
Assessment of the proposal for modification of PARNUT for the ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’

Reference number RP658

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Regulated Product Dossier Assessment

Safety Assessment finalised: 18/08/2023

Summary

An application was submitted to the Food Standards Agency in March 2021 from Phibro Animal Health Corporation (“the applicant”) for the modification of entry number 60 of the PARNUT regulation 2020/354¹, ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’, to include Dietary Cation-Anion Difference (DCAD) values below 0.

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 information from the applicant. Two main literature studies were presented to support the safety and efficacy of the PARNUT. No significant negative effect was seen on the health of animals fed the lower DCAD diets for any of the three studies. A further 14 studies presented through a literature review showed evidence of efficacy of the PARNUT when used at the proposed modified conditions.

The AFFAJEG concluded that a modification of the regulation to include DCAD levels between -200 and 100 mEq/kg dry matter would not pose any additional risks to the target species and would be expected to improve efficacy.

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

1. Introduction

The FSA and FSS have undertaken a risk assessment for the proposal of modification of entry number 60 of the PARNUT regulation 2020/3541, 'Reduction of the risk of milk fever and subclinical hypocalcaemia', to include Dietary Cation -Anion Difference (DCAD) values below 0. 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.

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. Adam Smith, Dr. Helen Warren and Dr. Nick Wheelhouse.

The dossier was evaluated by the AFFAJEG at their December 2021 meeting. The conclusions by the AFFAJEG were reviewed and approved by the ACAF at their July 2023 meeting.

This document outlines the discussion and conclusions of the AFFAJEG's assessment on the proposal of modification of entry number 60 of the PARNUT regulation 2020/3541.

2. Assessment

2.1. Characterisation of the PARNUT

The applicant proposed a modification of entry number 60 of the PARNUT regulation, 'Reduction of the risk of milk fever and subclinical hypocalcaemia' as per table 1:

Table 1: Proposed modification of entry N° 60

Entry N°	Essential nutritional characteristics	Species	Labelling declarations	Recommended length of time	Other provisions
60 Reduction of the risk of milk fever and subclinical hypocalcaemia	Low cations/anions ratio For the total ration: Minimum acidification via feed for particular nutritional purpose: 100 mEq/kg dry matter Objective: Range from negative DCAD values to <100 DCAD* *DCAD (mEq/kg dry matter) = (Na+K) – (Cl +S)	Dairy cows	Calcium Phosphorus Magnesium Sodium Potassium Chlorides Sulphur	From 3 weeks before calving until calving	Indicate in the instructions for proper use: "Stop feeding after calving"

2.2. Safety and Efficacy of the PARNUT

The applicant presented two main studies from the literature to support the safety and efficacy of the PARNUT. Study 1² concluded that feeding lower DCAD diets prepartum lowered urine pH, increased urinary Ca excretion and postpartum plasma Ca

concentration. Study 2³ showed that lower DCAD diets fed prepartum can increase postpartum dry matter intake and milk production of multiparous cows without affecting performance of primiparous cows. No significant negative effect was seen on the health of animals fed the lower DCAD diets for any of the three studies. A further 14 studies were identified in a literature review supporting the efficacy of the PARNUT when used at the proposed modified conditions. A compliant Safety Data Sheet for the final sample product was also provided by the applicant.

The AFFAJEG did not raise any safety concerns regarding the proposal of modifying the regulation to include negative DCAD values. Members determined that negative DCAD values are common practice in animal nutrition, and have been demonstrated to be safe by existing meta-analysis data⁴, which shows a reduction in risk of milk fever in parous cows and a reduced risk of retained placenta and metritis for both nulliparous and parous cows. The AFFAJEG concluded that a modification of the regulation to include DCAD levels between -200 and 100 mEq/kg dry matter would not pose any additional risks and would be expected to improve efficacy.

3. Conclusion

The AFFAJEG concluded that a modification of the regulation to include DCAD levels between -200 and 100 mEq/kg dry matter would not pose any additional risks to the target species and would be expected to improve efficacy.

4. References

1. EC (European Commission), 2020. Regulation No 2020/354 of the European Parliament and of the Council establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC. Available at <https://www.legislation.gov.uk/eur/2020/354/contents>
2. Leno BM, Ryan CM, Stokol T, Kirk D, Zanzalari KP, Chapman JD, Overton TR, 2017. Effects of prepartum dietary cation-anion difference on aspects of peripartum mineral and energy metabolism and performance of multiparous Holstein cows. J. Dairy Sci. 100:4604-4622. DOI: [10.3168/jds.2016-12221](https://doi.org/10.3168/jds.2016-12221)
3. DeGroot MA, Block E, French PD, 2010. Effect of partum anionic supplementation on periparturient feed intake, health and milk production. J. Dairy Sci. 93:5268-5279. DOI: [10.3168/jds.2010-3092](https://doi.org/10.3168/jds.2010-3092)
4. Santos JEP, Lean IJ, Golder H, Block E, 2019. Meta-analysis of the effects of prepartum dietary cation-anion difference on performance and health of dairy cows. J Dairy Sci. 102(3):2134-2154. DOI: [10.3168/jds.2018-14628](https://doi.org/10.3168/jds.2018-14628)

5. Abbreviations

ACAF Advisory Committee on Animal Feedingstuffs

AFFAJEG	Animal Feed and Feed Additives Joint Expert Group
Ca	Calcium
DCAD	Dietary Cation-Anion Difference
mEq	Milliequivalent
PARNUT	Particular Nutritional Purposes

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