European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

EUROPEAN PUBLIC MRL ASSESSMENT REPORT (EPMAR)

IRON FUMARATE

INTRODUCTION

On 9 June 2009 the European Commission adopted a Regulation[1] establishing maximum residue limits for iron fumarate in all food producing species, valid throughout the European Union. These maximum residue limits were based on the favourable opinion and the assessment report adopted by the Committee for Medicinal Products for Veterinary Use.

Iron fumarate is intended for use in all food producing species as a supplement in iron deficiency for oral administration.

Econ AG submitted a request for the inclusion of iron fumarate into Annex II of Council Regulation (EEC) No 2377/90 to the European Medicines Agency (EMEA), on 12 February 2008.

Based on the scientific justification of this recommendation the assessments performed and conclusions reached for iron salts and fumaric acid, substances with existing entries in Annex II of Council Regulation (EEC) No 2377/90, the Committee for Medicinal Products for Veterinary Use concluded that it was not necessary for the protection of public health to establish maximum residue limits in all food producing species for the substance therefore iron fumarate should be included in Annex II of Council Regulation (EEC) 2377/90, in accordance with Article 3. This recommendation was confirmed on 15 May 2009 by the Standing Committee on Veterinary Medicinal Products and adopted by the European Commission on 9 June 2009.

EXPLANATORY NOTE

The European Public MRL Assessment Report is a public document giving the overview of the assessment carried out by the Committee for Medicinal Products for Veterinary Use (CVMP) of an application submitted for the establishment of maximum residue limits (MRLs). The document is based on the CVMP assessment report of the application from which confidential information has been deleted.

KEY WORDS: iron fumarate, all food producing species

[1] Commission Regulation (EC) No 485/2009, O.J. L145, of 10.06.2009

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SUMMARY OF THE SCIENTIFIC DISCUSSION FOR THE ESTABLISHMENT OF MRLs

Substance name: **Iron fumarate**

Procedure number: **N/a**

Applicant: **N/a**[2]

Target species: **All food producing species**

Intended therapeutic indication: **As a supplement in iron deficiency**

Route of administration: **Oral**

1. Introduction

Iron salts are normally used as a supplement in iron deficiency anaemia in new-born domestic animals (mostly piglets and calves) and to treat iron deficiency. In veterinary medicine, the recommended doses of iron sulphate used are generally low (i.e. cattle 8 to 15 g/animal, horses 2 to 8 g/animal and sheep and swine 0.5 to 2 g/animal, given orally, each day for 2 weeks or more. Iron is indicated for metabolic disturbances and deficiency states. In human medicine, the usual therapeutic dose of iron is about 200 mg per day (2 to 3 mg/kg bw).

Several iron salts are currently included in Annex II of Council Regulation (EEC) No. 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
Iron ammonium citrate	All food producing species	
Iron dextran	All food producing species	
Iron dichloride	All food producing species	
Iron glucoheptonate	All food producing species	
Iron sulphate	All food producing species	

Iron gluconate (E 579) is a permitted food additive under the European Parliament and Council Directive 95/2/EC.

Fumaric acid (E 297) is a permitted food additive under the European Parliament and Council Directive 95/2/EC.

A request was submitted to the EMEA for the inclusion of iron fumarate (Fe(II)fumarate) in Annex II of Council Regulation (EEC) No 2377/90. Iron fumarate is indicated for the prevention of iron deficiency in piglets, given *ad libidum* continuously from 3 days old to 21 days old.

For the scientific justification of this recommendation the assessments performed and conclusions reached for iron salts and fumaric acid, substances with existing entries in Annex II of Council Regulation (EEC) No 2377/90, were taken into account. No further assessment was considered necessary.

[2] Request for consideration from Econ AG

2. Conclusions and recommendation

Having considered that:

- several iron salts have already been included in Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species,
- fumaric acid (E297) is authorised as a food additive under European Parliament and Council Directive No 95/2/EC and therefore included in Annex II of Council Regulation (EC)2377/90,
- iron fumarate dissociates completely in solution,
- the assessments performed for iron salts and fumaric acid also apply to iron fumarate,
- iron fumarate is not to be considered as a new active substance;

the Committee considers that there is no need to establish an MRL for iron fumarate and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Iron fumarate	All food producing species	