

## **FINDING OF NO SIGNIFICANT IMPACT (FONSI)**

for

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

**FVG Ltd.**

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.

FVG Ltd. has submitted a request to establish an import tolerance for azamethiphos residues in food derived from salmonids that has been imported into the US for human consumption. In support of the establishment of an import tolerance, FVG LTD., with input and assistance from CVM, has prepared the attached environmental assessment (EA), dated February 2016. The EA evaluated the potential effects of azamethiphos on the US environment arising through three potential points of introduction: (1) landfills that may hold seized materials (e.g., fish fillets) containing the drug, (2) wastewater treatment plant effluents that contain residues of the drug from human excreta, and (3) marine salmon farms in eastern Canada and other countries where drugs containing azamethiphos are currently authorized or used under an emergency authorization.

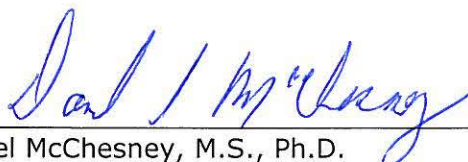
Information was incorporated and discussed as appropriate in the EA on azamethiphos metabolism and residues in fish tissues, adsorption and mobility, and degradation and persistence in water. The results of field and laboratory research studies conducted in Canada and Scotland were also included and discussed.

The EA evaluates the potential introduction of azamethiphos in the U.S. environment from landfills containing seized imported meat from salmonids treated with azamethiphos. Based on available tissue residue data for azamethiphos in Atlantic salmon immediately after treatment, an expectation for further declines in residues during the withdrawal period, and available environmental fate data (e.g., rapid degradation and short persistence in water), azamethiphos is not expected to migrate out of U.S. 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 or fluids into surrounding surface and groundwater.

Exposures of aquatic life to azamethiphos residues as a result of wastewater discharges were determined to be extremely low, approaching zero, due to the fact that residues in fish tissues are very low to begin with at the end of treatment and will continue to decline thereafter during the withdraw period. In addition, aquatic exposure is expected to be *de minimus* because of (1) further metabolism of azamethiphos residues in the human body after fish consumption, (2) spatial and temporal variability of the excreted residues throughout the U.S., and (3) additional degradation/transformation and removal of azamethiphos residues in wastewater treatment facilities.

In addition to the landfill and wastewater pathways, the EA also evaluates exposure and risk to the U.S. environment from use of azamethiphos on salmonids in seawater where it is legally authorized, including locations in close proximity to the U.S. border (e.g., use in Canada near the U.S./Canadian border). The analysis relies primarily on research data and information from eastern maritime Canada (e.g., New Brunswick) where the drug is currently used under an emergency authorization. This information, which includes toxicity test data and field monitoring (dispersion) studies, along with similar laboratory and field research from Scotland, collectively indicates that azamethiphos will rapidly disperse and degrade in the marine environment and pose no significant risk to aquatic life in the U.S.

The information available is adequate to conclude that establishing an import tolerance for azamethiphos in salmonids is not expected to have a significant impact on the environment of the United States.



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