



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees; scientific co-operation and networks

ASSESSMENT BY THE SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION OF THE SAFETY OF PRODUCT PACIFLOR® FOR USE AS FEED ADDITIVE¹

(Adopted on 16 May 2001)

Executive Summary

The strain of *Bacillus cereus*, the active component of the feed additive Paciflor®, was re-examined for toxin production in line with the SCAN recommendations (SCAN Opinion of 17 February 2000). The Paciflor® strain belongs to a group of bacteria commonly implicated as a cause of food poisoning in humans and known to produce enterotoxins and/or an emetic toxin. In the slaughtering process, there is a risk that meat products may be contaminated with *Bacillus* spores and spread to humans via the food chain. Any *Bacillus* strain fed to food-producing animals as an additive must, therefore, be shown not to be able to produce toxins damaging to human health.

The two commercially-available immunological tests used for the detection of *Bacillus cereus* enterotoxins (Oxoid and Tecra) were positive indicating the expression of elements of the haemolytic toxin (Hbl) and the non haemolytic toxin (Nhe). These tests were complemented by the use of PCR probes for detection of gene sequences coding for other protein fractions of the tripartite enterotoxins, which also proved positive. Additional cytotoxicity tests were made with culture supernatants of the strain using a variety of human and animal cell lines. Evidence of cytotoxicity was detected in all cell lines in the presence of dilutions of supernatants from fast grown bacteria, probably due to the Hbl and/or Nhe enterotoxins.

The additional information on Paciflor® provided by the Company demonstrated that the strain is able to produce, at least under favourable growth conditions, two major enterotoxins, known as a cause of foodborne toxi-infections in humans. Thus, because the deliberate addition to the animal gut flora of substantial numbers of a bacterial strain able to produce enterotoxins may be a contributory factor to the dissemination of common food poisoning micro-organisms, SCAN concluded that the use of Paciflor® as a feed additive poses a risk to human health.

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