The Catch with Seafood

Human Health Impacts of Drugs & Chemicals Used by the Aquaculture Industry

CENTER FOR FOOD SAFETY

Center for Food Safety (CFS) is a national, nonprofit membership organization working to protect human health and the environment by curbing the use of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. Membership and additional information about CFS is available at www.centerforfoodsafety.org or by writing to office@centerforfoodsafety.org

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Harvested Fish — Dewatering table as fish are harvested from an offshore cage in Hawaii. Courtesy of NOAA.

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Something's fishy about aquaculture.

Seafood has grown rapidly in popularity among consumers in recent years due to its important health benefits. However, as over-fishing and environmental degradation have depleted wild fish stocks, an increasing proportion of the seafood consumed in the U.S. is farm-raised. When eating farm-raised fish, consumers may not be aware that with every bite they are getting a dose of antibiotics, hormones, pesticides and/or other chemicals. Without a change in the way the U.S. Government regulates aquaculture, the side effects associated with these contaminants could negate the very health benefits consumers seek through fish consumption.

As one might expect, three of the most popular seafood items for American consumers are three of the top aquaculture imports: shrimp, salmon and tilapia. Together, they represented almost two billion pounds of seafood imported into the U.S. in 2003.

Salmon producers regularly use artificial dyes to make the pale grey meat of farm-raised salmon appear rich in color like healthy wild salmon. Not only are the dyes themselves potentially dangerous, with studies linking them to hyperactivity in children and retinal damage, but they also disguise farm-raised fish and deceive consumers. Lurking beneath the artificial pink coloring of farm-raised salmon is a hazardous concoction of potent antibiotics and chemicals. But producers have found a way to hide the conditions in which the fish were raised, conditions that may make the salmon unsafe for human consumption.

Farm-raised fish are packed into overcrowded pens that breed parasites, fungi and promote the rapid spread of disease. The close confinement necessitates the heavy use of pesticides, antibiotics and other chemicals, which producers often dump directly into the water, creating a stew of contaminants. Consumers eventually ingest the residues of these substances in the meat of farm-raised fish.

Antibiotics used in fish farms can be dangerous to human health for many reasons. Several antibiotics that have been banned in the United States due to their human health risks may be used illegally in fish farms that export tons of fish to this country. Chloramphenicol, one such antibiotic, leads to an increased risk of developing cancer, and in very low concentrations may trigger aplastic anemia, a disease that causes bone marrow to stop producing red and white blood cells and is often irreversible and fatal. Chloramphenicol has been detected in imported fish, and although exporting countries claim to have banned its use, monitoring of imported seafood by FDA is lax and may not detect such contamination.

Nitrofurans make up another group of antibiotics that has been banned in the United States due to its link with cancer. As aquaculture facilities attempt to reduce their reliance on chloramphenicol, they may be increasing their use of nitrofurans, which are even more difficult to detect. As a result, it is suspected that nitrofurans are being used in both domestic and foreign fish farms.

A drug used in Canadian fish farms is a sea lice medication called "Slice." Residues of the active ingredient in Slice, emamectin benzoate, have been found in Canadian farmed salmon–95 percent of which is exported to the United States–and is linked to behavioral and growth effects, and abnormal brain changes.

In addition to the health hazards associated with some antibiotics themselves, heavy antibiotic use in fish farms may also contribute to the creation of antibiotic-resistant bacteria. The Food and Drug Administration (FDA) has stated that many illnesses, such as tuberculosis, gonorrhea, malaria, and childhood ear infections, have

become more difficult to treat due to growing antibiotic resistance.

Another dangerous chemical found in farm-raised fish is malachite green, which is often used as a fabric dye but is also used extensively in aquaculture to prevent fungal growth on fish eggs and to treat parasitic infections in adult fish. Malachite green is toxic and carcinogenic to humans and increases the risk of genetic mutation. Although it is banned in the United States, Europe, and many exporting countries, malachite green was detected in fish imported into Europe as recently as last year.

