

# ACAF Annual Report 2023/24 - The Committee's work in 2023/24

## In this guide

### [In this guide](#)

1. [ACAF Annual Report 2023/24 - Foreward](#)
2. [ACAF Annual Report 2023/24 - Introduction](#)
3. [ACAF Annual Report 2023/24 - The Committee's work in 2023/24](#)
4. [ACAF Annual Report 2023/24 - Membership and appointments](#)
5. [ACAF Annual Report 2023/24 - Financial statement](#)
6. [ACAF Annual Report 2023/24 - Appendix I - Information about the Committee](#)
7. [ACAF Annual Report 2023/24 - Appendix II Self-assessment against the Good Practice Guidelines](#)

## The Committee's work in 2023/24

### Animal Feed Additives

During the 2023/2024 FY, the Committee considered thirty-five applications for authorisation of animal feed additives under assimilated Regulation (EC) 1831/2003. Members also reviewed and finalised the Committee's Advice document for an additional six applications that were assessed in the 2022/23 FY. Details of all the applications considered by the Committee are given in the Table below.

The FSA/FSS published 23 Safety Assessments based on the recommendations of the ACAF during this time. 14 of these were considered in meetings during the 2023/24 FY; the remaining 9 were considered in meetings prior to the period of this report.

Application	Description	Meeting	Committee's response
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RP859

Chlorophyllins

- Zootechnical feed additive proposed for use in poultry for fattening.

- Intended to function as a marker for detection of faecal matter contamination on carcasses.

April 2023

- Due to gaps in technical documentation, additional information was requested from the applicant.

- The dossier remains under review.

<p>RP1039 RP1040</p>	<ul style="list-style-type: none"> <li>• Zootechnical additive proposed for use in all porcine (RP1039) and avian (RP1040) species</li> </ul>	<p>April 2023  December 2023</p>	<ul style="list-style-type: none"> <li>• The Committee first considered these two linked dossiers in the April 2023 meeting. Due to gaps in technical documentation, additional information was requested from the applicant.</li> <li>• The ACAF considered the additional information provided in the December meeting and were satisfied.</li> <li>• Draft Committee's Advice documents are currently in preparation.</li> </ul>
<p>VTR-xylanase</p>			

RP1047

Powdered dry Quillaja saponaria and dry Yucca schidigera (MAGNI-PHI®)

- Zootechnical feed additive proposed for use in all avian species (excluding laying and breeding birds).

April 2023

September 2023

December 2023

January 2024

- First considered by the Committee in the April 2023 meeting. Due to gaps in technical documentation, additional information was requested from the applicant.
- In September, the Committee reviewed the response to the request for information. The applicant clarified which birds the efficacy claims should be extrapolated to, which the Committee deemed reasonable.
- The draft Committee's Advice document was reviewed in the December and January meetings.
- A Safety Assessment was published by the FSA/FSS in March 2024.

- First considered by the Committee April 2023. Due to gaps in technical documentation, additional information was requested from the applicant.
- Additional information supplied was reviewed in the September meeting. Members were unable to conclude that the additive would be stable in breeder feed due to high temperature used in processing.
- The draft Committee's Advice document was reviewed in the December and January meetings.
- At the request of risk managers, the Committee considered whether reclassification as a zootechnical (as opposed to nutritional) would affect safety. The
- Nutritional additive already authorised for use in chickens for fattening, April 2023 September 2023

RP593

Endo-1,4-beta-glucanase (Hostazym® C)

- Zootechnical feed additive containing endo-1,4-beta-glucanase, produced by the fermentation of the strain *Trichoderma citrinoviride* (IM SD142).
  - Applicant requested a renewal of authorisation for use in chickens for fattening, minor poultry species for fattening and weaned piglets.
  - Requested new authorisation for turkeys for fattening, turkeys reared for breeding, chickens reared for laying, minor
- Dossier first evaluated in October 2022.
  - Committee reevaluated in April and July after requests for additional information.
  - The draft Committee's Advice document was reviewed by members in the September and October meetings.
  - The FSA/FSS published a Safety Assessment in December 2023.
  - Based on the Committee's advice, the FSA/FSS concluded that previous conclusions drawn by The European Food Safety Authority (EFSA) could be accepted and the additive could, therefore, be considered safe for the target species, the consumer and
- April 2023
- July 2023  
September 2023
- October 2023

