

SCIENTIFIC OPINION

Scientific Opinion on consumer safety of a manganese chelate of hydroxy analogue of methionine (Mintrex[®]Mn) as feed additive for chickens for fattening¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to consider additional data provided by the applicant subsequent to the previous opinion from the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). In its former opinion, the Panel could not conclude on the safety of manganese (Mn) from Mintrex[®]Mn for the consumer because of the lack of data on Mn deposition in edible tissues. Data on tissue deposition has now been provided for chickens for fattening.

In a 35-day experiment with chickens for fattening the Mn retention from Mintrex[®]Mn was measured in liver, kidney, muscle, skin and fat in comparison to Mn sulphate and in relation to two supplementation levels (60 and 150 mg Mn/kg feed). There was no evidence for differences in Mn-concentrations in tissues of chickens for fattening fed Mn at two different supplementation levels and from the two Mn sources.

The FEEDAP Panel concluded that Mintrex[®]Mn would not increase Mn deposition in edible tissues of chickens for fattening compared to other authorised inorganic Mn sources for which it would substitute. Consequently, the use of Mintrex[®]Mn as a feed additive for chickens for fattening is unlikely to present a safety concern to consumers.

KEY WORDS

nutritional additive, trace element, manganese, safety for the consumer, chickens for fattening, tissue deposition

¹ On request from the European Commission, Question No EFSA-Q-2009-00489, adopted on 15 September 2009.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1831/2003³ establishes the rules governing the Community authorisation of additives for animal nutrition and in particular defines the conditions that a substance should meet to be granted the authorisation.

The FEEDAP Panel concluded in its opinion on the product Mintrex[®]Mn (manganese chelate of hydroxy analogue of methionine) (Question No EFSA-Q-2007-094, adopted on 15 April 2008) that the data available are limited and do not allow an assessment of consumer exposure to manganese derived from Mintrex[®]Mn. Consequently, it could not conclude on the safety for consumers of Mintrex[®]Mn when used in animal nutrition.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In view of the above, the Commission asks to the European Food Safety Authority to deliver an opinion on the safety of this product as feed additive for chickens for fattening, taking into account its earlier opinion on 15th April 2008 and the new data submitted.

ACKNOWLEDGEMENTS

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³ OJ L 268, 18.10.2003, p.29

ASSESSMENT

1. Introduction

Mintrex[®]Mn is a chelate containing a minimum of 13 % manganese (Mn) and 76 % hydroxy methionine analogue ((2-hydroxy-4-methylthio) butanoic acid, HMTBa), according to the specifications provided by the applicant. It is intended to be used in chickens for fattening as source of Mn up to the maximum authorised content of total Mn (150 mg/kg complete feed).

The FEEDAP Panel previously adopted an opinion on the efficacy and safety of Mintrex[®]Mn as feed additive for all species (EFSA, 2008). In this opinion, the FEEDAP Panel followed the conclusions of the former Scientific Committee on Food (SCF) on the potential neurotoxicity of Mn. The SCF was unable to establish an upper limit, but noted “that additional dietary exposure to manganese may carry a health risk” (EC, 2000). The FEEDAP Panel could not conclude on the safety of the product for the consumers due to the lack of specific data on tissue deposition of Mn from Mintrex[®]Mn.

In response to the FEEDAP Panel’s opinion on Mintrex[®]Mn, the applicant supplied further data on tissue deposition of Mn from Mintrex[®]Mn in chickens for fattening.⁴

2. Tissue deposition in chickens for fattening

The applicant provided a study to evaluate the effect on Mn tissue deposition of Mintrex[®]Mn compared to an authorised Mn source (Mn sulphate) in diets for chickens for fattening.

The trial was conducted with 800 chickens for fattening (Ross 308) allotted to four treatments with ten replicates per treatment of 20 birds each (five replicates with males and five with females). The animals were fed diets supplemented with Mn at 60 mg/kg feed and 150 mg/kg feed (total maximum EU authorised level) in the form of Mn sulphate or Mintrex[®]Mn. All diets were simultaneously enriched also with copper and zinc sulphate, which resulted in different final levels of Cu and Zn in the diets of the various treatments. The final content of the trace elements in the diets were analysed, as crude nutrients and minerals. No direct information on the background content of trace elements was provided.