Environmental contaminants are also found in higher concentrations in farm-raised fish than among wild fish. Some of these pollutants include PCBs (polychlorinated biphenyls, once used as lubricants and coolants but banned in the 1970s due to their extreme toxicity), Dioxin (found in the notorious defoliant Agent Orange), toxaphene and dieldrin (two banned pesticides), and PBDEs (polybrominated diphenyl ether, a flame retardant).

Carnivorous farm-raised fish like salmon contain higher levels of these contaminants because they are fed a diet high in fish oils and meal derived mainly from small pelagic fish that accumulate these contaminants in their fat. Furthermore, farmed salmon accumulate more contaminants because they are kept in crowded, confined pens, which restrict their exercise and cause them to develop more of the fat in which the contaminants are stored.

Despite the seriousness of the human health threats from these and other sources, enforcement of regulations in domestic and foreign aquaculture remains lax. The FDA, which is responsible for ensuring the safety of the U.S. seafood supply, fails to effectively enforce its own standards with foreign producers. For example, the agency inspects only a tiny fraction of the seafood imported into the U.S. and does not test at all for many of the illegal drugs and chemicals that may be used in foreign fish farms.

Among the report's findings:

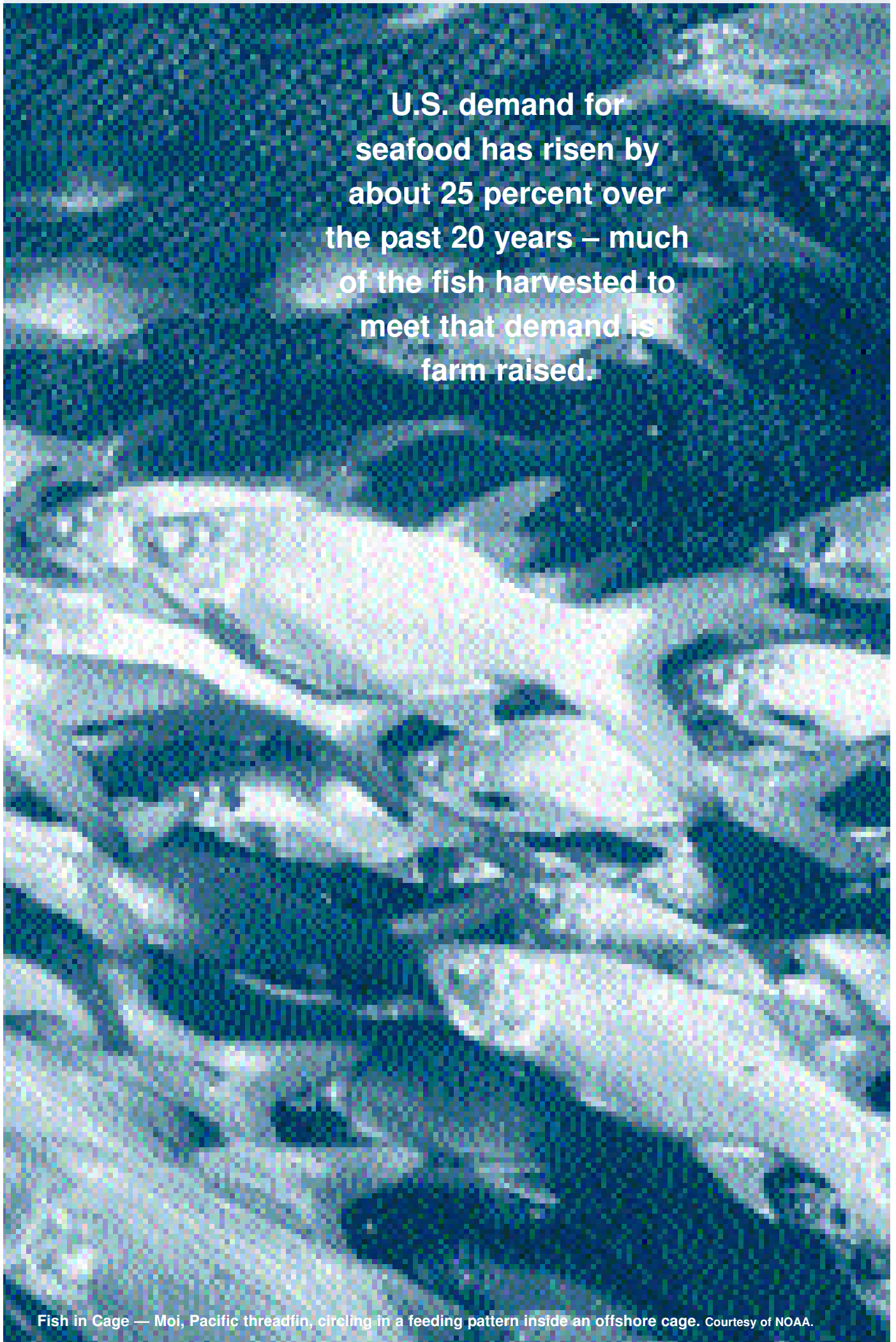
- Drugs and chemicals banned in the U.S. are being used in both foreign and domestic aquaculture, e.g., widespread, illegal use of unapproved antibiotics and fungicides.
- Even though fish dyes may be harmful to human health, they are commonly used in both domestic and foreign aquaculture.
- Dangerous environmental contaminants that accumulate in the body are found in farmed fish around the world.
- Potentially harmful genetically engineered fish and fish injected with hormones are being developed as food products.
- FDA is neither regulating nor enforcing its current regulations adequately enough to protect consumers from unsafe seafood.
- FDA does not properly inspect domestic aquaculture facilities or sufficiently test seafood imported from foreign producers.

