Annex M: RP1059 - 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction

Annex M: RP1059 - 3-nitrooxypropanol as a feed additive for ruminants for milk production and for reproduction (Bovaer® 10) DSM Nutritional Products Ltd., Switzerland (new)

Background

Name of applicant:

DSM Nutritional Products Ltd., in Switzerland

Address of applicant:

Wurmigsweg 576

4303

Kaiseraugst

Switzerland

FSA/FSS Safety Assessment:

FSA/FSS has undertaken a safety assessment of?application RP1059 for the use of 3-nitrooxypropanol (3-NOP) (Bovaer® 10) as a feed additive for ruminants (for example, cattle, sheep, goats) for milk production and for reproduction, from DSM Nutritional Products Ltd., Switzerland.

The application was evaluated by our independent Animal Feed and Feed Additives Joint Expert Group (AFFAJEG) and the Advisory Committee on Animal Feedingstuffs (ACAF). The FSA/FSS safety assessment was published on 31 March 2023 and can be found here. The assessment of 3-nitrooxypropanol shows that the conditions for authorisation in Article 5 of the Regulation are satisfied.

The FSA/FSS opinion is that 3-nitrooxypropanol, as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use and under the proposed terms of authorisation. The proposed terms of authorisation are set out below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:?

1. Article 16 and points 1(a) of Annex III: Labelling and packaging?requirements apply, if authorised.

2. Article 21: Analytical methods have been verified by the European Reference Laboratory (EURL) as used for the control of 3-nitrooxypropanol in animal feed as detailed in the EURL analytical method evaluation report (FAD-2019-0057). FSA/FSS?has?reviewed?the (EURL) evaluation report and determined the analytical method as appropriate for official controls for this feed additive. Valid analytical methods exist for:

- the quantification of 3-nitrooxypropanol activity in the feed additive, premixtures, feed materials and compound feed.

3. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation

Conclusions from the Safety Assessment:

The FSA/FSS?conclusion?on?3-nitrooxypropanol (Bovaer® 10) is that:??

- the additive is safe for the proposed target species under the conditions of use at a maximum dose of 200 mg/kg of dry matter.
- the feed additive is considered safe for consumers and the environment.
- 3-nitrooxypropanol is considered efficacious for reducing methane production in ruminants when fed daily at the proposed dose.
- On worker safety, the additive is to be considered an eye and skin irritant but not a skin sensitiser and a respiratory sensitiser.

Proposed terms of authorisation:

1:?Additive details

Category	Details
Additive category??	(4) Zootechnical
Functional group??	(c) Substances which favourably affect the environment
Feed additive??	3-nitrooxypropanol
ID No??	4c1
Target species??	Ruminants for milk production and reproduction
Authorisation Holder?	DSM Nutritional Products Ltd., Switzerland
Authorisation period??	10 years from the date of?authorisation?

2: Additive composition

Component???	Contents???

3-nitrooxypropanol	Preparation with a minimum of 10% of 3-nitrooxypropanol 0.4% of particles with diameter < 50µm

3:?Characterisation?/ identification?of?the?active substance(s)

- 3-nitrooxypropanol (Propan-1,3-diol-mononitrate) (C?H?NO?)
- CAS no: 100502-66-7.

4: Conditions of use

Species or category of animal???	**Maximum age???**	**Content of?3-nitrooxypropanol (mg/kg of complete feed?with a moisture content of 12%)?**
Ruminants for milk production and for reproduction	n/a	Minimum level: 53 Maximum level: 88

5:?Other?Provisions?

1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. The additive shall be incorporated into feed in the form of a premixture.

6:?Analytical?methods?

For quantification of 3-nitrooxypropanol in the feed additive, premixtures, feed materials and compound feed:

Reversed phase high performance liquid chromatography with spectrophotometric detection (HPLC-UV).

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The risk assessment identified that particular consideration should be given to hazards as a:

- skin and eye irritant

- respiratory sensitiser.

- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.
- Main animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.