Chickens were phase-fed, starter (0-21 days) and finisher (21-35 days) mash diets, that were nutritionally adjusted for total methionine to account the hydroxyl analogue of methionine from Mintrex[®]Mn using the calcium salt of the hydroxyl analogue of methionine. Feed and water were available *ad libitum*.

Performance was monitored over the entire experimental period. At day 35 blood samples were taken from ten birds per treatment (one bird/pen, five males and five females) for routine haematology (haematocrit, haemoglobin, MCH, MCV, RBC and WBC) and blood biochemistry (serum ALT, AST, AP, CK, GGT, amylase, total protein, albumin, globulin, cholesterol, glucose, creatinine, and electrolytes (Na, K, Cl, Ca, P and Mg)). Clinical observations were done throughout the whole trial. At the end of the trial samples of breast muscle, skin, fat, liver and kidney were taken from six animals (three male and three female) per treatment, and analysed for Mn concentration. The limit of quantification (LOQ) of the method was 0.49 mg/kg fresh tissue.

The overall mortality during the trial was 2.5 % and was not related to treatment. No significant differences were observed in body weight (1.86 kg), feed intake (79 g/day) or feed to gain ratio (1.52 kg/kg) between the different groups. Haematology and blood biochemistry parameters were not influenced by the dietary treatment.

Manganese concentrations in edible tissues of chickens for fattening (muscle, skin, liver, kidney and fat) are shown in Table 1. There was no evidence for differences in Mn concentrations in liver, kidney and skin of chickens for fattening fed Mn at two different supplementation levels (60 and 150 mg/kg

⁴ Dossier reference: FAD-2009-0008

feed) and from two sources (sulphate and methionine analogue). Values for muscle and fat were below the LOQ of the method and therefore a direct comparison is not possible. Any differences that might have occurred below the LOQ would not have a significant impact on the overall consumer exposure. Moreover, relevant differences in muscle Mn are not expected considering the unaffected Mn concentrations in other tissues and current knowledge on Mn tissue deposition patterns.

Table 1. Manganese deposition in edible tissue (mg/kg fresh tissue) of chickens for fattening (n = 6 per treatment)

	Supplemental levels of manganese (mg/kg complete feed)			
	Manganese sulphate		Mintrex [®] Mn	
	60	150	60	150
Analysed Mn (mg/kg feed), starter/finisher ¹	75/80	175/165	79/89	180/185
Breast muscle	<0.49	<0.49	<0.49 ²	<0.49
Skin	0.65	0.60	0.71	0.61
Liver	2.76	2.79	2.34	3.05
Kidney	2.65	3.05	2.83	2.89
Fat	<0.49	<0.49	<0.49	<0.49

¹: Original data as mg/kg DM, recalculated to standard complete feed (88 % DM)

²: Five samples, one sample 2.37 mg/kg

CONCLUSIONS

The FEEDAP Panel concludes that the use of Mintrex[®]Mn in chickens for fattening would not increase consumer exposure to Mn as compared to other authorised inorganic Mn sources for which it would substitute. Consequently, the use of Mintrex[®]Mn as a feed additive for chickens for fattening is unlikely to present a safety concern to consumers.

DOCUMENTATION PROVIDED TO EFSA

1. Mintrex[®]Mn. Chickens for fattening. February 2009. Submitted by Novus Europe SA.
2. Mintrex[®]Mn. Chickens for fattening. Supplementary information. August 2009. Submitted by Novus Europe SA.
3. Mintrex[®]Mn. Chickens for fattening. Supplementary information. September 2009. Submitted by Novus Europe SA.

REFERENCES

- EC (European Commission), 2000. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of manganese. http://ec.europa.eu/food/fs/sc/scf/out80f_en.pdf
- EFSA (European Food Safety Authority), 2008. Safety and efficacy of Mintrex[®]Mn (Manganese chelate of hydroxy analogue of methionine) as feed additive for all species - Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178706515725.htm