# Finding of No Significant Impact (FONSI)
# for
# Establishment of an Import Tolerance for Permissible Hexaflumuron Residues in Food Derived from Salmonids that has been Imported into the United States for Human Consumption

## PHARMAQ AS a part of Zoetis
## Kalamazoo, MI

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.

PHARMAQ AS a part of Zoetis has submitted a request to establish an import tolerance for hexaflumuron residues in food derived from salmonids that have been imported into the U.S. for human consumption. In support of the establishment of an import tolerance, PHARMAQ AS a part of Zoetis has prepared the attached environmental assessment (EA), dated May 2020. We have reviewed the EA and find that it supports a FONSI.

The EA evaluated the potential effects of hexaflumuron on the U.S. environment arising through three potential points of introduction: (1) landfills that may hold seized materials, waste from fish processing plants containing the drug, or unconsumed salmonid products, (2) wastewater treatment plant effluents that contain residues of the drug from human excreta, and (3) application of biosolids from wastewater treatment as fertilizer to soil, and (4) salmon farms in Canada and other countries where use of aquaculture drugs containing hexaflumuron may be authorized. Available data indicate that hexaflumuron is expected to adsorb to solids, will have low mobility in aquatic systems, and will degrade slowly.

*(1) Landfills:* Based on its molecular structure and physical-chemical properties , e.g., high hydrophobicity [log octanol-water partition coefficient of 5.68 at 20°C] and low water solubility, hexaflumuron 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.

*(2) Wastewater treatment plant effluent:* Exposures of aquatic life to hexaflumuron residues as a result of wastewater discharges were determined to be *de minimis* because of (a) spatial and temporal variability of the excreted residues throughout the U.S., (b) additional removal of hexaflumuron residues in wastewater treatment facilities, (c) low consumption rates of salmonids in the U.S. compared to most other types of meats consumed in the U.S., and (d) the expectation that hexaflumuron residues, if present, will be almost completely sorbed to solids and will ultimately be disposed of as biosolids to land or landfill, or be destroyed via incineration.

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

(4) *Aquaculture facilities in other countries where hexaflumuron may be authorized:* The EA also evaluates exposure and risk to the U.S. environment resulting from use of hexaflumuron in salmonids in foreign countries where the drug is currently or potentially could be legally authorized. The analysis in this EA focuses on the use of hexaflumuron in Canada due to the proximity of Canada to the U.S. even though use of the drug is currently not authorized in Canada. Based on the known use patterns and physico-chemical properties of hexaflumuron, it was determined that the use in foreign countries is unlikely to result in adverse impacts to the U.S. environment. Briefly, it is expected that following treatment with hexaflumuron by immersion of fish in enclosed treatment units (e.g., well boats), water with hexaflumuron residue is discharged to the marine aquatic environment where hexaflumuron will be rapidly diluted and dispersed in the water. Any hexaflumuron that discharged or released to waters would be expected to partition rapidly to the sediment phase and remain primarily, if not completely, in the country of use. Furthermore, it is expected that use of hexaflumuron in Canada is subject to regulation that prevent adverse impacts on the environment around the farms. Therefore, no significant environmental impacts are expected in the U.S. from use of hexaflumuron 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 hexaflumuron residues in food products derived from salmonids.

*{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) | 10/2/2020 |

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