviations

Abbreviation	Definition
DL-PCBs	Dioxin-like polychlorinated biphenyls
EFSA	European Food Safety Authority
EU	European Union
EC	European Commission
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
Impurity A	Di[3-[(3aS,4S,6aR)-2-oxohexahydrothieno[3,4-d]imidazol-4-yl]propyl]acetic acid
Impurity B	4-[(3aS,4S,6aR)-2- Oxohexahydrothieno[3,4-d]imidazol-4-yl]butane-1,1-dicarboxylic acid
Impurity E	5-[(3aS,4S,6aR)-3-benzy1-2-oxohexahydrothieno[3,4-d]imidazol-4-yl]pentanoic acid and 5-[(3aS,4S,6aR)-1-benzy1-2-oxohexahydrothieno[3,4-d]imidazol-4-yl]pentanoic acid
LOQ	Limit of quantification
ND	Not detected
nDL-PCBs	Non-dioxin-like polychlorinated biphenyls
PCBs	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzo-p-dioxins
PCDFs	Polychlorinated dibenzofurans
PSD	Particle size distribution
RH	Relative humidity
SD	Spray dried
UK	United Kingdom

assessment regarding safety or efficacy. The conclusions of the 2025 EFSA opinion have been reviewed in detail by the FSA and FSS, and are considered appropriate and consistent, including the caveats and uncertainties identified in the opinion which are applicable to GB. The conclusions of the 2012 EFSA opinions also remain applicable. Sufficient evidence has been demonstrated to conclude without further questions or risk assessment.

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