

Seafood HACCP regulations are required to register with FDA.

FDA is using the term “fish” to describe the cargo of fishing vessels in order to be consistent with the use of the term in 21 CFR Part 123. “Fish” is defined in § 123.3(d) as “fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited, to alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.”

(Comment 30) A commenter asks FDA to clarify whether any facilities would be required to register in the following scenario: Company A purchases fish from a Mexican fisherman, loads it onto refrigerated trucks, and transports it to Company B, which is located in the United States.

(Response) Under the interim final rule, fishing vessels are exempt from registration unless processing is done on board the ship. For purposes of this exemption, “processing” is defined in § 123.3(k)(1) as “[h]andling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.” Importantly, however, according to § 123.3(k)(2), harvesting and transport vessels that engage in “[h]arvesting or transporting fish or fishery products, without otherwise engaging in processing,” or “[p]ractices such as heading, eviscerating, or freezing, intended solely to prepare a fish for holding on board a harvest vessel,” are exempt from registration under 21 CFR 1.126(f). Under the scenario described in the comment, the Mexican fisherman would have to register the vessel if he catches fish and processes it aboard the vessel under § 123.3(k). If the fisherman does not process the fish (other than heading, eviscerating, or freezing the fish to prepare it for holding on board his vessel), the vessel would not need to register. Whether Company A or Company B would be required to register depends upon their activities. If either company engages in manufacturing/processing, packing, or holding the fish, all facilities at which such activities occur must be registered (unless a facility qualifies for one of the exemptions from registration, e.g., a restaurant). A transportation vehicle is not a facility and would not need to register if it holds the fish only in its usual course of business as a carrier (§ 1.226(f).)

7. Facilities Regulated Exclusively, Throughout the Entire Facility, by USDA

(Comment 31) Several commenters ask FDA to clarify which facilities are regulated exclusively by USDA, as USDA versus FDA jurisdiction is not clear to foreign facilities.

(Response) Whether a facility is regulated exclusively by USDA (and thus, is exempt from registration, 21 CFR 1.226(g)) depends upon the products manufactured/processed, packed, or held at the facility. Any facility that manufactures/processes, packs, or holds some foods subject to FDA jurisdiction does not satisfy the exclusivity part of the exemption in § 1.226(g) and thus, must register with FDA.

More specifically, under the Meat Inspection Act (MIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), USDA inspects facilities that slaughter poultry, cattle, sheep, swine, equines, or goats and facilities that process “poultry products” or “meat food products” as defined under the MIA and the PPIA (21 U.S.C. 453(f), 455, 601(j), 603). Any USDA-inspected facility that slaughters only poultry, cattle, sheep, swine, equines, or goats is solely under USDA jurisdiction and is exempt from registration. Facilities that slaughter these animals, but that also slaughter other animals, such as deer or elk, are under both USDA and FDA jurisdiction and must register. Facilities that manufacture/process only “poultry products” or “meat food products,” as defined by USDA, are exempt from registration. Facilities that manufacture/process “meat food products,” such as pizzas with meat topping, and other products, such as cheese pizzas, are under both FDA and USDA jurisdiction and must therefore register with FDA.

Under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), USDA inspects facilities that process “egg products,” which are “any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been * * * considered by consumers as products of the egg food industry * * *” (21 U.S.C. 1033(ff)). A facility is regulated exclusively by USDA if it manufactures/processes only “egg products.” If a facility manufactures/processes other food in addition to, or instead of, egg products, the facility is not regulated exclusively, throughout the entire facility, by USDA and it must be registered. Thus, a facility is regulated exclusively, throughout the

entire facility, by USDA if it manufactures/processes, packs, or holds only “meat food products,” “poultry products,” or “egg products” as defined above. If a facility manufactures/processes, packs, or holds other food in addition to meat food products, poultry products, or egg products, the facility is not regulated exclusively, throughout the entire facility, by USDA and thus, would not be exempt from registration.

(Comment 32) One commenter requests FDA to expand this exemption by including all facilities that are subject to USDA jurisdiction, even if they are also subject to FDA jurisdiction. Another commenter asks why, under this exemption, FDA exempts such a considerable part of the production chain from the registration requirements, while also establishing strict requirements for other facilities.

(Response) The Bioterrorism Act requires that, unless exempt, all facilities that manufacture, process, pack, or hold food for consumption in the United States must register (21 U.S.C. 350d(a)). However, section 315 of the Bioterrorism Act states that no part of Title III should be construed to alter the jurisdiction between USDA and FDA. Under current practice, FDA may have jurisdiction over a food facility, USDA’s Food Safety and Inspection Service may have jurisdiction over a food facility, or the two agencies may have joint jurisdiction over a food facility. Under section 315, the Bioterrorism Act does not change this structure. Accordingly, only those facilities that manufacture/process, pack, or hold food that is regulated exclusively by USDA is exempt from registration under section 315. In response to the comment asking why FDA exempts such a considerable part of the production chain from registration under this exemption, the authority in the Bioterrorism Act only extends to facilities manufacturing/processing, packing, or holding food under FDA’s jurisdiction. Congress did not extend these requirements to facilities under USDA’s exclusive jurisdiction. (USDA has other existing authority over facilities under their jurisdiction.) Moreover, even though a facility is exempt from registration with FDA this does not mean that it is exempt from all statutes and regulations that protect the safety and security of food consumed in the United States.

(Comment 33) Several commenters urge FDA to exempt from the registration requirement other facilities in addition to those exclusively regulated by USDA, such as USDA-approved, federally licensed grain storage silos and elevators, low acid