Among the report's recommendations:

- To protect consumers from unsafe drugs and chemicals used in aquaculture, FDA must improve testing of seafood products, implement new regulatory programs, tighten its standards, provide incentives for producers to reduce drug and chemical use, and give consumers enough information to make informed decisions.
- To protect themselves, consumers should look for labels and ask questions, demand that grocery stores comply with labeling requirements and carry seafood free of antibiotics, and urge FDA to properly enforce its regulations.

As consumption of farm-raised fish grows, consumers need to know the risks involved with eating it and feeding it to their children, who are at highest risk from the drugs, chemicals and contaminants found in aquaculture products. Consumers wanting to avoid farm-raised seafood are encouraged to ask seafood sellers if their products are wild or farm-raised.

In April 2005, consumers received some much-needed help in determining the origins of seafood when the U.S. Department of Agriculture's Country of Origin Labeling (COOL) rules became effective. COOL designates the country of origin and the method of production (farmed or wild) of fish and shellfish, allowing consumers to begin making informed choices about the seafood products they purchase.



Fish in Cage — Moi, Pacific threadfin, circling in a feeding pattern inside an offshore cage. Courtesy of NOAA.

Farming Fish:
What's in it for you?

Conscientious consumers increasingly are choosing to eat seafood for its nutritional benefits, which include heart-healthy oils, high protein, low saturated fat, and vitamin and mineral content. Nutritionists and health experts are pushing seafood such as salmon as healthful alternatives to red meat, driving demand for seafood in the U.S. up by about 25 percent over the past 20 years to over 16 pounds per person per year.[1] Yet most consumers who eat seafood for its health benefits are unaware that much of the seafood sold in this country is raised in aquaculture facilities and, as a result, is likely to contain drugs and chemicals that may actually be harmful to them.

