

**FINDING OF NO SIGNIFICANT IMPACT**  
**for**  
**Establishment of an Import Tolerance for**  
**Teflubenzuron Residues in Atlantic Salmon**  
**Imported into the United States**  
**for Human Consumption**

**Skretting ARC**

**FOR PUBLIC DISPLAY**  
**(HFA-305)**

## FINDING OF NO SIGNIFICANT IMPACT

for

### Establishing an Import Tolerance for Teflubenzuron Residues in Atlantic Salmon Imported into the United States for Human Consumption

#### Skretting ARC

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.

Skretting ARC has submitted a request to establish an import tolerance for teflubenzuron residues in Atlantic salmon imported into the U.S. for human consumption. In support of the establishment of an import tolerance, Skretting ARC has prepared the attached Environmental Assessment (EA), dated November 1, 2011.

The potential introduction and effects of teflubenzuron in the U.S. environment through wastewater treatment (containing excreted drug) was evaluated in the EA. The predicted environmental concentrations in water ( $PEC_{\text{water}}$ ) for teflubenzuron residues from wastewater discharges were determined to be very low (0.136-0.272 ng/L) due to the infrequent use of teflubenzuron in a species that is a minor part of the U.S. consumer diet. In addition, the CVM evaluated the potential introduction and effects of teflubenzuron in the U.S. environment from landfills containing seized imported salmon. Based on available fate data, teflubenzuron is not expected to migrate out of U.S. landfills containing seized materials due to the low water solubility (3, 9, 19  $\mu\text{g/L}$  for seawater, water, and pure water, respectively) and a high affinity to adsorb to soil and sediments (log octanol-water partition coefficient = 4.3-5.4) where it will likely degrade over time (half-life in sediment is 35-100 days). Thus, no effects are expected to occur in the U.S. due to a limited exposure to teflubenzuron.

The potential for teflubenzuron to migrate out of Canada, in which it is currently approved, and cause significant environmental effects in the U.S. was also evaluated in the EA. Teflubenzuron is typically administered to farmed Atlantic salmon (*Salmo salar*) as a feed additive no more than twice in an 18-24 month period for the control of sea lice (*Lepeophtheirus salmonis*). Teflubenzuron is known to be administered to farmed Atlantic salmon contained in net pens located along the coastline of Canada and in close proximity to the U.S. border. Based on the analysis provided in the EA, CVM has determined that teflubenzuron is not expected to migrate out of Canadian coastal waters due to its low water solubility and high affinity to adsorb to sediments. Teflubenzuron is expected to remain in the sediment close to the net pens where the drug is administered and will degrade over time. Ecomonitoring studies support that teflubenzuron disappears from water within 1-3 days following administration, and is expected to remain in the sediment within 100 meters from the site of introduction. In addition, the ecomonitoring studies found that effects on caged lobsters, a sensitive invertebrate species, were limited to within 100 meters of the net pens. Generally, net pens are located in coastal waters of Canada and will likely be greater than 100 meters from the U.S. border. Thus, the use of

teflubenzuron along the U.S./Canadian border (or in other foreign countries) is not expected to cause significant impacts on the environment of the US.

An assessment of the exposure and effects data leads to the conclusion that no significant environmental impact is expected from the introduction of teflubenzuron residues from wastewater or landfills into the U.S. environment. In addition, no significant environmental impact is expected in the U.S. environment due to the use of teflubenzuron on Atlantic salmon in Canadian coastal aquaculture facilities located along the U.S. border or its use on Atlantic salmon in other foreign countries. Thus, no further assessment of environmental impact is necessary.

The information available is adequate to conclude that establishing an import tolerance for teflubenzuron in Atlantic salmon is not expected to have a significant impact on the U.S. environment.

5/23/2014  
Date

  
Director, Office of Surveillance and Compliance  
HFV-200

Attachment: Environmental Assessment for the Teflubenzuron Import Tolerance, dated November 1, 2011

**Electronic Signature  
Addendum for Submission ID**

V-005958-Q-0013-OT

<b>Signing Authority (Role)</b>	<b>Letter Date</b>
Daniel Mcchesney (Office Director)	3/14/2014

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