RP309	Endo-1,4-beta-xylanase (Hostazym® X)	<ul style="list-style-type: none"> <li>• Zootechnical feed additive containing endo-1,4-betaxylanase, produced by fermentation of the strain <i>Trichoderma citrinoviride</i> (IM SD 135).</li> </ul>	<ul style="list-style-type: none"> <li>• Applicant requested a renewal of authorisation for its use in chickens for fattening, laying hens, turkeys for fattening, minor poultry species for fattening, minor poultry species for laying, weaned piglets, pigs for fattening, chickens reared for laying and carp.</li> </ul>	September 2023	October 2023	<ul style="list-style-type: none"> <li>• The dossier was evaluated previously by the AFFAJEG in 2021 and the ACAF in 2022.</li> <li>• The conclusions by the AFFAJEG were reviewed and approved by the ACAF at their October 2023 meeting. The Committee agreed that the additive can be considered safe for the target species, the consumer and the environment. The ACAF agreed that the product should be considered a potential skin and eye irritant, and a potential skin and respiratory sensitiser, and the respirable particles were a potential hazard for the workers. It was concluded the additive remains efficacious and that these conclusions can be extrapolated to the new uses proposed.</li> </ul>
		<ul style="list-style-type: none"> <li>• Proposed new use in breeding hens, turkeys reared for breeding, ornamental birds</li> </ul>				

- The dossier was first assessed in December 2022.
- In the April 2023 meeting, members considered the applicant's response to a request for further information. Members were satisfied with the information supplied.

RP791

Lactobacillus buchneri  
NCIMB  
40788 CNCM I-4323

Lactiplantibacillus  
plantarum CNCM I-  
3235

Lactiplantibacillus  
plantarum CNCM I-3736  
DSM 11672

Pediococcus acidilactici  
CNCM I-3237

Pediococcus acidilactici  
DSM 11673

Pediococcus  
pentosaceus NCIMB  
12455

Acidipropionibacterium

- Technological silage additive, consisting of a preparation of 9 bacterial strains. April 2023  
July 2023
- Applicant requested renewal of authorisation. June 2023

- The draft Committee's Advice document was reviewed in June and July meetings.

- The Committee concluded that the additives can be considered safe for the target species, consumers and the environment, based on the Qualified Presumption of Safety (QPS) status of the microorganisms. All additives were assumed to be respiratory sensitisers. Members



			<ul style="list-style-type: none"> <li>• Additive was first considered by the AFFAJEG in April 2022, and again by the ACAF in December 2022.</li> </ul>
			<ul style="list-style-type: none"> <li>• A response to the second request for information was considered at the April 2023 meeting.</li> </ul>
			<ul style="list-style-type: none"> <li>• The draft Committee's Advice document was reviewed at the June and July meetings.</li> </ul>
RP416	<ul style="list-style-type: none"> <li>• Zootechnical feed additive.</li> </ul>		
Endo-1,4-betaxylanase and endo-1,3(4)-beta-glucanase (Aextra® XB)	<ul style="list-style-type: none"> <li>• Applicant requested a renewal of authorisation for use in a number of animal species.</li> </ul>	<p>April 2023</p> <p>June 2023</p>	<ul style="list-style-type: none"> <li>• Members concluded that the strain can be considered safe for the target species, consumer and environment, and that the applicant demonstrated the product under renewal is the same as the original application. The Committee concluded that the product should be considered a respiratory sensitiser and a</li> </ul>
	<ul style="list-style-type: none"> <li>• Proposed addition to a modification of authorisation for use of a reduced minimum dose in turkeys for fattening and</li> </ul>	<p>July 2023</p>	

<p>RP420</p>	<ul style="list-style-type: none"> <li>The dossier had been previously evaluated by the AFFAJEG and the ACAF, but due to gaps in the technical documentation, additional information had been requested from the applicant.</li> </ul>		
<p>6-phytase (Aextra® Phy Gold)</p>	<ul style="list-style-type: none"> <li>The applicant sought authorisation for use of this zootechnical feed additive in all poultry and pigs.</li> </ul>	<p>April 2023</p> <p>June 2023</p> <p>July 2023</p>	<ul style="list-style-type: none"> <li>The Committee reviewed the applicant's response in the April 2023 meeting and were satisfied with the information provided.</li> </ul>
			<ul style="list-style-type: none"> <li>The ACAF concluded that the additive is safe for the target species, consumer and environment, and that it is not an irritant to eyes and skin or a skin sensitiser, although it is considered a respiratory sensitiser.</li> <li>The FSA/FSS published a Safety</li> </ul>

RP666

Sodium benzoate  
(Protural™)

- Zootechnical feed additive.