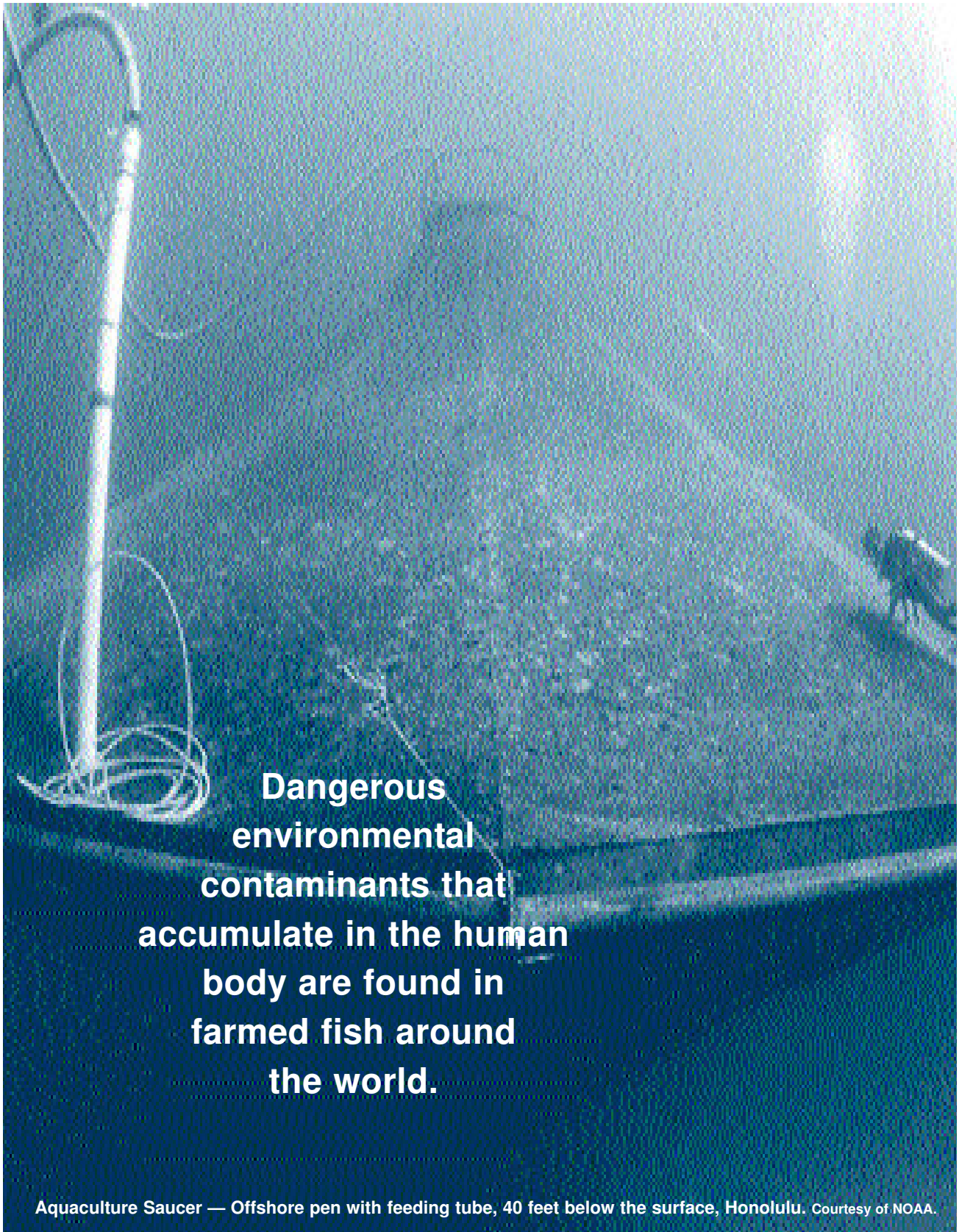
Aquaculture is the production of fish under controlled conditions. The United Nations Food and Agriculture Organization (FAO) defines aquaculture as the "farming of aquatic organisms, including fish, mollusks, crustaceans, and aquatic plants. Farming implies some form of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators, etc. Farming also implies individual or corporate ownership of the stock being cultivated."[2] The facilities used to raise farmed fish include ponds, net pens, raceways, and enclosed tanks. These systems use fresh, brackish, or salt water, depending on the species being raised.

