Finding of No Significant Impact (FONSI)
for
Establishment of an Import Tolerance for Permissible Residues of Emamectin Benzoate in Edible Tissues Derived from Salmonids that have been Imported into the United States for Human Consumption

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The Center for Veterinary Medicine (CVM) has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment in the United States (U.S.). Therefore, an environmental impact statement will not be prepared.

Intervet Inc. has submitted a request to establish an import tolerance for emamectin benzoate residues in edible tissues derived from salmonids that have been imported into the U.S. for human consumption. In support of the establishment of an import tolerance, Intervet Inc. has prepared the attached environmental assessment (EA), dated March 5, 2019. We have reviewed the EA and find that it supports a FONSI.

The EA evaluated the potential effects of emamectin benzoate on the U.S. environment arising through four potential points of introduction: (1) wastewater treatment plant effluents that contain residues of the drug from human excreta, (2) application of biosolids from wastewater treatment as fertilizer to soil, (3) landfills that may hold seized materials, waste from fish processing plants containing the drug, or unconsumed salmonid products, and (4) freshwater and marine salmon farms in Canada and other countries where drugs containing emamectin benzoate may be authorized. Environmental fate data for emamectin benzoate is presented and discussed in the EA, including adsorption in soil and degradation in soil and the aquatic environment. These data indicate that emamectin benzoate is expected to adsorb to solids, is not highly mobile in aquatic systems, and will degrade slowly.

(1) Wastewater treatment plant effluent: Exposures of aquatic life to emamectin benzoate residues as a result of wastewater discharges were determined to be *de minimis* because of (a) spatial and temporal variability of the excreted residues throughout the U.S., (b) additional removal of emamectin benzoate residues in wastewater treatment facilities, (c) low consumption rates of salmonids in the U.S. compared to most other types of meats consumed in the U.S., and (d) the expectation that emamectin benzoate residues, if present, will be almost completely sorbed to solids and will ultimately be disposed of as biosolids to land or landfill, or be destroyed via incineration.

(2) Application of biosolids: Exposures to emamectin benzoate resulting from application of biosolids from wastewater treatment to soil were also determined to be *de minimis* for the first three reasons described above for wastewater discharges, as well as considerable dilution in biosolids and then soil. Furthermore, emamectin benzoate, if present in biosolids applied to land, would remain predominantly bound to solids (i.e., would not mobilize), and would not be expected to result in significant groundwater or surface water concentrations.

(3) *Landfills:* Based on available environmental fate data, e.g., high adsorption to soils [organic carbon normalized soil-to-water partition coefficient (K_{oc}) ranged from 8,687 to 728,918 kg/L], emamectin benzoate is not expected to migrate out of U.S. landfills containing seized materials and waste from fish processing plants. Migration is also precluded because landfills are highly regulated by local, state, and federal authorities to prevent environmental contamination, and most landfills are required to have caps and liners to prevent leaching of water and other fluids into surrounding surface and groundwater.

(4) *Aquaculture facilities in other countries where emamectin benzoate may be authorized:* The EA also evaluates exposure and risk to the U.S. environment resulting from use of emamectin benzoate in salmonids in foreign countries where the drug is legally authorized. The analysis in this EA focuses on the use of emamectin benzoate at freshwater and saltwater aquaculture facilities in Canada due to the proximity of Canada to the U.S. Based on the known use patterns, and physico-chemical properties and fate of emamectin benzoate, it was determined that the use in foreign countries is unlikely to result in adverse impacts to the U.S. environment. Briefly, it is expected that the majority of emamectin benzoate residues at aquaculture farms will be contained in uneaten feed or fish feces. For the freshwater aquaculture facilities, most of these residues will adsorb to solids and will likely be removed by filtration and/or settling prior to discharge. Any emamectin benzoate that reaches receiving waters from these facilities would be expected to partition to the sediment phase and remain primarily, if not completely, in the country of use. Similarly, residues entering the environment from marine aquaculture sites are expected to deposit underneath and near the net pens and remain primarily, if not completely, in the country of use and its territorial waters. Additional degradation, adsorption, dispersion, and dilution of the drug would be expected to occur before any drug residues reach the U.S. border. Furthermore, it is expected that use of emamectin benzoate in Canada is subject to regulation that prevent adverse impacts on the environment around the farms. Therefore, no significant environmental impacts are expected in the U.S. from use of emamectin benzoate in Canada, or in other countries that are located further away from the U.S.

Based on the information in the EA, no significant impacts to the U.S. environment are expected from the establishment of an import tolerance for emamectin benzoate residues in edible tissues derived from salmonids.

{see appended electronic signature page}

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Electronic Signature
Addendum for Submission ID

Signing Authority (Role)	Letter Date
Matthew Lucia (Office Director)	5/2/2019

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