- Proposed for use April 2023  
in piglets from  
weaning to 35 June 2023  
kg (renewal),  
and in other  
growing Suidae  
(new use).

- The dossier was first evaluated in 2022 by the AFFAJEG, and in October 2022 and February 2023 by the ACAF.
- In the April and June meetings, the ACAF reviewed the draft Committee's Advice document.
- The Committee concluded that additive is safe for the target species, consumers and the environment at the proposed conditions of use. It is potentially harmful by inhalation and an eye irritant, although not a skin irritant. The Committee concluded that the additive was efficacious at a dose of 4000 mg/kg in piglets, and that the results could be extrapolated to other growing Suidae at the same developmental stage.

RP694

Saccharomyces cerevisiae CNCM I-1079

- Zootechnical feed additive containing dried viable cells of Saccharomyces cerevisiae CNCM I-1079.

April 2023

- Proposed for use in calves, all other ruminant species (for rearing and fattening), and camelids (for rearing and fattening).

June 2023

- The dossier was first evaluated by the ACAF in October 2022, and again in February 2023 after a request for additional information from the applicant.
- In the April and June 2023 meetings, members reviewed the draft Committee's Advice document. The Committee concluded that the additive was correctly identified and characterised, and safe for the target species, consumer and environment, although should be considered a respiratory sensitiser for the user. The Committee agreed that the additive was efficacious in calves, all other ruminant species at the correspondent developmental stage (for rearing and for fattening),

RP748

Amprolium  
hydrochloride  
(Coxam®)

- Coccidiostat proposed to reduce parasitic infection levels of *Eimeria* spp. April 2023

- Intended for use in chickens for fattening and chickens reared for laying. June 2023

- The Committee first evaluated the dossier in 2022. Members assessed evidence sent by the applicant in the form of a report. Original studies referenced were not provided, despite requests.

- The Committee were unable to conclude on safety for consumers due to lack of supporting data.

- The FSA/FSS published a Safety Assessment in December 2023 based on the recommendations of the ACAF.

RP226

Endo-1,4-beta-xylanase  
(Xygest® HT)

- Zootechnical additive, proposed for use in all poultry. April 2023

- The dossier was first evaluated by the AFFAJEG in 2021, and again by the AFFAJEG and the ACAF in several subsequent meetings.
- In the April 2023 meeting, members gave feedback on the draft Committee's Advice document. The ACAF concluded that it is safe for target species, efficacious in laying and growing poultry, and that claims can be extrapolated to all poultry. The additive can be considered safe for consumers and the environment. The additive should be considered a respiratory sensitiser, but is not an eye irritant, skin irritant or skin sensitiser.

- The FSA/FSS published a Safety Assessment based on the Committee's recommendations

RP686

Lactococcus lactis DSM  
11037

- Technological silage additive to improve silage quality April 2023

- The dossier was first assessed by the Committee in October 2022.
- In the April 2023 meeting, the ACAF reviewed the draft Committee's Advice document. The Committee concluded that the additive can be considered safe for the target species, consumers and the environment, based on the QPS status of Lactococcus lactis DSM 11037 and the evidence presented through a literature review. The additive was considered an eye and skin irritant, and a skin and respiratory sensitiser. As the additive is dusty and contains a large proportion of small particles, the Committee recommended that measures should be taken to reduce inhalation exposure by workers.

<p>RP1072</p> <p>Lasalocid A sodium (Avatec® 150G) for use in chickens</p>	<ul style="list-style-type: none"> <li>• Coccidiostat proposed for use in chickens for fattening and chickens reared for laying.</li> </ul>	<p>June 2023</p>	<ul style="list-style-type: none"> <li>• The Committee considered this request for reauthorisation in the context of two other related applications in the June 2023 meeting.</li> </ul>
	<ul style="list-style-type: none"> <li>• Linked to applications RP1070 and RP1071.</li> </ul>	<p>January 2024</p>	<ul style="list-style-type: none"> <li>• Due to gaps in existing documentation, additional information was requested from the applicant and reviewed in the January 2024 meeting. There were still gaps so the Committee requested additional information from the applicant.</li> <li>• The dossier remains under review.</li> </ul>



RP1071

Lasalocid A sodium  
(Avatec® 150G) for use  
in turkeys

- Coccidiostat proposed for use in turkeys.

