Webinar on call for data on the use of 3-nitrooxypropanol in ruminants

26 February 2026 | Questions & Answers

This document contains answers to questions received either during registration or live at the Webinar held 26 February 2026 to provide stakeholders with guidance on EFSA's call for data on the use of 3-nitrooxypropanol in ruminants, including the regulatory context, the evidence types requested, how to submit data and key timelines.

Q1: When submitting farm raw data, what is the recommended time frame (in weeks) for data before and after Bovaer administration? Is it an issue if there is no data available from periods prior to and following 3-NOP use? Is the absence of before-and-after data less problematic in research trials that include a control group?

Ideally, comprehensive data covering several months both before and during 3-NOP use should be provided (ideally 1 year before). Research studies/trials with a control group are also acceptable. Details on data requirements are further described in the call for data submission form, and in the published webinar PPT presentation.

Q2: If you lack raw datasets but have observations or reports about welfare or practical experiments, such as authority or parliamentary documents, can these be used as initial or supplemental datasets, even if you're not a farmer?

Yes, publicly available information such as official reports and documentation may be submitted as complementary datasets.

Q3: How do you ensure the authenticity of submitted data?

To ensure verification of the material submitted, we require original data from the farms. Additionally, we reserve the right to contact the farmer or data provider to request clarifications or further evidence, if needed.

Q4: What is the anticipated timeline for concluding this call for data? Approximately, how long will it take EFSA to evaluate the data? Additionally, what is the expected duration for the process of collecting data and preparing an opinion.

The process of evaluating the data by EFSA will commence after the deadline for data submission, which is set for 31 March 2026. According to the EC mandate, EFSA aims to prepare and deliver its opinion by 30 June 2026. This timeline might be affected depending on the volume of data received.

Q5: Is it possible to upload multiple files simultaneously, or can additional files be uploaded later? Is there an option to modify or update existing uploads? Additionally, would it be beneficial to share metadata, such as comprehensive information from dairy farms?

Yes, several packages of data may be submitted on different dates, as long as within the deadline of the call. Even different people within an institution may submit the data on different occasions, given that they clearly identify the company/organization that they are representing, to allow for easy identification of the data packages under the same provider and avoid duplications. Each submission should follow the guidelines for confidential and public versions. Sharing meta-data is welcome. Details on data requirements are further described in the call for data submission form and in the published webinar PPT presentation.

Q6: Is it possible to submit data packages more than once during the open call? If yes, do all submissions need to include two ZIP files (one confidential and one public) as well as a signed cover letter? Also, if there are no confidentiality concerns and only a public ZIP file is provided, does the ZIP file still need to contain a signed cover letter describing the content and scope of the submission?

Yes, multiple submissions are allowed. Each submission should contain two ZIP files (one confidential, one public) and a signed cover letter describing the submission's content and scope. Even when submitting only public data, a signed cover letter describing the content and scope is recommended.

Q7: Could you please confirm whether, as for feed additives applications, the Questionnaire (Word file) should be submitted as two readable PDF files: one version with confidential information clearly marked, and a second version in which the confidential sections are blackened/redacted?

Yes, that is correct.

Q8: Who is permitted to access the raw data? Is it kept confidential and solely used by EFSA? Can data from experimental studies be considered confidential, or does EFSA require its publication?

Raw data will be treated as confidential or not depending on whether confidentiality has been claimed for the raw data. EFSA may grant confidential treatment only with respect to the items of information described in the provisions of Article 39 of Regulation (EC) No 178/2002 (General Food Law). Only non-confidential information will be published; confidential data is protected and used exclusively by EFSA for assessment purposes. You can find further details on our dedicated webpage Confidentiality and sanitization.

Q9: Concerning information obtained before and after the trial with 3-NOP, some of the data may also be linked to other trial groups. What is the recommended approach for managing this situation?

Data may be submitted as research trials with multiple groups, including control groups for comparison, and other trials. Information concerning other unrelated trial groups not relevant to the call can be claimed as confidential and will be treated as such. They will not be considered for the assessment.

Q10: Considering that data will be gathered from farmers, veterinarians and other stakeholders, and must be submitted in English and scientific format (which may not be accessible for everyone), do you offer support in stakeholders' native languages to assist with preparation and submission process?

Data may be submitted in other EU languages. Regarding the call for data, there is a function in the call webpage for translating content from English to other languages. No direct support systems in stakeholders' native languages are foreseen to assist them in preparing and submitting information in the required scientific format.

The following questions fall outside the scope of the webinar, which is focused on the call for data. These aspects may be addressed as part of broader risk assessment processes or in future evaluations. Stakeholders are encouraged to submit comprehensive data and all relevant information for risk assessment.

Q11: *I would like to request additional clarification regarding the practical application of 3-NOP across various farming environments. Specifically, I am interested in understanding how factors such as diet composition, production system, and physiological stage may influence its efficacy.*

Q12: *The necessity of post-marketing surveillance; A long-term experimental trial observed mild negative effects on feed intake and milk production linked to the use of canola meal as a feed ingredient. H2S production was not considered, which is important within a One Health framework.*

Q13: *From a regulatory and control perspective, insights into best practices for ensuring correct incorporation, traceability, and compliance within official control frameworks would also be highly valuable.*

Q14: *Given that 3-NOP has already undergone an authorisation process and is currently being used in farms, and considering the recent reports from Danish authorities describing clinical signs of digestive and metabolic disorders in a proportion of dairy herds following its introduction: how will EFSA take such post-market observations into account when evaluating forthcoming zootechnical additives aimed at reducing methane emissions in ruminants? In particular, could these developments lead to updated guidance or additional considerations regarding target animal safety requirements, study duration, or post-market monitoring for similar methane-reducing compounds?*

Q15: *Will the updated assessment evaluate potential health and welfare implications associated with reduced feed intake, behavioral changes, and clinical signs of digestive/metabolic disorders under practical conditions? Furthermore, how will EFSA address uncertainty and variability related to feeding and management systems in the safety evaluation of 3-NOP?*

Q16: *The methane reduction potential has been demonstrated in several studies. However, the same studies have reported a statistically significant decrease in dry matter intake (DMI) and, consequently, in milk yield. Why has this harmful effect, already demonstrated in dairy cows, not been more widely discussed?*

Q17: *How will EFSA ensure that field observations from practical farming conditions, including reported changes in feed intake, animal behaviour and general welfare indicators, are systematically assessed in the updated risk assessment of 3-NOP? In particular, how will potential variability related to feeding and management conditions be addressed when evaluating both safety and welfare implications?*