

Outcome of assessment of 3-Nitrooxypropanol “3-NOP” - Introduction

The FSA and FSS have undertaken a risk assessment for an additive (Bovaer® 10, DSM Nutritional Products Ltd., UK, Heanor Gate Ind. Est., Heanor, Derbyshire, DE75 7SG, UK) containing a minimum 10% 3-nitrooxypropanol, under Regulation (EC) No 1831/2003¹ under the category of ‘zotechnical’ additives, functional group ‘substances which favourably affect the environment’. To support the safety assessment by FSA and FSS, the AFFAJEG and the ACAF provided advice to the FSA and FSS outlined in this document.

The dossier was evaluated on behalf of the FSA and FSS by the AFFAJEG. In line with Article 8 of 1831/2003, the assessment has considered whether the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect; potential impairment of the distinctive features of animal products. This, and the guidance put in place by EFSA for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

With thanks to the members of the AFFAJEG and ACAF during the course of the assessment, who were: Professor John Wallace, Professor Nicholas Jonsson, Martin Briggs, Dr. Katrina Campbell, Susan MacDonald, Professor Matthew Fisher, Christine McAlinden, Dr. Donald Morrison, Derek Renshaw, Dr. Michael Salter, Dr. Helen Warren and Dr. Nick Wheelhouse. Dr. Adam Smith declared a direct conflict of interest for the application and did not take part in the assessment.

The dossier was evaluated by the AFFAJEG at their December 2021, February 2022 and April 2022 meetings. Further information was provided by the applicant in September 2021 and March 2022, responding to queries by the Secretariat and the AFFAJEG. The conclusions by the AFFAJEG were reviewed and approved by the ACAF at their October 2022 meeting.

This document outlines the discussion and conclusions of the AFFAJEG’s assessment on the safety and efficacy of 3-nitrooxypropanol as a feed additive.