- Applicant requested renewal of authorisation.

- Linked to applications RP1070 and RP1072.

June 2023

- The dossier was first evaluated by the AFFAJEG in May 2022 meeting, and again by the ACAF in February 2023.

- In the June meeting, the Committee considered additional information sent by the applicant following a request for information. The ACAF were satisfied with applicant's response.

- Awaiting clarification from applicant on proposed dose. Final assessment will be performed with other linked applications.

- The dossier remains under review.

RP1070

Lasalocid A sodium  
(Avatec® 150G) for use  
in game birds

- Coccidiostat proposed for use in game birds.

- Applicant requested renewal of authorisation.

- Linked to applications RP1071 and RP1072.

January  
2024

- Committee considered this request for a renewal of authorisation in the context of two other related applications in the January 2024 meeting.

- Due to gaps in existing documentation, additional information was requested from the applicant.

- The dossier remains under review.

RP1101

Saccharomyces  
cerevisiae CNCM I-4407  
(Actisaf® Sc 47)

- Zootechnical feed additive (functional group: gut flora stabiliser) for use in rabbits for fattening and non-food producing rabbits June 2023

- Committee considered this request for a renewal of authorisation in June 2023.
- Due to gaps in existing documentation, additional information was requested from the applicant.
- The dossier remains under review.

RP1105

L-Histidine  
monohydrochloride  
monohydrate

- Nutritional additive for use in all animal species.

- Produced by fermentation with Escherichia coli KCCM 80212 (H010)

June 2023

- Application was first assessed by the Committee in the June 2023 meeting.
- Due to gaps in existing documentation, additional information was requested from the applicant.
- The FSA/FSS published a Safety Assessment in September 2023 based on the EFSA opinion. Therefore, no further involvement was required from the Committee.

RP552

*Pediococcus*  
*pentosaceus* DSM  
32292

- Technological silage additive

June 2023

January  
2024

- The Committee considered the dossier in the June 2023 meeting, together with additional information that had been requested by the FSA.

- Members felt that efficacy had not been demonstrated and submitted a further request for information.

- At the January meeting, the Committee reviewed a draft of the Committee's Advice document.

			<ul style="list-style-type: none"> <li>• The dossier was first evaluated by Committee in December 2022.</li> <li>• In the June and September 2023 meetings, the Committee reviewed additional data supplied by the applicant after requests for information.</li> </ul>
RP709	<ul style="list-style-type: none"> <li>• Zootechnical digestibility enhancer</li> </ul>	June 2023	<ul style="list-style-type: none"> <li>• Members reviewed and finalised the draft Committee's Advice document in the October and December meetings.</li> </ul>
ProAct 360 (additive containing subtilisin protease)	<ul style="list-style-type: none"> <li>• Subtilisin protease produced by <i>Bacillus licheniformis</i> DSM 33099</li> </ul>	September 2023	
	<ul style="list-style-type: none"> <li>• Proposed for use in all growing poultry species</li> </ul>	October 2023  December 2023	<ul style="list-style-type: none"> <li>• The FSA/FSS published a Safety Assessment based on the Committee's recommendations in March 2024. The FSA/FSS concluded that the additive is efficacious is growing poultry and safe for consumers, the target animal and the environment. The additive should be considered a potential</li> </ul>

RP746

Alpha-galactosidase and endo-1,4-betaglucanase (Agal-Pro BL and Agal-Pro BL L®)

- Zootechnical feed additive intended for use in chickens for fattening, minor poultry species for fattening and chickens reared for laying.
- June 2023  
December 2023  
September 2023  
January 2024

- The dossier was first evaluated by the ACAF at the December 2022 meeting.
- In the June 2023 meeting, members considered additional information sent by the applicant, but some information was missing. A third request for information was sent to the applicant, after which the Committee were satisfied.
- The Committee's Advice document was finalised in the September and January meetings.
- The FSA/FSS published a Safety Assessment in March 2024 based on the Committee's advice.
- The FSA/FSS concluded on a recommended dose at 50, 100 mg/kg of

RP1015

Lactococcus lactis  
NCIMB 30117

- Technological silage additive

June 2023

December 2023

January 2024

- The dossier was first evaluated by the Committee in February 2023, but there were gaps in the technical documentation.
- In June, members considered additional information supplied by the applicant following a request by the Committee. Some technical documentation was still missing.
- The applicant supplied additional information which was assessed in the December meeting and found to be satisfactory.
- Members gave feedback on the draft Committee's Advice document in January.



