

## **EUROPEAN COMMISSION**

DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific Health Opinions
Unit B3 - Management of scientific committees II

Assessment by the Scientific Committee on Animal Nutrition (SCAN) of a micro-organisms product : Neoferm BS-10 <sup>®</sup> <sup>1</sup>

## **EXECUTIVE SUMMARY**

(adopted on 10 June 1999)

The two strains of bacteria, which are the active components of the feed additive Neoferm BS-10<sup>®</sup>, derive from a pharmaceutical preparation registered for human use. Because the pharmaceutical preparation was designed for use as an adjunct to antibiotic therapy, its constituent strains were deliberately selected to demonstrate resistance to a number of clinically important antibiotics. These include the \beta-lactams, macrolides, lincosamides, and rifampicin, all important in human and veterinary medicine. While the selection of antibiotic-resistant strains was appropriate for short-term therapeutic use in humans, the same justification cannot be applied to a product designed for long-term use as feed additive. Animals are thought to act as a reservoir of bacteria resistant to antibiotics and their transfer to humans via the food chain or other routes may be a contributory factor in the developing resistance to antibiotics in clinical use. The high level of resistance to erythromycin (>128 mg/l) and lincosamides shown by the two Neoferm BS-10<sup>®</sup> strains was considered by SCAN to be of particular concern. This level of resistance has not been observed in other bacteria of the same genus selected for use in feed additives. Resistance to the macrolide antibiotics in the Neoferm strains is a consequence of the presence of erythromycin-methylase genes (erm genes) or structurally related genes. Both chromosomal and plasmid-borne erm genes are known to be transferable, by various mechanisms, to other bacteria. Thus, because of the risk of dissemination of genes that confer resistance to clinically important antibiotics, SCAN concluded that the use of Neoferm BS 10<sup>®</sup> as a feed additive would be unsafe.

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<sup>1</sup> See also the SCAN "Report on the use of certain micro-organisms as additives in feedingstuffs"