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# **Assessment of a new PARNUT proposal for the reduction of large colon feed impaction**

**Reference number RP1307**



**Regulated Products Risk Assessment Unit  
Science, Evidence and Research Division, FSA**

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**Regulated Product Dossier Assessment  
Assessment finalised: 04/12/2023**

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# Abbreviations

<b>Acronym</b>	<b>Definition</b>
ACAF	Advisory Committee on Animal Feedingstuffs
AFFAJEG	Animal Feed and Feed Additives Joint Expert Group
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FSA	Food Standards Agency
FSS	Food Standards Scotland
mOsmol/L	Milliosmoles per litre
PARNUT	Feed for Particular Nutritional Purposes

# Summary

An application was submitted to the Food Standards Agency in October 2021 for the inclusion of a new PARNUT (feed for particular nutritional purposes) under regulation 2020/354<sup>1</sup>, 'Reduction of large colon feed impaction', for use in equine species.

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.

A literature review was presented showing evidence of efficacy of sodium chloride and potassium chloride for the reduction of large colon impaction. The literature review showed the PARNUT ingredients are well tolerated by horses.

The ACAF concluded that the PARNUT could be considered efficacious to reduce large colon feed impaction without posing additional risks to the target species.

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 to add a new PARNUT (Reduction of large colon feed impaction – Colic Sachet) under retained regulation No 2020/354<sup>1</sup>, for use in equine species. 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 Nicholas Jonsson, Martin Briggs, Professor 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 July 2022 meeting and by the ACAF at their April 2023 meeting. Further information was provided by the applicant in November 2022, responding to queries by the FSA.

## 2. Assessment

### 2.1. Characterisation of the PARNUT

The applicant proposed a new entry in the PARNUT regulation, as per Table 1:

**Table 1: Proposed new entry ‘Reduction of large colon feed impaction’**

Particular nutritional purpose	Essential nutritional characteristics	Species	Labelling declarations	Recommended length of time	Other provisions
Reduction of large colon feed impaction	Sodium chloride, potassium chloride  To be given as an isotonic solution, between 270-312 mOsmol/L	Equine	Sodium  Potassium  Chlorides	Until resolution is achieved	1. To be given in 5 L solution of clean water. Repeat as necessary, minimum 2 h between dosing  2. May be given in drinking water or via nasogastric tube  3. In the case of administration via tubing, indicate on packaging and label, ‘Administration by veterinary surgeon only’. In case of administration via drinking water indicate ‘Administration under veterinary supervision only’  4. Indicate on labelling, a. ‘During periods of, and recovery from, colic’ b. ‘Clean fresh drinking water should be available at all times’

## 2.2. Safety and Efficacy of the PARNUT

The applicant presented an initial PARNUT proposal including sodium chloride, potassium chloride in a complex with other nutrients, and presented a literature review supporting the safety and efficacy of the product.

The review showed that enteral fluid therapy is the treatment of choice for large colon impactions<sup>2,3</sup>, and normal practice includes administration of five litres of isotonic fluids per dose<sup>4,5</sup>. The use of an isotonic electrolyte solution, including sodium chloride and potassium chloride, was shown to be beneficial and well tolerated in horses by several authors<sup>2,3,6,7</sup>.

The ACAF concluded in the first instance that the information presented in the application did not relate to the combination of nutrients as proposed and requested that the applicant should provide further information. The applicant provided an amended version of the PARNUT, including only sodium chloride and potassium

chloride as essential nutritional characteristics. The ACAF subsequently concluded that the modified proposed PARNUT could be considered efficacious to reduce large colon feed impaction without posing additional risks to the target species.

### 3. Conclusions

The ACAF concluded that the PARNUT could be considered efficacious to reduce large colon feed impaction without posing additional risks to the target species.

### 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.](#)
2. Lopes MAF, Walker BL, White NA, Ward DL, 2002. Treatments to promote colonic hydration: enteral fluid therapy versus intravenous fluid therapy and magnesium sulphate. *Equine vet. J.* 34(5):505-509
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6. Monreal L, Navarro M, Armengou L, Jose-Cunilleras E, Cesarini C, Segura D, 2010. Enteral fluid therapy in 108 horses with large colon impactions and dorsal displacements. *Veterinary Record.* 166:259-263
7. *Veterinary Medicine (2017) Disturbances of free water, electrolytes, acid-base balance and oncotic pressure.* In *Veterinary Medicine.* Pub: Elsevier Ltd. P113-152



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