RP1142

RONOZYME® Multigrain  
(preparation of endo-  
1,4-beta-xylanase,  
endo-1,3(4)-beta-  
glucanase  
and endo-1,4-beta-  
glucanase)

- Zootechnical digestibility enhancer

- Preparation of enzymes produced by *Trichoderma reesei* ATCC 74444.

- Applicant requested a renewal of authorisation for use in poultry for fattening, poultry for laying and weaned piglets.

- Applicant proposed new use in pigs for fattening.

July 2023

- The Committee considered the dossier in the July 2023 meeting.
- Due to gaps in technical documentation, additional information was requested from the applicant.
- The dossier remains under review.

RP1055  
RP1582

Preparation of endo 1,4  
betaxylanase, endo 1,4

betaglucanase and  
xyloglucan-specific-  
endo-beta-1,4-  
glucanase) (Huvezym®  
neXo)

- Zootechnical feed additive.
- Preparation of enzymes produced by *Trichoderma citrinoviride* B-125 DSM 33578.

July 2023

- Proposed for use in poultry, ornamental birds and piglets (RP1055) and pigs for fattening, sows, minor species for fattening and reproduction (RP1582).

- The Committee assessed these two linked dossiers in the July 2023 meeting.
- Due to gaps in existing documentation, additional information was requested from the applicant.
- The dossiers remain under review.

RP1111

Bifidobacterium longum  
CNCM I-5642 (PP102I)

- Zootechnical feed additive proposed for use in dogs and cats
- July 2023  
December 2023

- Members assessed this dossier in the July 2023 meeting.
- Additional information was requested from the applicant. This was assessed in the December meeting and found to be satisfactory.
- The Committee's Advice document is currently in preparation.

RP1154

Bacillus subtilis  
DSM5750 and Bacillus  
licheniformis DSM5749  
(BioPlus® 2B)

- Already authorised as zootechnical feed additive for use in feed and water for weaned piglets, pigs for fattening, sows, calves for rearing, turkeys for fattening and suckling piglets. July 2023
- Applicant proposed a new use in calves for fattening and other growing ruminants at the same developmental stage, and piglets (suckling and weaned)

- The dossier was first assessed in the July 2023 meeting.
- Due to gaps in the technical documentation, additional information was requested from the applicant.
- The dossier remains under review.

RP634	Chromium propionate	<ul style="list-style-type: none"> <li>Zootechnical feed additive proposed for use in all growing poultry species</li> </ul>	<ul style="list-style-type: none"> <li>The dossier was first assessed by the ACAF in February 2023.</li> <li>In July, the Committee considered additional information supplied by the applicant following a request after the previous meeting.</li> <li>The ACAF had requested input of an external expert to consider the validity of the efficacy trials supplied by the applicant. The Committee reviewed the opinion of the expert and concluded that the trials were valid, but that efficacy was not demonstrated at the lower inclusion rate. The applicant was required to submit additional efficacy data or accept the Committee's conclusion</li> </ul>
		July 2023	
		October 2023	
		January 2024	

RP1137	CanBiocin K-9	<ul style="list-style-type: none"> <li>Zootechnical gut flora stabiliser for use in canines, comprising of a mixture of 4 lactic acid bacterial strains.</li> </ul>	September 2023	<ul style="list-style-type: none"> <li>The dossier was assessed in the September 2023 meeting. The Committee were unable to conclude on efficacy with data provided. Additional information was requested from applicant.</li> </ul>
RP1243	L-methionine	<ul style="list-style-type: none"> <li>Nutritional additive for use in all animal species. L-methionine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80245 and <i>Escherichia coli</i> KCCM 80246</li> </ul>	September 2023	<ul style="list-style-type: none"> <li>The dossier remains under review.</li> <li>The Committee assessed the dossier in September 2023. Due to gaps in existing documentation, additional information was requested from the applicant.</li> <li>The dossier remains under review.</li> </ul>

RP1258

Preparation of 3 strains of *Bacillus velezensis* (previously known as *B. amyloliquefaciens*) (Enviva® PRO 202 GT)

- Zootechnical feed additive.

