

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Fecinor[®] soluble and Fecinor[®] soluble plus (*Enterococcus faecium* CECT 4515) as a feed additive for piglets and chickens for fattening¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)^{2,3}

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The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

ABSTRACT

Fecinor[®] is a preparation of a strain of *Enterococcus faecium* currently authorised for use in feeds for weaned piglets and chickens for fattening at the level of 1×10^9 colony-forming units (CFU)/kg. An application was then made for Fecinor[®] soluble and Fecinor[®] soluble plus, two new formulations which differ by the replacement of one excipient. Fecinor[®] soluble and Fecinor[®] soluble plus are intended for use in water for drinking for weaned piglets and chickens for fattening at 5×10^8 CFU/L. The safety of Fecinor[®] for consumers, users and the environment has been assessed in previous opinions. The safety for chickens for fattening and weaned piglets and the efficacy of the product when used in feeds for these target species have also been established at that time. The data provided on the physical properties of the two new formulations do not introduce concerns for the user not already considered. The Panel on Additives and Products or Substances used in Animal Feed is unaware of any new data that would lead it to revise its conclusions. Therefore, the focus of the present opinion is on the consequences of the new use in water for drinking. The dose proposed for use in water for drinking would provide essentially the same exposure as the dose currently authorised for use in feedingstuffs. Consequently, the conclusions on the safety and efficacy of the additive when used in feedingstuffs also apply to use in water for drinking for weaned piglets and chickens for fattening.

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KEY WORDS

zootechnical additive, Fecinor[®] soluble, *Enterococcus faecium*, piglets, chickens for fattening, efficacy, safety

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SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Fecinor[®] soluble and Fecinor[®] soluble plus when used in water for weaned piglets and chickens for fattening.

Fecinor[®] is a feed additive consisting of viable cells of a single strain of *Enterococcus faecium* and is currently authorised as a zootechnical additive for use in feed for weaned piglets and chickens for fattening at the level of 1×10^9 colony-forming units (CFU)/kg. The applicant is seeking authorisation of Fecinor[®] soluble and Fecinor[®] soluble plus, two new formulations which differ from that currently authorised by the replacement of one excipient. Fecinor[®] soluble and Fecinor[®] soluble plus are intended to be used in water for drinking for weaned piglets and chickens for fattening at the level of 5×10^8 CFU/L.

The safety of Fecinor[®] for consumers, users and the environment has been assessed in previous opinions. The safety for chickens for fattening and weaned piglets and the efficacy of the product when used in feed for these target animals were also established at that time. The data provided on the physical properties of the two new formulations do not introduce concerns for the user that have not already been considered. The FEEDAP Panel is unaware of any other new data that would lead it to revise its conclusions. Therefore, the focus of the present opinion is on the consequences of the new use in water for drinking.

In its statement on the use of feed additives authorised/applied for use in feed when supplied via water the FEEDAP Panel established that there is no need to separately assess safety and efficacy of an additive administered via water when an application for its use in feed is submitted or an authorisation exists, provided that the exposure of the animals is essentially the same. The level proposed for use in water for drinking would provide essentially the same exposure as the level currently authorised for use in feedingstuffs. Consequently, the conclusions on safety and efficacy of the additive when used in feedingstuffs also apply to use in water for drinking for weaned piglets and chickens for fattening.