

reported in the public comments, detailed surveys, and literature as used at CAAP facilities in the U.S. These chemical/therapeutic substances include anaesthetics, antibiotics, pesticides, antifungals, disinfectants, algicides, antifoulants, feed additives, and hormones used under EPA-approved, FDA-approved, and veterinary prescribed extra-label use, and FDA's investigational new animal drug (INAD) provisions. For several of the more commonly used substances, EPA collected information on quantities used from the detailed survey and industry-supplied data. EPA also has environmental assessments from the FDA docket for oxytetracycline, formalin, Romet, and canthaxanthin (see DCNs 40417, 40477, 40492, 40567). In addition, EPA obtained and is evaluating studies of the fate and effects of these chemical/therapeutic substances, when available. We placed a draft preliminary reference list in the public record (DCN 62454). EPA will work with appropriate internal and external experts to interpret these studies.

Second, EPA met with FDA to clarify FDA's environmental assessment requirements for the substances over which FDA has jurisdiction (DCN 31126). EPA met with USDA's Animal and Plant Health Inspection Service (APHIS) to discuss how the requirements and objective of the CAAP rule relate to authorities under their jurisdiction (DCN 31123). At the meeting, USDA discussed the Animal Health Protection Act ("2002 Farm Bill"), which gives APHIS the authority to develop and implement aquatic animal health programs. This law gives authority to APHIS for aquatic farm-raised animal disease management including emergency responses actions to invasive pathogen outbreaks. APHIS is also authorized to implement control programs using drugs or chemicals and biosecurity practices to reduce disease risk and impact on the industry.

EPA is also reviewing, industry and professional association guidelines on using antimicrobial agents responsibly (e.g., DCN 70720). EPA will continue to work closely with the JSA National Aquatic Animal Health Task Force and other Federal, State, and scientific experts to better understand the relationships between current technical and regulatory aspects of chemical applications at CAAP facilities and EPA's proposed requirements.

3. Non-Native Species

EPA also received comments about non-native species (described in more

detail in Section III.D). Briefly, comments included:

- Arguments supporting or opposing the establishment of controls on non-native species.
- EPA's regulatory involvement with non-native species issues.
- Specific scientific information to correct or supplement data on potential impacts of CAAP non-native species that EPA considered in developing the proposed rule.
- Descriptions of specific Federal, State, local, or industry requirements and programs to reduce or mitigate non-native concerns at CAAP facilities.

First, EPA is evaluating the comments and the supplementary literature submitted with them. Second, we continue our dialogue with Federal agencies that set policy for non-native species to facilitate coordination among relevant programs. EPA met with the APHIS, which has a broad mandate to address import and interstate movement of exotic species under the Federal Plant Pest Act and the Plant Quarantine Act (DCN 31123). EPA is also communicating with the National Invasive Species Council (NISC) regarding the non-native species aspects of the CAAP rule. Third, as some commenters urged, EPA is also more closely examining State, regional, and other requirements and programs designed to reduce or mitigate concerns about non-native species and that may already apply to facilities within the scope of the CAAP rule. One source of information of which EPA has become aware since proposal is the Environmental Law Institute's August 2002—*Halting the Invasion—State Tools for Invasive Species Management*. This publication analyzes legal tools available at the State level to address non-native species (including aquatic invasive species), identifies critical components of such tools and discusses examples of effective programs. The document also describes specific legal tools in each State (DCN 40637).

EPA is also considering supplemental information provided by members of the National Association of State Aquaculture Coordinators (NASAC). NASAC gave EPA a summary of information from their members regarding non-native species requirements and State regulating agencies (DCN 40607). Several States recognize and actively implement measures to address potential risks about non-native aquatic species. For example, the California Department of Fish and Game (CDFG) instituted several requirements to prevent the introduction of non-native species into bodies of water and to prevent the

dissemination of fish diseases and parasites to wild populations and cultured stocks (DCNS 40593, 40594). A forthcoming report (*Non-native Oysters in the Chesapeake Bay*) by the National Research Council (NRC) may also provide insight into the effectiveness of existing regulations and programs, and recommendations for more effective approaches to non-native species issues (DCN 62456). While this study targets an industry sector EPA is not proposing to regulate (molluscan shellfish), certain discussions and findings regarding approaches for addressing non-native species concerns may be informative.

EPA has identified several non-North American species currently raised at CAAP facilities that might pose an environmental threat if they were to escape and become established (e.g., several species commonly referred to as tilapia) (DCN 40649). To identify species of interest, EPA reviewed the database of facility responses to EPA's 2001 screener survey (DCN 10001). The database includes information on facility location and species raised for each of over 2,300 respondents who produce aquatic animals. Although this is a much larger population than the facilities covered by the proposed rule, EPA used this information to identify general trends in the production of non-native fish that could become invasive. EPA compared species and facility location with a State-by-State list of invasive fish derived from the United States Geologic Survey (USGS) (Fuller *et al.*, 1999).

We faced several challenges with using this information for our evaluation. Most of the facilities contained in the screener survey database did not provide enough taxonomic detail to determine if cultured species were non-native and potentially invasive. In several cases where we had enough taxonomic detail, the species being cultured had already been widely introduced throughout North America. In addition, several facilities in the database raise fish hybrids, and evaluating the invasive potential of hybrids poses a unique challenge because the characteristics may not be a simple blending of parent species' characteristics. Genetic effects may influence the ecological niche of a hybrid, making it difficult to predict its possible geographic distribution. Such genetic effects include dominance, polygenic inheritance (where traits are influenced by the cumulative effects of multiple genes), epistasis (where one gene influences the expression of another), and pleiotropy (where a single gene influences the multiple traits).