Aquaculture has taken place for centuries in subsistence cultures but recently has become a large and rapidly growing industry. In recent years, global aquaculture has grown more quickly than all other food-growing sectors. Much has been written about the adverse environmental impacts of aquaculture, such as the pollution of fresh and coastal waters and the elimination of fish habitat.[3] Often overlooked, however, are the types and amounts of drugs and chemicals, both approved and unapproved, used by the aquaculture industry. The use of these substances raises serious food safety and human health concerns.

Given the dramatic rise in the production and consumption of farm-raised fish, the Center for Food Safety undertook this study to assess the human health impacts of drug and chemical use in aquaculture operations.

This report first analyzes the wide range of antibiotics, fungicides, dyes, and hormones currently being used in producing farm-raised fish. The report then

assesses the performance of FDA in identifying and regulating the threats posed to consumers by the ongoing use of drugs and chemicals in aquaculture. Finally, the report provides recommendations to both policymakers and consumers on actions they can take to address and avoid the human health risks posed by fish-farming practices.



Dangerous environmental contaminants that accumulate in the human body are found in farmed fish around the world.

Aquaculture Saucer — Offshore pen with feeding tube, 40 feet below the surface, Honolulu. Courtesy of NOAA.

Global Aquaculture:
Outgrowing its controls?

Aquaculture has experienced rapid worldwide growth since the 1970s, with greater increases in production than all other animal food producing sectors. According to the FAO, aquaculture's contribution to global fish production increased from 3.9 percent of total weight in 1970 to 27.3 percent in 2000.[4] Globally, the aquaculture industry has increased at an average rate of 9.2 percent per year since 1970, in contrast with 1.4 percent for commercial fisheries and 2.8 percent for farmed meat production.[5] As a result, one in four finfish and one in three shrimp purchased by consumers is farmed raised.[6] And by 2007, aquaculture is predicted to produce over 50 percent of food fish.[7] In the U.S., the value of the domestic aquaculture industry grew by 400 percent between 1980 and 1998.[8] Similar growth is expected to continue in coming years.

CONSUMPTION OF AQUACULTURE PRODUCTS IN THE U.S.

According to the Government Accountability Office (GAO), consumption of seafood in the U.S., particularly farm-raised seafood, rose by about 25 percent between 1980 and 2002, and the National Oceanic and Atmospheric Administration (NOAA) recently found that Americans consumed a record 16.3 pounds of fish and shellfish per person in 2003.[9] Nearly one third of the seafood consumed in the U.S. is produced by the aquaculture industry,[10] and 75 percent of that is imported.[11] Aquaculture products are imported from at least 62 countries, including many developing countries.[12] The top aquaculture products imported into the U.S. include tilapia, salmon, and shrimp (*See Table 1*).[13]

