

Lists of Foreign Processors of Fish and Fishery Products Approved by their Governments

Fish and Fishery Product Imports: Affirmative Steps

FDA is providing, below, the website locations of lists provided by foreign government inspection authorities of processors of fish and fishery products that, according to those authorities, are in good standing and are meeting the requirements of the FDA seafood Hazard Analysis Critical Control Point (HACCP) regulations.

The regulations for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (21 CFR part 123) require that all seafood products in interstate commerce in the United States must have been processed in accordance with both the HACCP principles and the sanitation prerequisite requirements that are specified in those regulations. These requirements apply to imported as well as domestic products. Importers have a responsibility under those regulations to verify that the fish and fish products they are importing meet those requirements.

There are essentially two ways in which importers may satisfy their verification obligations. First, they may obtain products from a country that has an active equivalence or compliance agreement with FDA covering fish and fishery products. Under such an agreement, FDA has determined that government of the foreign country is operating a regulatory system for seafood safety that ensures that the products being exported to the U.S. satisfy U.S. safety concerns.

Second, if no such agreement exists with the country of origin, importers must take their own "affirmative steps" to verify that the products they are importing have been processed in accordance with the regulations (21 CFR part 123.12). FDA is inspecting importers to review the adequacy of these "affirmative steps."

The regulations do not mandate what affirmative steps importers must take, but give examples of affirmative steps that importers may select. One of these examples include obtaining either a continuing or lot-by-lot certificate from a competent private party or from an appropriate foreign government inspection authority attesting that the products were produced in accordance with the U.S. requirements (21 CFR 123.12(a)(2)(B)).

The inspection authorities of some countries are issuing lists of processors that are in good standing with those authorities and are, according to the authorities, processing in accordance with the U.S. requirements. These lists, if regularly updated, may serve the same purpose as the issuance of "continuing" certificates by the foreign government inspection authority. Importers may consider purchasing from processors that are on such lists, and documenting that they are doing so, as one way of meeting their affirmative steps responsibility.

Importers should always consider, however, whether the steps they have chosen adequately verify that the fish and fishery products they are importing have been processed in accordance with part 123. Thus, importers should assess the credibility of the lists by considering factors such as those that will be considered by FDA (as discussed below) when doing so. In addition, importers should be aware that FDA has not verified the lists or the information on them. In considering whether to accept importation of products from processors on foreign government-supplied lists as satisfying the affirmative step obligation, FDA may consider such factors as the length of time since the foreign government inspection authority updated its list, the compliance history of the country and the individual foreign processor, and what is known generally about the regulatory structure of the foreign country.

The foreign countries and their websites are as follows:



Canada (<http://www.inspection.gc.ca/eng/1297964599443/1297965645317>). <http://www.fda.gov/about-fda/website-policies/website-disclaimer>): Canadian Food Inspection Agency (CFIA (<http://www.inspection.gc.ca/english/toce.shtml>)). <http://www.fda.gov/about-fda/website-policies/website-disclaimer>)



Japan (<http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/jigyousya/taibei/3.html>). <http://www.fda.gov/about-fda/website-policies/website-disclaimer>): Ministry of Health, Labour and Welfare, Department of Food Safety, Inspection and Safety Division



Norway

(https://www.mattilsynet.no/om_mattilsynet/godkjente_produkter_og_virksomheter/). <http://www.fda.gov/about-fda/website-policies/website-disclaimer>): Norwegian Food Safety Authority (NFSA)

Requests by foreign government inspection authorities for FDA to provide links to official website locations that list processors that, according to those authorities, are in good standing and are meeting the requirements of FDA's Hazard Analysis Critical Control Point (HACCP) regulation should be submitted to: FDA-CFSAN-International-Engagement@fda.hhs.gov (<mailto:FDA-CFSAN-International-Engagement@fda.hhs.gov>).

Was this helpful?

Yes

No