FINDING OF NO SIGNIFICANT IMPACT (FONSI)

for

Establishment of an Import Tolerance for Permissible Lufenuron Residues in Food Derived from Salmonids that has been Imported into the United States for Human Consumption

Elanco Animal Health

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

Elanco Animal Health has submitted a request to establish an import tolerance for lufenuron residues in food derived from salmonids that has been imported into the U.S. for human consumption. In support of the establishment of an import tolerance, Elanco Animal Health has prepared the attached environmental assessment (EA), dated September 5, 2016. The EA evaluated the potential effects of lufenuron on the U.S. environment arising through four potential points of introduction: (1) landfills that may hold seized materials (e.g., fish fillets) or waste from fish processing plants containing the drug, (2) wastewater treatment plant effluents that contain residues of the drug from human excreta, (3) application of biosolids from wastewater treatment as fertilizer to soil, and (4) freshwater and marine salmon farms in eastern Canada[1] and other countries where drugs containing lufenuron may be authorized in the future.

Information was incorporated and discussed as appropriate in the EA on lufenuron metabolism and residues in fish tissues, adsorption and mobility in soil and sediment, and degradation and persistence in the aquatic environment.

Based on available environmental fate data, e.g., sorption primarily to soils and sediments (mean soil-to-water partition coefficient (K_d) = 1,056 kg/L and mean organic carbon normalized soil-to-water partition coefficient (K_{oc}) = 41,182 kg/L), lufenuron 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.

Exposures of aquatic life to lufenuron residues as a result of wastewater discharges were determined to be *de minimis* because of (1) spatial and temporal variability of the excreted resides throughout the U.S., and (2) additional degradation/transformation and removal of lufenuron residues in wastewater treatment facilities, (3) low consumption rates of salmonids in the U.S. compared to most other types of meats consumed in the U.S., and (4) lufenuron, if present, will

[1] Lufenuron is not currently approved for use in salmonids in Canada; however, approval in Canada is a reasonably foreseeable future action that could occur because salmonid farming is a major industry in Canada. Therefore, the use of lufenuron in salmonids in Canada was evaluated under the National Environmental Policy Act.

be almost completely sorbed to solids and be disposed of as biosolids to land, landfill, or incineration.

Exposures to lufenuron resulting from application of solid residues (biosolids) from wastewater treatment to soil were also determined to be *de minimis* for the three reasons described above for wastewater discharges, as well as considerable dilution in biosolids and then soil. Furthermore, lufenuron, 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.

In addition to the landfill and wastewater pathways, the EA also evaluates exposure and risk to the U.S. environment resulting from use of lufenuron on salmonids in foreign countries were the drug is legally authorized or may become legally authorized in the future. This includes locations in close proximity to the U.S. border (e.g., use in Canada near the U.S./Canadian border).[1] Lufenuron is expected to be used in salmonids (juvenile) reared in freshwater hatcheries that are subsequently moved to seawater for grow out. The analysis relies primarily on the expectation that an environmental evaluation of lufenuron would be conducted by the regulatory agencies in these countries to determine if environmental impacts would be likely to occur in the country of use, and that the country would not authorize the use of a drug that would cause significant impacts. Therefore, it is unlikely there will be significant environmental impacts in the country of use, and thus, there should be no significant environmental impacts from this use on the U.S. environment. This is especially the case considering that the physico-chemical properties of lufenuron indicate that the majority of residues entering the freshwater aquatic environment via uneaten feed or fish feces will be removed by filtration and or settling prior to discharge at the freshwater aquaculture sites. Any lufenuron that reached receiving waters would be expected to partition primarily to the sediment phase and thus remain primarily within the country of use. In addition, lufenuron excreted in fish feces after transfer of the fish to the marine environment will settle and dissipate to the sediment phase near the site of use and also primarily remain within the country of use. Therefore, it is highly unlikely that use of lufenuron in salmonids in foreign countries would result in adverse impacts to the U.S. environment.

Based on the information in the EA, it is concluded that establishing an import tolerance for lufenuron in salmonids is not expected to have a significant impact on the environment of the U.S.

{see appended electronic signature page}

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