- Already authorised as gut flora stabiliser for use in chickens and minor poultry species for fattening and chickens and minor poultry species reared for laying.

September 2023

- Applicant have requested that authorisation is extended to turkeys for fattening and turkeys reared for breeding.

- The dossier was assessed in September 2023. The Committee concluded that there was sufficient evidence to support efficacy, but additional information was requested from applicant to demonstrate the identity and characterisation.

- The dossier remains under review.

RP1275

6-phytase enzyme  
preparation  
(Quantum® Blue)

- Zootechnical digestibility enhancer proposed for use in fin fish. September 2023

- Produced by a strain of *Trichoderma reesei* January 2024

- The Committee considered the dossier in September 2023 and concluded that the product was efficacious for trout but not other fin fish.

- Additional information was requested from applicant, and this was reviewed in January. There were still gaps in the existing documentation, so a further request for information was sent to the applicant.

- The dossier remains under review.



RP812

Dicopper chloride trihydroxide (Intellibond® C)

- Applicant requested renewal of authorisation for use of this nutritional additive in all animal species

September 2023

December 2023

- The dossier was first assessed by members in February 2023.
- The Committee requested the appointment of an independent expert to assess the environmental safety.
- In the September meeting, the Committee reviewed the opinion of the independent expert. Additional information was requested from the applicant.
- After reviewing the additional data, the Committee concluded that the additive is safe when used at the proposed levels for terrestrial species and land-based aquaculture systems. However, members could not conclude on the safety of the additive for marine sediment

RP814

Zinc chloride hydroxide monohydrate (Intellibond® Z)

- Applicant requested renewal of authorisation of this nutritional additive for use in all animal species

September 2023

December 2023

- The dossier was first assessed by members in February 2023.
- The Committee requested the appointment of an independent expert to assess the environmental safety.
- In the September meeting, the Committee reviewed the opinion of the independent expert. Additional information was requested from the applicant.
- After reviewing the additional data, the Committee concluded that the additive is safe when used at the proposed levels for terrestrial species and land-based aquaculture systems. However, members could not conclude on the safety of the additive for marine

RP1282

Levilactobacillus brevis  
DSMZ 21982

- Technological silage additive

- Applicant requested renewal of authorisation

October  
2023

- The Committee reviewed this dossier alongside additional data that had been requested by the FSA in October 2023.
- There were still gaps in the technical documentation, so additional information was requested from the applicant.
- The dossier remains under review.

RP1298

Preparation of 6-  
phytase (Ronozyme®  
HiPhos)

- Zootechnical feed additive containing 6-Phytase produced by *Aspergillus oryzae* DSMZ 33699.

October  
2023

- Applicant requested renewal and extension of authorisation for use in poultry, weaned piglets, pigs for fattening and sows.

- Members evaluated the dossier in October 2023. It was noted that the production strain listed in the technical documentation was different to the strain intended for authorisation. A request was sent to applicant to clarify strain intended for authorisation and to request additional data.
- The dossier remains under review.

RP1341

Preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase (Avizyme® 1505)

- Zootechnical feed additive.
  - Mixture of 3 enzymes produced from 3 different genetically modified microorganisms.
  - Applicant requested renewal of authorisation in chickens and turkeys for fattening, ducks and laying hens. October 2023
  - Applicant proposed a modification of use in turkeys for fattening, and new use in all avian species for laying, for fattening, reared for breeding and reared for laying (except for ducks). December 2023
- The dossier was first assessed in October 2023, and again in December alongside complementary information that had been supplied to address areas of concern highlighted by the EFSA opinion.
  - There were still gaps in the technical documentation so additional information was requested from the applicant.
  - The dossier remains under review.

RP1280

Formaldehyde

- A hygiene condition enhancer to be used in chickens for fattening, laying hens, weaned piglets and pigs for fattening.

December  
2023

- An additional request was put to extend the scope of the authorisation to turkeys.

- The dossier was assessed in December 2023. Due to gaps in the technical documentation, additional information was requested from the applicant.

- The dossier remains under review.

RP1317  
RP1350

25-  
hydroxycholecalciferol  
(Vitamin D)

- Nutritional additive in the functional group “vitamins, pro vitamins and chemically well-defined substances having a similar effect”.

