SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Avatec® 150G (lasalocid A sodium) for turkeys[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

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.

SUMMARY

Following a request from European Commission, the European Food Safety Authority was asked to deliver an opinion on the safety and efficacy of Avatec®150G (containing 15 % lasalocid A sodium as active substance), a coccidiostat for turkeys for fattening to be used up to an age of 16 weeks, at a dose range of 75–125 mg lasalocid sodium per kg complete feed.

Lasalocid A sodium from Avatec® 150G was considered safe for turkeys for fattening at the maximum dose applied (125 mg/kg complete feed) up to 16 weeks of age. A margin of safety could not be determined.

Lasalocid sodium may be dangerous for equine species and its simultaneous use with certain medicinal substances could be contra-indicated in turkeys, as it is in chickens for fattening.

The additional data provided on the metabolic fate of lasalocid sodium in chickens and rats gave sufficient evidence to the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) to conclude on the similarity of metabolic pathways in chickens, turkeys and rats. Unchanged lasalocid A is the marker residue.

In the absence of new data, the FEEDAP Panel reiterated its former conclusions that lasalocid A sodium is not genotoxic, carcinogenic or teratogenic. A lowest NOAEL of 0.5 mg/kg bw/day was established from the two-year chronic oral toxicity study in rats and maternal toxicity study in rabbits. A toxicological ADI of 0.005 mg/kg/person/day (or 0.3 mg/60 kg person/day) was derived applying a safety factor of 100.

Consumer exposure after a one-day withdrawal period complied with the ADI. Considering the slower decline of residues in kidney and skin/fat compared to liver and the inherent variation of data, the

[1] On request from the European Commission, Question No EFSA-Q-2008-751, adopted on 7 April 2010.

[2] Panel members: Gabriele Aquilina, Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht, Noël Albert Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Reinhard Kroker, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Derek Renshaw and Maria Saarela. Correspondence: FEEDAP@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Coccidiostats.

FEEDAP Panel concluded that a five-day withdrawal period is appropriate to ensure compliance with the MRLs already in force in the EU.

In the absence of new data, the FEEDAP Panel reiterated its former conclusions that it is unlikely that lasalocid A sodium from Avatec®150G would pose a risk to the user/worker handling the additive.

The FEEDAP Panel could not identify a safety concern for the environment resulting from the use of Avatec® 150G in turkeys, at the maximum recommended feed concentration.

The FEEDAP Panel considered that Avatec® 150G is effective in controlling coccidiosis in turkeys at a minimum dose of 75 mg lasalocid A sodium/kg complete feed.

The FEEDAP Panel made some recommendations concerning the antimicrobial and *Eimeria* resistance monitoring.