

understand environmental concerns with net pen systems and the actual impacts of current operations in the U.S. in the context of existing State and other requirements. At present, EPA concludes that net pens should continue to be included in the CAAP rule. Again, it appears that most net pen operations potentially in the scope of the regulation are already using practices and technologies at least as stringent as those EPA is considering for this subcategory.

One commenter questioned the need for a national regulation when the extent and size of the net pen industry is small. Data regarding in-scope facilities indicate that net pen facilities are used to raise salmon in three States (Alaska, Maine and Washington). A limited number of net pen facilities also produce other fish species as well. While net pen systems in Maine and Washington raise salmon to harvestable weights, net pen systems in Alaska also rear salmon before their release in the ocean.

Offshore aquatic animal production is another new area under development. The National Marine Fisheries Service (NMFS) proposed codes of conduct for these offshore operations announced in an August 2002 **Federal Register** notice (67 FR 54644). NMFS held six regional workshops in the fall of 2000 to discuss the codes of conduct for these types of operations. In 2002, NMFS published *Current and Future Regulation of Marine Aquaculture*, which describes best management practices similar to those we are considering in this rule. These include feed management to minimize waste, minimizing escapes, and minimizing negative effects of escapes on wild populations. The NMFS report also states that disease prevention through vaccinations is preferred over using antibiotics. NMFS has five research stations of which three have aquatic animals. Demonstration projects include sea cages in Puerto Rico, Hawaii, Gulf of Mexico, and eastern Gulf of Maine. EPA did not identify quantitative estimates of future U.S. mariculture activity. However, as research efforts move forward, offshore aquatic animal production may be of greater interest and provide opportunities for future industry growth in this area (see DCN 20428 for information about programs and future prospects). EPA is considering whether to identify as new sources subject to these requirements new offshore production facilities located in the territorial seas (e.g., three to eight miles from shore) that use open water net-like structures.

3. Molluscan Shellfish Operations

EPA did not propose to include certain categories or types of facilities within the scope of the proposed rule. Floating or bottom culture molluscan shellfish operations were among the production systems not within the scope of the proposal. Although these operations were excluded, the proposed regulation did not specifically address nursery operations for molluscan shellfish, whose shellfish nurseries tend to be flow-through systems. We received requests to clarify the scope of the proposal and exclude shellfish nurseries from the regulation. We reviewed the information provided in the comments on this issue (see DCNs 70147, 70218, 70236, 70238, and 70268). Based on our review, EPA determined that these operations (e.g., shellfish hatcheries, nursery operations, shore based wet storage (live holding) facilities and depuration (cleaning shellfish of impurities) facilities) discharge or add very little, if any pollutants to the receiving water. In some cases, they may remove some of the materials in source water. Some of these comments (DCNs 70147 and 70236) also indicated that shellfish hatcheries and nurseries produce less than 100,000 pounds annually and thus would not be subject to the proposed regulations.

Two comments indicated that adverse environmental effects, primarily accumulation of silt and solids, of excessively large and densely seeded molluscan shellfish operations were reported in the scientific literature (e.g., DCN 70270, 70511). However, these sources acknowledge that adverse impacts are unusual and have not been reported in the United States.

EPA is, however, aware of concerns about deliberately introducing non-native shellfish into coastal waters of the United States. For example, there is ongoing debate about the comparison of possible benefits compared to the possible risks of introducing non-native pacific oysters (*Crassostrea ariakensis*) in the Chesapeake Bay. The National Academy of Sciences (NAS) issued a report (DCN 62456) summarizing the potential risks and benefits of introducing *C. ariakensis* in the Chesapeake Bay. The NAS report also recommends that States and regional authorities develop protocols to reduce the possibility of release of reproductively viable non-native oysters into the bay, including hatchery biosecurity. Although the National Academy of Sciences concludes that there is not an adequate group of laws and regulations in the United States to address the introduction of non-native

shellfish into marine waters, the Academy does recommend that the Chesapeake Bay Program be evaluated as a model for interjurisdictional decision-making system with binding authority over introductions that might affect the coastal areas of several States.

C. Drugs and Chemicals

EPA's proposal and technical literature in the record identified several human and aquatic life health and environmental issues of potential concern related to using drugs and chemicals at AAP facilities. These issues included evidence of drug and/or chemical residues in sediments in the receiving waters of AAP facilities or in non-target organisms in the receiving waters (e.g., DCN 20141). The Agency proposed limited reporting requirements for certain types of drug applications. It also proposed establishment and implementation of BMP plans that would help reduce the unintended release of covered drugs and chemicals. EPA could not, however, quantify either baseline loadings of drugs and chemicals, or expected reductions in these loadings due to proposed requirements. Consequently, we did not try to quantify environmental benefits for measures addressing drugs and chemicals.

Some comments asserted that those who apply drugs and chemicals at CAAP facilities consider environmental safety in their decision-making process (DCNs 70236 and 70263). Other commenters added that EPA did not provide evidence that drugs and chemicals used at aquatic animal production facilities lead to environmental problems. They also argued that FDA is the appropriate Federal agency to assess the environmental safety of drugs used in aquatic animal culture (DCNs 70165, 70192, 70216, 70228, 70230, 70236, 70239, 70262, 70263, 70273, 70286). EPA also received other comments arguing that the proposed reporting and BMP requirements relating to drugs and chemicals should be more stringent (DCN 70145).

In addition to drugs and chemicals used as therapeutants or to maintain process water quality, some commenters believe that EPA should regulate the discharge of feeds that contain pigments (such as astaxanthin or canthaxanthin). They believe that these color additives are harmful to humans, especially in the fish flesh of cultured fish that consume the feed. Astaxanthin and canthaxanthin, two widely used color additives in fish feed, are approved by FDA as color additives in fish feed when used in accordance with