

Safety and efficacy of Bactocell PA (*Pediococcus acidilactici*) as feed additive for fish

Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed

(Question No EFSA-Q-2007-205)

Adopted on 1 April 2009

SUMMARY

Following a request from European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the efficacy and safety for the target animals, the consumer, user and the environment of the product Bactocell PA.

Bactocell PA is the trade name for a feed additive based on viable cells of *Pediococcus acidilactici*. The product is intended for use with fish to improve the quality of the animal product by increasing the number of well-conformed fish, reducing the incidence of spinal deformities. It is recommended to be included in feed for the entire production period at a minimum content of 1×10^9 and a maximum content of 3×10^9 CFU kg^{-1} complete feedingstuff. The additive is incorporated as a suspension in fish oil before being added to the feed. This product is already authorised for use in pigs and chickens for fattening. The Company has applied for an authorisation for a period of ten years under the category of zootechnical additives (functional group: other zootechnical additives).

This organism is considered by EFSA to have QPS status, therefore no assessment of safety for the target species, the consumer and the wider environment is required. Consequently, in the present assessment the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has considered only the efficacy of Bactocell PA for the target species and the safety for the users.

Evidence that the additive is able to produce a beneficial effect, increasing the number of well-conformed salmonids, was shown in three studies with rainbow trout. However, the data provided supported efficacy only at the maximum proposed dose. In the absence of any information on the mode of action, the FEEDAP Panel is unable to predict whether the product could also be efficacious in non-salmonid fish.

On the basis of the evidence presented, Bactocell PA can be considered to be non-irritant to the skin and eyes of the users. The small particle size and high dusting potential of the product represent a risk of respiratory sensitisation.

Key words: zootechnical additive, vertebral column compression syndrome, Bactocell PA, *Pediococcus acidilactici*, micro-organism, fish, salmonids, safety, QPS