Table 1. **Top Imported Aquaculture Products in 2003**

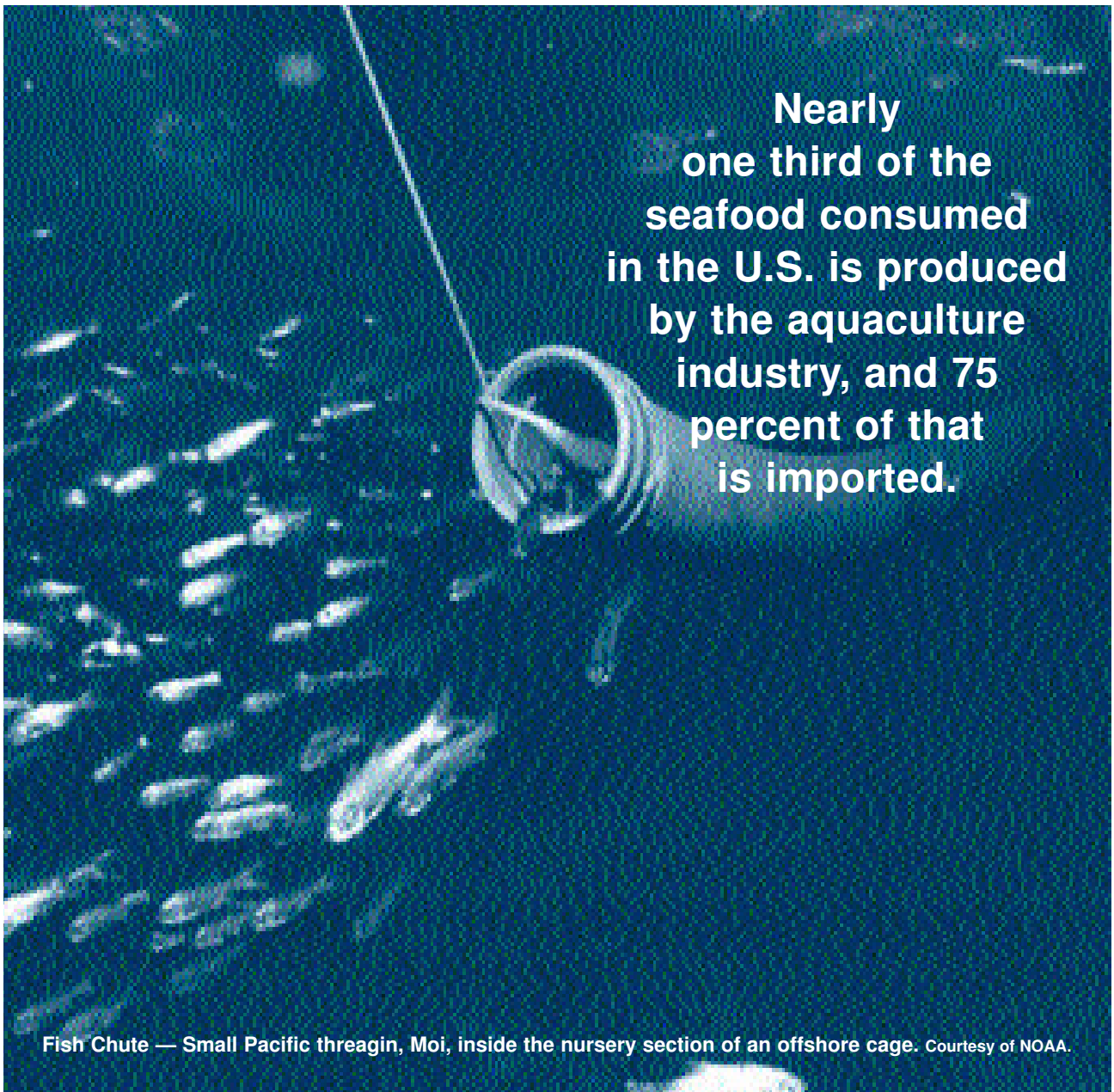
Farmed Fish	Volume	Value	Primary Exporting Country
Shrimp	1.1 billion lbs.	US $3.8 billion	Ecuador, Brazil, Vietnam, China
Salmon	414 million lbs.	US $916 million	Canada and Chile
Tilapia	199 million lbs.	US $241 million	China, Ecuador, Costa Rica, Honduras

Source: David J. Harvey, Domestic Aquaculture Production Higher and Imports Up, Aquaculture Outlook (U.S. Dep't of Agric., D.C.), Mar. 12, 2004, at LDP-AQS-19, available at http://usda.mannlib.cornell.edu/reports/erssor/livestock/ldp-aqs/2004/aqs19.pdf.

