Finding of No Significant Impact (FONSI)
for
Establishment of an Import Tolerance for Permissible Residues of Imidacloprid in Muscle with Adhering Skin Derived from Salmonids that have been Imported into the United States for Human Consumption

Benchmark Animal Health Ltd
Sheffield, United Kingdom

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.

Benchmark Animal Health Ltd requested the establishment of an import tolerance for imidacloprid residues in muscle with adhering skin derived from salmonids that have been imported into the U.S. for human consumption. In support of the request to establish an import tolerance, Benchmark Animal Health Ltd prepared the attached environmental assessment (EA), dated April 25, 2022. CVM has reviewed the EA and found that it supports a FONSI.

The EA evaluated the potential effects of imidacloprid residues on the U.S. environment arising through five potential points of introduction: (1) disposal of seized materials, waste from fish processing plants, or unconsumed salmonid products to landfills; (2) wastewater treatment plant effluent containing residues of the drug from human excreta; (3) application of biosolids from wastewater treatment as fertilizer to soil; (4) incineration of solid waste streams containing seized or discarded salmonid materials or biosolids containing drug residues; and (5) salmon farms in Canada and other countries where use of aquaculture drugs containing imidacloprid may be authorized. Fish metabolism and environmental fate data for imidacloprid are presented and discussed in the EA, including degradation in the aquatic environment. The fish metabolism data indicate that residues of imidacloprid are expected to rapidly decline in fish tissues following a one-hour treatment. Environmental fate data indicate that imidacloprid is expected to be moderately mobile in soils and may undergo degradation via photolysis and hydrolysis in aquatic environments.

(1) Landfills: Introductions of imidacloprid residues into landfill leachate are expected to be diffused and at low levels based on the rare and sporadic nature of material seizures and the geographic and temporally disperse nature of disposal of waste or unconsumed fish materials from processing plants or U.S. households, respectively. Introduction of imidacloprid into air via volatilization is expected to be minimal due to its low vapor pressure. Furthermore, substantial migration from landfills is precluded because landfills are regulated by local, state, and federal authorities to prevent environmental contamination.

(2) Wastewater treatment plant effluent: Exposures to imidacloprid residues as a result of wastewater treatment plant effluent discharges were determined to be unlikely to pose a risk in receiving waters due to (a) the spatial and temporal variability of the residue excretion pattern throughout the U.S.; (b) anticipated high degree of dilution through waste streams not including residues of imidacloprid from treated and imported salmonids; and (c) low consumption rates of fish in the U.S. compared to most other types of meats. In addition, any imidacloprid present in receiving waters could be susceptible to photolysis and, to a lesser extent, hydrolysis.

(3) Application of biosolids: Exposures to imidacloprid resulting from the application of biosolids from wastewater treatment to soil were determined to be de minimis based on imidacloprid's anticipated low degree of partitioning to biosolids during wastewater treatment and additional dilution in soils.

(4) Incineration: With imidacloprid's thermal degradation point of 230°C, it is considered unlikely that incineration would release imidacloprid to the environment. Therefore, incineration of solid waste streams containing imidacloprid residues should pose no risk to the U.S. environment.

(5) Aquaculture facilities in other countries where imidacloprid may be authorized: The EA also evaluated exposure and risk to the U.S. environment resulting from the use of imidacloprid in salmonids in foreign countries where the drug could potentially be legally authorized. The analysis in the EA focused on the potential use of imidacloprid in Canada due to its proximity to the U.S., though its use in salmonids is not currently authorized in Canada. Based on existing regulations in Canada that clarify conditions for aquaculture operators to minimize and mitigate any potential detriments to fish and fish habitat, the administration of medicines and subsequent discharges of active ingredients in foreign countries are unlikely to result in adverse impacts to the U.S. environment. In addition, any imidacloprid discharged to the marine aquatic environment in Canada is expected to be rapidly diluted and could be susceptible to photolysis and, to a lesser extent, hydrolysis. Therefore, no significant environmental impacts are expected in the U.S. from use of imidacloprid 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 imidacloprid residues in muscle with adjoining skin in food products derived from salmonids.

{see appended electronic signature page}

Matthew Lucia, DVM
Director
Office of New Animal Drug Evaluation, HFV-100
Center for Veterinary Medicine
U.S. Food and Drug Administration

Electronic Signature
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