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

Elanco US Inc.
Greenfield, IN

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 (US). Therefore, an environmental impact statement will not be prepared.

Elanco US Inc. has submitted a request to establish an import tolerance for monepantel residues in edible tissues derived from cattle that have been imported into the US for human consumption. In support of the establishment of an import tolerance, Elanco US Inc. has prepared the attached environmental assessment (EA), dated November 27, 2018. We have reviewed the EA and find that it supports a FONSI.

The EA evaluated the potential effects of monepantel and its primary metabolite, monepantel sulfone, on the US environment arising through two potential points of introduction: 1) landfills that may hold seized materials containing the drug, and 2) wastewater treatment systems (via effluent and bio-solids) that contain residues of the drug from human excreta. CVM also evaluated 3) waste that ends up in landfills from meat processing plants, or unconsumed meat products originating from treated animals, and 4) waste that ends up in wastewater treatment systems from meat processing plants that process products from treated animals and is discharged in effluent, contained in biosolids applied to land, or incinerated. Metabolism, adsorption, and biodegradation in soil and sediment for monepantel is presented and discussed in the EA. These data indicate that monepantel is expected to adsorb to solids, is not highly mobile in the environment, and will degrade.

(1) *Landfills:* Based on available environmental fate data, e.g., high adsorption to soils and sediments (log organic carbon normalized soil-water partition coefficient = 3.78-3.95), monepantel is not expected to migrate out of US landfills containing seized materials. 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. In addition, introductions of monepantel residues into landfills 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 cattle tissues from processing plants or US households, respectively.

(2) *Wastewater treatment plant effluent and biosolids:* Exposures of aquatic life to monepantel residues as a result of human excreta from US consumers or waste from meat processing plants that process meat products originating from treated animals were determined to be negligible because of 1) low levels of monepantel residues would be expected in imported meat (i.e., levels would be below the maximum residue limit), 2) additional metabolism of residues may occur in the human body, 3)

spatial and temporal variability would occur with the excreted residues throughout the US, 4) the amount of imported beef consumed in the US is low (less than 15% of total beef consumed in the US), 5) the US consumption of offal (e.g., fat and liver), where the highest residues of monepantel are found in edible tissues, is low (less than 0.5 kg consumed per capita per year), and 6) a high degree of dilution through waste streams is expected.

Exposures to monepantel resulting from application of biosolids from wastewater treatment to soil were also determined to be negligible for the four reasons described above for wastewater effluent discharges, as well as considerable dilution in biosolids and then soil. Furthermore, monepantel, if present in biosolids applied to land, would remain predominantly bound to solids (i.e., would not mobilize), degrade and not be persistent, and would not be expected to result in significant groundwater or surface water concentrations. Any monepantel residues in biosolids originating from wastewater treatment systems that are incinerated would be degraded.

Based on the information in the EA, no significant impacts to the US environment are expected from the establishment of an import tolerance for monepantel residues in edible tissues derived from cattle.

{see appended electronic signature page}

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

Electronic Signature
Addendum for Submission ID

Signing Authority (Role)	Letter Date
Matthew Lucia (Office Director)	8/25/2022

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