

## **FINDING OF NO SIGNIFICANT IMPACT**

**for**

### **Establishment of an Import Tolerance for Permissible Monensin Residues in Food Derived from Sheep 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 (US). Therefore, an environmental impact statement will not be prepared.

Elanco Animal Health has submitted a request to establish an import tolerance for monensin residues in food derived from sheep<sup>1</sup> that has been imported into the US for human consumption. In support of the establishment of an import tolerance, Elanco Animal Health, with input and assistance from CVM, has prepared the attached environmental assessment (EA), dated March 14, 2016. The EA evaluated the potential risk for impacts in the US environment arising from three potential points of introduction of monensin: (1) landfills that may hold seized materials (e.g., sheep tissues) containing the drug, (2) wastewater treatment plant effluents that contain residues of the drug from human excreta, and (3) farms in countries where monensin is currently authorized for use in sheep (e.g., Australia), or likely to be authorized in the future (i.e., Canada)<sup>2</sup>. The potential for cumulative impacts from the environmental introduction of monensin from multiple sources was also considered. Information was described as appropriate in the EA on monensin residues in sheep tissues, adsorption and mobility in soil, and degradation and persistence in water.

Based on low residues of monensin in sheep shortly after treatment, an expectation for further declines in residues during the withdrawal period, rapid degradation (soil degradation half-life of 13 to 18 days) and ability to adsorb to soil (log organic carbon adsorption coefficient = 2.57 to 2.91), monensin is not expected to be present in leachate and runoff from US landfills containing seized materials. Migration of monensin from landfills 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 or fluids into surrounding surface and groundwater.

Aquatic exposures to monensin residues originating from imported food derived from sheep as a result of wastewater discharges are expected to be extremely low, approaching zero, due to (1) low residues of monensin in treated sheep shortly after treatment that will continue to decline during the withdraw period, (2) further metabolism of monensin residues in humans after consumption of sheep meat, (3) spatial and temporal variability of the excreted residues throughout the US, and (4) additional degradation/transformation and removal of monensin residues in wastewater treatment facilities.

In addition to the landfill and wastewater pathways in the US, the EA also evaluated exposure and risk to the US environment from use of monensin in sheep in countries where it may be legally authorized in the future, including locations in close proximity to the US

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<sup>1</sup> The term sheep is used in this document when referring to food derived from sheep, but this includes both young sheep (lambs) and old sheep (mutton).

<sup>2</sup> Monensin is not currently approved for use in sheep in Canada; however, approval of monensin in sheep is a reasonably foreseeable future action that could occur and, therefore, was evaluated under NEPA.

border (e.g., use in Canada near the US/Canadian border)<sup>2</sup>. The analysis relies primarily on the expectation that an environmental evaluation of monensin 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, if there were no risk of significant environmental impacts in the country of use, there should be no significant environmental impacts from this use on the US environment, especially considering that additional degradation, adsorption, dispersion, and dilution of the drug would be expected to occur before any drug residues reach the US border.

Although monensin is not approved for use in sheep in the US, it is approved for use in other food producing animals in the US including cattle, goats, chickens, turkeys, and quail. Therefore, the EA also evaluated the potential for cumulative impacts from the environmental introductions of monensin due to importation of sheep tissues and from the approved uses of monensin in other food producing animals in the US. As part of the new animal drug approval process in the US, the potential environmental impacts of the current approvals of monensin were evaluated. CVM concluded that these approvals of monensin would not have a significant effect on the quality of the US environment and prepared FONSI's. As discussed above, the additional monensin residues that may enter the US environment from imported sheep tissues are expected to be negligible, and are not expected to substantially increase any existing concentrations of monensin in the US environment that are present due to approved uses in the US. Therefore, the importation of sheep meat containing residues of monensin is not expected to change the existing potential for environmental impacts from monensin exposure.

Based on the information in the EA, it is concluded that establishing an import tolerance for monensin in sheep is not expected to have a significant impact on the environment of the US.

*{ see appended electronic signature page }*

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