

Summary of Microbial Criteria for fishery products intended for export to US (ex. bivalve products)

This document is prepared for training purposes July 2018. For regulatory purposes consult also the original documents. Else Marie Andersen

Type of Product	FDA Guidance (Table 5A in Fish and Fishery Products Hazards and Controls Guidance Fourth Edition, Table A5 – APRIL 2011)
Ready to Eat products	<p><i>Listeria monocytogenes</i>: Presence of organism in 25 gram sample <u>not</u> accepted.</p> <p><i>Vibrio cholera</i>: Presence of toxigenic O1 or O139 or non-O1 and non-O139 in 25 gram sample <u>not</u> accepted.</p> <p><i>Vibrio parahaemolyticus</i>: Levels equal to or greater than 1 x 10⁴/g (Kanagawa positive or negative) <u>not</u> accepted.</p> <p><i>Vibrio vulnificus</i>: Presence of organism <u>not</u> accepted.</p>
All other fish products	<p><i>Staphylococcus aureus</i>: Positive for staphylococcal enterotoxin <u>not</u> accepted; or <i>Staphylococcus aureus</i>: Level equal to or greater than 10⁴/g (MPN) <u>not</u> accepted.</p> <p><i>Clostridium botulinum</i>: Presence of viable spores or vegetative cells <i>in products that will support their growth</i> <u>not</u> accepted; or <i>Clostridium botulinum</i>: Presence of toxin not accepted.</p>
Fishery products from fish species associated with a high amount of histidine. (EU: Particularly fish species of the families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae. US: Tuna, mahi-mahi, and related fish. Myanmar: Lotia, Hilsa	<p><i>Histamine</i>: 500 ppm based on toxicity not accepted; 50 ppm defect action level.</p>
Bivalve molluscs (Clams, oysters, scallops)	See the Guidance for microbiological criteria for pathogenic bacteria, indicator bacteria and biotoxins.