Among the seafood that is farmed domestically, the catfish industry is the largest aquaculture sector. Most catfish are grown in Mississippi, Alabama, Arkansas, and Louisiana.[14] The other major seafood species grown in the U.S. include trout, salmon, tilapia, hybrid striped bass, sturgeon, walleye, yellow perch, crawfish, shrimp, abalone, oysters, clams, and mussels[15] (*See Table 2*).

Table 2. **Examples of Species Raised in U.S Aquaculture**

Farmed Fish		
Catfish	Crawfish	Walleye
Salmon	Shrimp	Mussels
Tilapia	Abalone	Trout
Yellow Perch	Oysters	Hybrid Striped Bass
Sturgeon	Clams	



Fish Chute — Small Pacific threagin, Moi, inside the nursery section of an offshore cage. Courtesy of NOAA.

Drugs & Chemicals:
Potential effects on human health

The aquaculture industry's use of drugs and chemicals, such as antibiotics, fungicides, dyes, and hormones, in its production of farm-raised fish, raises serious human health and food safety concerns that remain largely unaddressed (*See Table 3*). Aquaculture production methods involving the use of drugs and chemicals must be investigated, monitored, and reformed where necessary.

Table 3. **Potential Health Effects from Drugs & Chemicals Used in Aquaculture**

Drug or Chemical	Examples	Some Species Affected	Potential Risks
Antibiotic	Oxytetracycline, Chloramphenicol, Sulfadimethoxine-ormethoprim, Amoxicillin trihydrate, Nitrofurans	Catfish, Salmon, Shrimp	Development of resistant bacteria, residues in food
Dye	Astaxanthin, Canthaxanthin	Salmon	Hyperactivity in young children, eye problems
Environmental Contaminant	PCBs, PBDEs, Dioxins	Salmon	Suspected carcinogens
Fungicide	Malachite green	Salmon, Catfish	Suspected carcinogen
Genetically Modified Fish	Growth hormones, antifreeze protein	Salmon, Tilapia, Oysters	Allergenicity, toxicity, unintended effects
Hormone	Bovine growth hormone (rBGH)	Tilapia	Links to cancer

ANTIBIOTICS

Why Antibiotics Are Used

Antibiotics have been widely used in aquaculture to treat infections caused by bacterial pathogens such as Aeromonas hydrophila, Aeromonas salmonicida, Edwardsiella tarda, Pasteurella piscicida, Vibrio anguillarum, and Yersinia ruckeri.[16] The prevalence of these diseases in farm-raised fish increases as producers crowd larger numbers of fish into smaller production facilities.[17] Although specifically prohibited by FDA, many aquaculture facilities, especially shrimp farms, around the world use antibiotics for prophylactic purposes to prevent disease and for growth promotion.[18] In fact, FDA acknowledges this potential hazard in its guidelines by listing the following reasons aquaculture producers might administer drugs: "1) treat and prevent disease; 2) control parasites; 3) affect reproduction and growth; and 4) tranquilization (e.g. during transit)."[19]

Despite growing concern over the safety of using antibiotics in aquaculture, it is extremely difficult to determine the full extent of their use.[20] In the U.S., for example, "with one exception, there are no public sources of aquaculture drug use data (citation omitted)," only estimates.[21] One report estimates that as much as 204,000 to 433,000 pounds of antibiotics are used annually by the domestic aquaculture industry.[22] Despite the volume of drugs administered to diseased fish, a U.S. Department of Agriculture (USDA) survey of the catfish industry revealed that less than 60 percent of aquaculture facilities keep records on such treatments.[23]

In other parts of the world, there is ample evidence of high and/or increasing antibiotic usage. For instance, in 2001, the Chilean aquaculture industry administered 40,000 kilograms of antibiotics on salmon farms, as compared with a modest 645 kilograms administered in Norway.[24] Also, in 2003, salmon farms in Canada's British Columbia used more than 25,000 kilograms of antibiotics, twice the amount the province used in 1995.[25] Another large share of the world's aquaculture takes place in countries where both legal and illegal drug use may escape any documentation at all.[26] This overall gap in record-keeping presents a strong indication of the extent to which potential human health impacts of excessive antibiotic use in aquaculture may be occurring.

