17 August 2000

## Joint Administrative Order <u>No. 2</u> s.2000

## SUBJECT: <u>Declaring a Ban/Phase-Out of the Use of Nitrofurans in Food</u> – <u>Producing Animals.</u>

The Nitrofurans is a group of synthetic anti-bacterial compounds that have a broad spectrum of activity, being of value against Gram-positive and Gramnegative bacterial infections. Nitrofurans use today is mainly on topical preparations for the eye, ear, mucous membranes and skin; with a limited use in treating bacterial gastro-intestinal and urinary tract disorders. The major disadvantage of nitrofurans to treat systemic infections is that the concentrations needed to reach the Minimum Inhibitory Concentration (MIC) also induce systemic toxicity.

There have been many reports in the veterinary literature on toxicities induced when the nitrofurans are used systemically. The toxicity of Furazolidone has been investigated extensively in laboratory, food and companion animals as well as in human and has recently been reviewed. Toxic signs seen with extensive doses of nitrofurans derivatives include central nervous system involvement (excitement, tremors, convulsions, peripheral neuritis), gastrointestinal disturbances, poor weight gain and depression of spermatogenesis. Various sensitivity reactions can also occur. Furazolidone has also been demonstrated to be carcinogenic when used at 0.15% w/w concentration in feed for one year, including mammary tumors in dose-related manner.

Nitrofurans has been recognized by the Food and drug Administration in United States as both a mutagen and a carcinogen can no longer be used in the U.S.A. since 1991. In Germany, the Federal Health Office has announced that it has withdrawn approvals for veterinary products containing nitrofurans except furazolidone for food producing animals.

On the basis of the European Commission Regulations 2901/93 of 18 October 1993 and 2377/90 of 26 June 1990 on the establishment of a community procedure for the stipulation of maximum permissible concentrations for veterinary drug residues in foods of animal origin, all nitrofurans except furazolidone were included in the list of pharmacologically active substances for

which no maximum permissible concentrations can be stipulated. Nitrofurazone and Furazolidone are banned for use in food-producing animals and are no longer available as feed additives in the U.S.A.

On account of these new evidences, the Subcommittee on Veterinary Drugs of the National Drug Committee of the Department of Health therefore concludes that the nitrofurans should be banned for use in food producing animals and should no longer be used as feed additives.

Now, therefore, we the Secretary of Agriculture and the Secretary of Health, jointly order the following:

- 1. Nitrofurans should be banned for use in all food-producing animals, including aquaculture regardless of the route of administration.
- 2. Registration of nitrofurans for use in food producing animals is withdrawn and future application for similar registrations shall be disapproved.
- 3. All concerned personnel are instructed to implement the ban and educate the public on the reasons to such ban.
- 4. In order to carry out a smooth implementation of the phase-out, no importation shall be allowed after 29 February 2000; manufacturers may continue producing the product until 31 May 2000. All nitrofurans are not allowed for use in food-producing animals after 31 August 2000.

This Order shall take effect fifteen (15) days from the date of publication in two (2) newspapers.

(SIGNED) ALBERTO R. ROMUALDEZ, MD Secretary Department of Health (SIGNED) EDGARDO J. ANGARA Secretary Department of Agriculture