



Elanco Animal Health

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Executive Summary: CODEX MRL Harmonisation: avilamycin

On 8 May 2015, the U.S. Food and Drug Administration approved for use in swine the veterinary medicine Kavault® (NADA 141-438). Kavault's active pharmaceutical ingredient is avilamycin, a compound which a Codex Alimentarius maximum residue level (MRL) standard for pig meat was established in 2009 based on data from JECFA evaluation. JECFA's 70th report from 2008 summarizes the findings and recommendations for maximum residue limits (MRL) for pig meat. The JECFA avilamycin monograph and residues summary are attached (Attachment 2 and 3 respectively).

The establishment of an import standard for avilamycin is requested because of the long standing trade relationship for pig meat between the United States and Australia and the potential for this to increase. In the years 2010-2015, Australia on average imported between \$150 million to \$200 million USD of pig meat from the United States. There are no tariffs on pig meat from the U.S. and it is reasonable to consider that this trade relationship will continue into the future.

Therefore, because it is possible that more swine in the U.S. will use the newly approved product and the potential for pig meat from animals that received treatment may, in the future, be destined for Australia, the establishment of a standard is requested.