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

## ALVIS Inc.
## Tokyo, Japan

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.

Exponent on behalf of ALVIS Inc has submitted a request to establish an import tolerance for ampicillin residues in food derived from Perciformes fish that have been imported into the U.S. for human consumption. In support of the establishment of an import tolerance, Exponent (U.S. Agent of ALVIS Inc) has prepared the attached environmental assessment (EA), dated March 25, 2021. We have reviewed the EA and find that it supports a FONSI.

The EA evaluated the potential effects of ampicillin on the U.S. environment arising through four potential points of introduction: (1) wastewater treatment plant effluents that contain residues of the drug from human excreta, (2) application of biosolids from wastewater treatment as fertilizer to soil, (3) landfills that may hold seized materials, waste from fish processing plants containing the drug, or unconsumed Perciformes fish products, and (4) Perciforms fish farms in Canada and other countries where use of aquaculture drugs containing ampicillin may be authorized.

(1) *Landfills:* Ampicillin 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 ampicillin 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 ampicillin residues in wastewater treatment facilities (e.g., available data indicate that ampicillin is expected to be largely, if not completely, removed during the wastewater treatment processes), and (c) low consumption rates of fish in the U.S. compared to most other types of meats consumed in the U.S.

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

(4) *Aquaculture facilities in other countries where ampicillin may be authorized:* In addition to the landfill and wastewater pathways, the EA also evaluates exposure and

risk to the U.S. environment resulting from use of ampicillin in Perciforms fish in foreign countries where the drug is currently or potentially could be legally authorized. The analysis in this EA focuses on the use of ampicillin 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 described in the EA (i.e., Perciforms fish are mainly treated in net pens), ampicillin enters the marine aquatic environment via uneaten feed or fish excreta. It is expected that most of the feed containing ampicillin will be consumed by fish, and thus, ampicillin residue from the uneaten feed will be low. Ampicillin residues from fish feed and feces are expected to deposit directly underneath the net pens and to some extent around the vicinity of the fish farm, with incorporation in sediment over time. Any ampicillin released would have to travel to the U.S., and during that time, exposure to non-target species in the U.S. would be further reduced or eliminated due to substantial dilution and other physical and chemical processes. Furthermore, it is expected that use of ampicillin 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 ampicillin 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 ampicillin residues in food products derived from Perciformes fish.

*{see appended electronic signature page}*

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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) | 09/17/2025 |

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