

<b>Rule Title</b>	<b>Importer Verification under Seafood HACCP Regulation</b>
<b>Agency</b>	FDA
<b>Applicable CFRs</b>	21 CFR Part 123.12
<b>Final Rule Publication Date</b>	<p>The Seafood HACCP regulation (21 CFR 123) published December 18, 1995.</p> <p><a href="#">Section 123.12 Special requirements for imported products</a></p> <p><a href="#">Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (text version)</a></p> <p><a href="#">Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (pdf)</a> (page 105-106)</p>
<b>Rule Summary</b>	<p>SUMMARY: The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123. You must have the following:</p> <ol style="list-style-type: none"> <li>1. <u>Written Verification Procedure</u> (21CFR123.12(a)(2))</li> <li>2. <u>Product Safety Specifications</u> are designed to ensure that the fish and fishery products you import are not injurious to health (21CFR 123.12(a)(2)(i)).</li> <li>3. <u>Affirmative Step</u> which ensures that the fish and fishery product you import are processed in accordance with the Seafood HACCP regulation (21CFR 123.12(a)(2)(ii)).</li> </ol> <p>For the Affirmative Step you must have <u>at least one</u> of the following:</p> <ol style="list-style-type: none"> <li>1. Obtain HACCP and sanitation monitoring records from the foreign processor relating to the specific lot.</li> <li>2. Obtain a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent 3<sup>rd</sup> party certifying the product was processed in accordance with US FDA Seafood HACCP regulations.</li> <li>3. Regularly inspect the foreign processor to ensure HACCP requirements are met.</li> <li>4. Maintain a copy of the processors HACCP plan (in English) and a written guarantee that product was processed according to plan.</li> <li>5. Periodically test the product and maintain a written guarantee.</li> </ol>

	<p>6. Develop and maintain other verification measures that ensure the product is in compliance with HACCP</p> <p>4. <u>Records</u> which document performance and results of the Affirmative Steps. (21CFR 123.12(c).</p>
<b>Agency Resources</b>	<p><a href="#">Fish and Fishery Product Hazard and Control Guide</a></p> <p><a href="#">FDA Seafood HACCP page</a></p>
<b>Additional Resources</b>	<p><a href="http://seafood.oregonstate.edu/Seafood HACCP Alliance">http://seafood.oregonstate.edu/Seafood HACCP Alliance</a></p>
<b>Compliance Dates</b>	Effective December 18, 1997