

Outcome of assessment of 3-Nitrooxypropanol “3-NOP” - Analytical methods evaluation

Conclusions on the analytical methods are presented here as an extract from the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of the Analysis for Bovaer® 10⁴:

“In the current application authorisation is sought under Article 4(1) for 3-nitrooxypropanol (preparation of minimum of 10% of 3-nitrooxypropanol) under the category/functional group 4(c) ‘zootechnical additives’/ ‘substances which favourably affect the environment’, according to Annex I of Regulation (EC) No 1831/2003. Specifically, the authorisation is sought for the use of the feed additive for dairy cows and cows for reproduction, dairy sheep and ewes for reproduction, dairy goats and goats for reproduction, other ruminants for milk production and reproduction.”

For the quantification of the 3-nitrooxypropanol content in the feed additive, premixtures and feedingstuffs the applicant proposed a single-laboratory validated method based on reversed phase high performance liquid chromatography (HPLC) coupled to spectrophotometric (UV) detection.

The following performance characteristics were reported by the applicant in the frame of the validation studies for the quantification of 3-nitrooxypropanol content:

- In the feed additive: a relative standard deviation for repeatability (RSDr) ranging from 0.2% to 1.0%; a relative standard deviation for intermediate precision (RSDip) ranging from 0.3% to 1.0%; and a recovery rate (Rrec) ranging from 100% to 101%.
- In premixtures (2,870–17,390 mg/kg): a RSDr ranging from 0.4% to 1.1%; a RSDip ranging from 0.8% to 1.5%; and a Rrec ranging from 100% to 101%.
- In feedingstuffs (29–132 mg/kg): a RSDr ranging from 0.6% to 5.2%; a RSDip ranging from 1.0% to 5.2%; a Rrec ranging from 98% to 101%; and a limit of quantification (LOQ) ranging from 8 to 14 mg of 3-nitrooxypropanol/kg feedingstuffs.

Based on the experimental evidence available the EURL recommends for the official control the above mentioned single-laboratory validated and further verified reversed phase HPLC-UV method for the quantification of 3-nitrooxypropanol in the feed additive, premixtures and feedingstuffs.

FSA/FSS accepts the EURL analytical method evaluation reports. FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.