- Applicant requested a renewal of authorisation in pigs and poultry (RP1350) and a modification to extend to ruminants (RP1317).

December  
2023

- The Committee assessed these two dossiers together, as they shared some technical documentation.
- Due to gaps in existing data, additional information was requested from the applicant. The applicant was asked to confirm that the production strains were the same in both applications, to confirm that they can be assessed together.
- The dossiers remain under review.

RP1393

Endo-1,4- $\beta$ -xylanase  
(RONOZYME® WX)

- Zootechnical feed additive
- Xylanase enzyme expressed by *Aspergillus oryzae*.
- Applicant requested a renewal of authorisation for December use in poultry for 2023 fattening, piglets (weaned), pigs for fattening, lactating sows and laying hens.
- Applicant proposed extension for use in all poultry and pig species.
- The dossier was considered by the Committee in the December 2023 meeting.
- Due to gaps in the technical documentation, additional information was requested from the applicant.
- The dossier remains under review.



<p>RP1512</p> <p>Bacillus velezensis ATCC PTA-6737 (PB6)</p>	<ul style="list-style-type: none"> <li>• Zootechnical gut flora stabiliser.</li> <li>• Applicant requested a renewal of authorisation for use in weaned piglets and weaned minor porcine species and as a feed additive for sows.</li> </ul>	<ul style="list-style-type: none"> <li>• Additional information had been requested by the FSA but was not available when the Committee assessed the dossier in January 2024.</li> <li>• The Committee concluded that the additive only had the potential to be efficacious in sows, based on the data provided.</li> </ul>
	<ul style="list-style-type: none"> <li>• The applicant also proposed an extension for use to all pig species</li> </ul>	<ul style="list-style-type: none"> <li>• Additional information was requested from the applicant. The dossier remains under review.</li> </ul>

## Feed for Particular Nutritional Uses (PARNUTs)

During the 2023/2024 FY, the Committee considered two applications for modification of the PARNUT legislation, assimilated Regulation (EU) 2020/354. Members also reviewed and finalised the Committee’s Advice document for one application that was assessed in the 2022/23 FY. Details of all the applications considered by the Committee are given in the Table below.

Two Safety Assessments were published by the FSA/FSS, based on the recommendations by the ACAF.

Application	Description	Meeting	Committee's response
RP1307	The applicant requested the inclusion of a new PARNUT under regulation 2020/354, 'Reduction of large colon feed impaction', for use in equine species.	April 2023 July 2023 September 2023	<ul style="list-style-type: none"> <li data-bbox="1046 293 1455 768">• The dossier was first evaluated by the Committee in April 2023, but had previously been considered by the AFFAJEG, after which additional information had been requested from the applicant.</li> <li data-bbox="1046 880 1455 1205">• The applicant submitted an amended version of the PARNUT which members considered to be efficacious and safe for the target species.</li> <li data-bbox="1046 1317 1455 1552">• The draft Committee's Advice document was considered in the July and September meetings.</li> <li data-bbox="1046 1664 1455 1935">• The FSA/FSS published a Safety Assessment in December 2023 based on the recommendations of the ACAF.</li> </ul>
Colic sachet			

RP658

Modification of PARNUT for the 'Reduction of the risk of milk fever and subclinical hypocalcaemia'

Applicant requested a modification of entry number 60 of the PARNUT regulation 2020/354, 'Reduction of the risk of milk fever and subclinical hypocalcaemia', to include Dietary Cation-Anion Difference (DCAD) values below 0.

July 2023

- The application was previously evaluated by the AFFAJEG in December 2021.
- In July 2023, the ACAF reviewed and approved the draft opinion.
- The opinion concluded that a modification of the regulation to include DCAD levels between -200 and 100 mEq/kg dry matter would not pose any additional risks to the target species and would be expected to improve efficacy.
- The FSA/FSS published a Safety Assessment in August 2023 based on the Committee's conclusions.

RP2059

Copper bolus  
(Tracesure®)

Applicant requested a modification of entry number 59 of the PARNUT regulation 2020/354 to allow inclusion of up to 75% copper.

October  
2023

- The Committee considered the risk assessment provided by the applicant for the proposed amendment.
- The risk assessment considered safety for target animal, safety for the consumer, safety for the user and safety for the environment. The Committee requested that the applicant provided a more comprehensive risk assessment, supported by quality assured studies.
- The dossier remains under review.