

prescribed conditions on the label. FDA found that these additives would not have a significant impact on human health and the environment (DCN 40417 and 40421).

EPA also collected more information about CAAP drugs and chemicals (see Section II.E of today's notice). EPA has met with other Federal authorities such as USDA/APHIS and FDA to clarify and coordinate regulatory and program goals. EPA will work closely with Federal, State, and other appropriate scientific experts to fully consider the available information described here.

Based on our consideration of public comments and information described in Section II.E relating to chemicals applied at CAAP facilities, EPA believes that further evaluation is needed to fully understand the potential for adverse environmental impacts from discharges of chemicals, including therapeutants, applied at CAAP facilities. However, the information we have reviewed to date suggests that the FDA environmental assessment process and site-specific regulatory, professional, or industrial requirements or practices address adverse impacts to a significant degree. We will continue to evaluate this information and consult with relevant authorities.

In addition, EPA and FDA are working on a formal agreement that would address environmental concerns about the discharge of drugs used at aquatic animal production facilities. This agreement, which might help protect the aquatic environment from harm, would facilitate information sharing about effluent concentrations of active drug ingredients. When appropriate, FDA would include in the labeling of approved new animal drugs, effluent concentrations of the active drug ingredient which should not be exceeded in wastewater discharges. EPA would notify permitting authorities who would incorporate these effluent concentrations into the NPDES permits as enforceable requirements. EPA seeks comments on including these labeling concentrations into NPDES permits.

EPA identified research on the use of activated carbon filtration to treat and remove active ingredients in drug and pesticides from CAAP facility wastewater. We also estimated the cost of applying this treatment at facilities (DCN 62451). Based on the information we collected, EPA estimated the cost of applying wastewater treatment to remove drugs and chemicals from CAAP effluent before discharge. EPA considers these costs to be economically unachievable, (see Section V.C. of this notice). However, management practices intended to ensure proper storage, use

and disposal of drugs and chemicals and to minimize the need for their use may be an effective approach for minimizing their discharge. To address this issue, EPA is evaluating an additional option (Option A) that would be similar to Option 1 but would substitute a drugs and chemicals BMP plan for the solids control BMP plan proposed in Option 1. The Option A BMP plan would also have to address potential escapes of non-native species.

In developing this option, EPA evaluated practices that involve the early identification of health problems, recordkeeping, and proper use and storage of drugs and chemicals by employees. In addition, EPA found that biosecurity practices that contain and prevent the spread of disease throughout the facility are effective at reducing the use of drugs at CAAP facilities. Health screening involves observing the normal behavior of aquatic animals at a facility (e.g., feeding behavior and abnormal activities). EPA recognizes that more intensive screening activities, such as diagnostic tests for specific pathogens, may not be technologically feasible or economically achievable.

Recordkeeping and the regular review of the records should help facilities evaluate the effectiveness of health management and modify their practices to further reduce health problems in the aquatic animals that may lead to greater use and disposal of drugs and chemicals.

D. Non-Native Species

EPA received comments presenting discussions about CAAP as a pathway for the introduction of non-native species. Some commenters feel that existing State and local permitting programs and regulations provide adequate protection. Several State agencies commented that while they concur that measures to address potential risks associated with aquatic nuisance or invasive species are important, such measures are most appropriately and effectively developed at a State or Tribal level and that in many cases, specific requirements and policies already exist. Some of these States briefly described their relevant programs and regulations. We also received comments from States suggesting that proposed new national requirements might threaten existing State efforts addressing invasive species.

However, a State permitting authority (DCN 70067) and a State coastal resources agency (DCN 70225) commented that EPA should require CAAPs to report escapes of non-native species to the permitting authority.

They gave their rationale for this requirement, including arguing that timely notification of escapes would allow State natural resource and environmental agencies to evaluate and, if necessary, control the spread of the non-natives. These agencies also recommended that EPA prohibit the intentional release from CAAPs of non-native species that might harm wild species. One of these agencies suggested that facilities should be equipped with physical barriers to prevent the incidental discharge of all life stages of non-native species. One agency supported a Federal regulation corresponding to existing State rules that would prohibit unauthorized release of harmful or potentially harmful exotic and non-native species.

Other commenters urged more coverage (e.g., ponds, molluscan shellfish) and control for escapes. They identified several specific concerns: escapes of the cultured organisms themselves (e.g., Atlantic salmon in the Pacific Northwest), including genetically modified species, and escapes of pathogens and parasites potentially associated with the cultured organisms. Commenters also proposed potential control requirements (e.g., prohibitions on reproductively viable non-native species; containment requirements). Some commenters believe that current practices to minimize or prevent the release or escape of non-native species are effective.

EPA also received comments questioning our interpretations of technical literature about non-native species concerns. The JSA pointed out that EPA cited a comprehensive 2001 NOAA technical memorandum on the net pen salmon farming industry in the Pacific Northwest in its discussions on possible concerns with escapes of non-native species (DCN 40149) but that EPA did not also cite the conclusions of the report regarding the "very low or no" risk of interactions or problems from accidental releases of Atlantic salmon in the Pacific Northwest. That report states that the escape of Atlantic salmon, a non-native species, is "deemed to carry very little or no risk" with respect to potential for hybridization with other salmonids, colonization of salmonid habitat, competition with native species for forage, predation on indigenous species, and serving as vectors for the introduction of exotic pathogens. The report reviews and discusses scientific evidence and reasoning to support this conclusion. The report also states that "[t]he possible negative consequences of such [accidental escape] events have