RP1059 Outcome of assessment of 3-Nitrooxypropanol "3-NOP" - Summary

Results available: Results available

Maes o ddiddordeb ymchwil: <u>Novel and non-traditional foods, additives and processes</u> Research topics: <u>Food additives</u> Cod prosiect: RP1059 Awduron: Regulated Products Risk Assessment Unit Science, Evidence and Research Division, FSA Risk Assessment Team Science Division, FSS Cynhaliwyd gan: DSM Nutritional Products DOI: https://doi.org/ Statws y prosiect: Wedi'i gwblhau PDF <u>Gweld Safety Assessment: Outcome of assessment of 3-Nitrooxypropanol "3-NOP" as a feed</u> additive for all ruminants for milk production as PDF(Open in a new window) (395.33 KB)

An application was submitted to the Food Standards Agency in April 2021 from DSM Nutritional Products Ltd., UK ("the applicant") for the authorisation of an additive (Bovaer® 10) containing a minimum 10% 3-nitrooxypropanol (3-NOP), under the category of 'zootechnical' additives, functional group 'substances which favourably affect the environment'.

The additive is a preparation of a minimum 10% 3-NOP, aiming to supply a minimum of 52.8 mg 3-NOP and a maximum of 88 mg 3-NOP per kg of complete feedstuff (moisture content of 12%) for all ruminants for milk production and reproduction.

To support the Food Standards Agency (FSA) and Food Standards Scotland (FSS) in evaluating the dossier, the Animal Feed and Feed Additives Joint Expert Group (AFFAJEG) and the Advisory Committee on Animal Feedingstuffs (ACAF) were asked to review the dossier and the supplementary information from the applicant. ACAF concluded that 3-NOP can be considered safe for the target species, establishing a margin of tolerance of 2. The additive can be considered safe for consumers, with an established ADI of 0.3 mg/kg bw. The additive should be considered corrosive to the eyes, a skin irritant and potentially harmful by inhalation; it is not a skin sensitizer. It was concluded the additive poses an acceptable risk to the environment. ACAF concluded that the additive can be considered efficacious.

The views of AFFAJEG and ACAF have been taken into account in the safety assessment which represents the opinion of the FSA and FSS.