Info session on Feed for Particular Nutritional Purposes

QUESTIONS & ANSWERS

13 March 2026

Questions submitted during the registration phase

- **Usually, the conditions of use for Particular Nutritional Purposes (PNP) refer to complete feed. How to adapt those conditions in the case of complementary feed?**
  In case of complementary feed, its contribution to the daily ration should be clearly detailed in the application.

- **Does animal feed include aquaculture feed and pet food?**
  A PARNUT can be formulated for any animal species, including aquatic species and pets.

- **How you define animal feed and nutritional purposes in the new guidance? What will be the content for the technical dossier? When will the new guidance be implemented?**
  The relevant definitions are included in the Regulation (EC) No 767/2009:
  Particular nutritional purpose: The purpose of meeting the specific nutritional needs of animals whose process of assimilation, absorption or metabolism is, or could be, temporarily or irreversibly impaired and who can therefore benefit from the ingestion of feed appropriate to their condition
  Feed intended for particular nutritional purpose (PARNUT): Feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Feed intended for particular nutritional purposes does not include medicated feedingstuffs within the meaning of Directive 90/167/EEC
  The guidance is scheduled for endorsement by the FEEDAP Panel in May/July 2026, and for adoption in November 2026.

- **Regarding the demonstration of efficacy (and safety, where relevant) through literature/scientific evidence. Which rules will EFSA apply regarding inter-species/categories extrapolation?**
  Applicants should support any read-across between species with scientific evidence.

- **Greater detail on the expected hierarchy of evidence (in vivo studies, biomarkers, mechanistic data, field trials) would be highly valuable to ensure alignment between research design and regulatory assessment logic.**
  Applicants should assess which is the most appropriate means to provide evidence of safety and efficacy of the PARNUT. Published studies and already existing scientific evidence may be used; however, if such evidence is incomplete or unreliable, in vivo studies on the target species may be required.

- **I would like to know how EFSA will be involved in when the dossiers start getting into the EC. Will the dossier be submitted through the ESFC or through other tools (e.g. Circa). Also, if EFSA is involved will this make the process longer?**
  Applications shall be submitted to the European Commission by email; the possibility to the ESFC platform for the submission is under consideration. The Commission and Member

States verify validity, and if EFSA review is needed, EFSA shall issue an opinion within six months, extendable if extra data is required.

- **How EFSA plans to address borderline cases between feed for particular nutritional purposes (Reg. 767/2009) and feed additives (Reg. 1831/2003), especially for innovative ingredients with both nutritional and functional properties?**
  Additives cannot be PARNUTs, but PARNUTs may contain certain additives, in addition to feed materials. If a substance that provides the essential nutritional characteristics to the PARNUT has a specific functional activity, it should be considered a feed additive and must first be authorized as such under Regulation 1831/2003. Substances with additive-like functions should not be incorporated into PARNUTs without proper authorization as feed additives. In any case, the use of feed additives should be according to the conditions of use stated, and only for the target animals covered in the authorisation.

Live Q&A session

- **What kind of substance in feed could be if it is not a feed additive or a feed material?**
  Only feed materials listed in the Catalogue or the Register of Feed Materials, and authorised feed additives, may be included in a PARNUT as part of the essential nutritional characteristic. Other substances that are neither feed materials nor feed additives may be present in the PARNUT (e.g. ingredients of a bolus); however, their inclusion would require a safety assessment[1]

- **When will the first EFSA opinions on partner dossiers be available, and is there a dedicated working group for PARNUTS?**
  There are four applications under assessment, all in clock stop awaiting applicant's responses, and opinions may be adopted soon. The Animal Nutrition Working Group is assessing these dossiers.

- **When can we expect the guidance for PARNUTS to be available for applicants?**
  Endorsement for public consultation is planned for May/July, and its adoption is expected in November.

- **What is considered a highly digestible ingredient or high level of magnesium for PARNUT number 62 (reduction of stress in pigs), and how can operators justify these claims?**
  The definition of "highly digestible" is intentionally flexible, and operators should justify their choices.

- **Regarding the demonstration of efficacy, it has been said that three in vivo studies may be necessary if there is no reliable information on the effect. How is "not reliable information" defined, and when is one study required instead of three?**

  There are three levels of evidence needed. If existing publications clearly link a proposed PARNUTS mode of action to the impaired metabolism, no further efficacy data are required. If information is incomplete, such as not available for the specific target species or physiological state, one in vivo study may be necessary. If there is no prior evidence connecting mode of action, nutrients, or additives to the impaired metabolism or relevant

biomarkers, then typically three studies are required. This explains the need for zero, one, or three studies, depending on what is already known.

- **Will the Commission and Standing Committee reject applications where the claimed purpose is not compatible with the authorized use of the additive (e.g., flavourings used for physiological stabilization)?**
  Commission and Member States will check compatibility and may reject such applications during the validity check.

- **For companion animals, what scientific justification would EFSA accept to show that an effect demonstrated in one species may also be present in another?**
  Justification relies on similarity of the possible impairment and on metabolic factors. If knowledge is insufficient, further data may be required.

- **Is it possible to use a PARNUT for prevention (e.g., prevention of stress reactions) or is it only for reduction, and does this require a different type of application?**
  Some PARNUTS are for prevention of physiologically expected conditions (e.g., hypocalcemia), but prevention of other conditions (like stress) may not fit, and the Commission will decide case by case.

Chat Q&A

- **Whom within the EC does receive and handle the applications? DG Sante?**
  DG Sante - Unit G5 receives these applications

- **If I refer to the Purpose of another applicant, where can I find the detailed description of this purpose as originally handed in to EFSA?**
  For applications evaluations assessed in the past are covered by confidentiality and cannot be shared without the consent of the original applicants. For applications assessed by EFSA you may find the relevant information in the EFSA opinion and in the non-confidential version of the dossier that is published in accordance with the transparency regulation.

- **How would be the process to apply for a modification of an existing entry?**
  The procedure will remain the same as a new entry, with particular emphasis in the modifications applied.

- **What kind of substance in feed could this be: not a feed additive and not a feed material? Do you mean a feed material which is not yet in the EU catalogue?**
  Answered during live Q&A.

- **Could be used the PARNUT registration to assess the safety efficacy of a new additive, which is intended to be added to the PARNUT?**
  A feed additive must always be authorized in accordance with Regulation 1831/2003 prior to its use in a PARNUT.

- **If DG Sante, send the mandate to EFSA for assessment of the PARNUTS will it fall under transparency regulation?**
  Yes, PARNUT applications, received as general mandates, will be subject to the relevant provisions of the transparency regulation. For instance, the mandate as well as all scientific data and information supporting the mandate will be proactively disclosed under Article

38(1)(c) of the GFL, as implemented by the EFSA PAs concerning transparency and confidentiality. However, the provisions of the General Food Law (GFL) regarding pre-submission advice (Article 32a GFL), notification of studies (Article 32b GFL), and public consultations (Article 32c(2) GFL) are not applicable.[1]

- **Shall we assume that an assessment fee will not apply (same as feed additive registrations)?**
  Confirmed, no fee is applicable for PARNUT applications.
- **For companion animals where the scientific literature is often limited compared to food-producing species, what scientific justification would EFSA accept to show that an effect demonstrated in one species (e.g., dogs) can also be expected in another (e.g., cats)? The pet food sector is always aiming at minimising trials on pets, because of welfare considerations for long living animals.**
  Answered during live Q&A.

[1] The answer provided during the meeting has been complemented with further information.