

26 (EU) 18

9 July 2026

FEFAC comments on the draft EFSA guidance document on the information needed to support the evaluation of the applications for feed intended for particular nutritional purposes as provided for in Regulation (EC) No 767/2009.

Scope of the guidance:

Article 10 par.2 of Regulation 767/2009 makes it clear that "A valid application shall include a dossier demonstrating that the specific composition of the feed fulfils the particular intended nutritional purpose and that it has no adverse effects on animal health, human health, the environment or animal welfare." It is therefore the specific composition that matters here. It should therefore be specified in the scope that the the assessment of the safety is restricted to those safety aspects that are specific to the feed for particular nutritional purpose (e.g. specific nutritional composition or specific feed materials whose presence is required to perform the nutritional objective). All other elements which are not specific to the nutritional purpose such as the presence of feed materials other than those linked to the nutritional purpose should not require the provision of information as part of the application.

2.2.3: Conditions of use

Lines 172-173: "It describes usually the first time of the administration." What does this mean? First administration of the dietetic feed? Is it expected that the further administrations will be different from the first?

Line 175: All forms of administration are expected to deliver the expected nutritional purpose in the same way and may not need to be specified in the application. Exception is indeed boluses, that should be addressed as an exception.

Lines 176-178: The sentence is not clear: if the form of the dietetic feed is a bolus, what other forms are expected to be delivered to the animal at the same time?

2.2.4: Characterisation of the dietetic feed:

Lines 193-197: What does composition mean? Nutritional characteristics or types of ingredients? The latter case would unduly restrict the scope of the assessed nutritional purpose to a very specific type of complete feed, which would restrict the possibilities to use a dietetic feed.

Line 204: Same comment as for line 175

Lines 207-209: Stability is already assessed as part of the application for authorisation of the feed additives. It should not be required here.

Line 213-216: The requirement to provide Information on the daily release rate of feed additives should be extended to feed materials contributing to the essential nutritional characteristics of the dietetic feed (e.g. calcium salts).

2.3 Safety

Line 225: We do not understand the discrimination between a feed material listed in the catalogue from a feed material listed in the EU Catalogue. The safety of both is under the exclusive responsibility of the placer on the market. The safety of feed materials is ruled through other legal texts (ABP, undesirable substances, GM feed) and apply the same way to feed listed in the catalogue and the register. The words "listed in the Catalogue of feed materials" should be deleted.

2.3.1 Safety for the target species:

Lines 246-247: same comment as for Line 225

Lines 254-256: If feed additives are authorised without maximum limits, this is because there is no risk whatever the dose.

Lines 261-262 and 263-264: same comment as Line 225.

2.3.2 Safety of the consumer

Line 285: same comment as for Line 225