One report estimates that as much as 433,000 pounds of antibiotics are used annually by the U.S. aquaculture industry.

Dangers of Overuse of Antibiotics

The human ingestion of antibiotics used to treat farm-raised fish can occur when people consume drug residues in the fish themselves. One Canadian study, for example, showed that between 1990 and 1994, 29 to 50 percent of the farmed salmon tested showed drug residue levels above the Maximum Recommended Level established by the Canadian Food Inspection Agency.[27] By eating fish that have been treated with antibiotics, consumers may be ingesting harmful levels of unsafe antibiotics. Although there is a disconcerting lack of data on antibiotic usage and residue levels in U.S. aquaculture,[28] the evidence suggests that many farmed fish contain high levels of antibiotic residues.

Consumers may also ingest antibiotics when the antibiotics used in aquaculture facilities contaminate wild seafood. The most common method of distributing antibiotics to farmed fish is through fish feed. Diseased fish have a reduced appetite, and as a result, a large portion of the antibiotics enters the environment by way of uneaten fish feed.[29] In addition, a large portion of the

antibiotics consumed by farm-raised fish are excreted and enter the environment through their feces.

Some predictions suggest that 80 percent of most antibiotics are released into the environment.[30] The unused antibiotics accumulate in wild fish and shellfish that feed on the food and feces of farmed fish.[31] By eating wild fish exposed to the antibiotics, humans ingest residues of antibiotics that may be harmful.[32] For example, in one study, drug residues in wild fish were found to exceed FDA safety levels. The researchers explained that:

> . . . drug residues of up to at least 3.8 ppm were found in edible crab meat. In comparison, the U.S. Food and Drug Administration prohibits marketing of fish containing concentrations of oxytetracycline exceeding 0.1 ppm. The health risks associated with ingesting food containing antibacterial residues are unclear and highly controversial, but exceeding maximum acceptable tissue residue levels as defined by public health authorities suggests the issue merits further attention (citation omitted).[33]

Despite the serious public health problems that can be caused by the use and misuse of antibiotic drugs in fish feed, the aquaculture industry is undeterred. First, there may be illegal use of legal antibiotics for purposes not specifically approved by FDA and delineated on the label, called "extralabel" use. When FDA approves a new animal drug, the approval conditions are listed on the label and include: "the species for which the drug is approved; the approved dosage; the approved route of administration; the approved frequency of use; and the approved indications for use."[34] Once a drug is approved, FDA allows a veterinarian to prescribe the drug either for intended use or for extralabel use, a purpose that is not specified on the label.[35] Although FDA requires veterinary approval for extralabel use of antibiotics, there is little enforcement that would prevent the illegal extralabel use that is believed to occur in some aquaculture facilities.

Some producers in the aquaculture industry use harmful and illegal antibiotics, such as chloramphenicol and nitrofurans, in their seafood production, some of which have been linked to cancer and other adverse health effects. During the past five years, the United States and the European Union have rejected imported aquaculture products from various countries due to their contamination with two banned drugs.[36] One of these drugs is chloramphenicol. According to FDA, chloramphenicol is:

> …a potent, broad spectrum antibiotic drug used only for treatment of serious infections in humans. The drug has known side effects, including an increased risk of certain cancers and other diseases, such as leucopenia, anemia and aplastic anemia. Due to the unpredictable effects of dose on different patient populations, it has not been possible to identify a safe level of human exposure to chloramphenicol.[37]

Some producers in the aquaculture industry use harmful and illegal antibiotics, some of which have been linked to cancer and other adverse health effects.

Aplastic anemia, one of the diseases caused by chloramphenicol, causes the bone marrow to stop producing red and white blood cells and is often irreversible and fatal. The FAO has stated that the disease may be triggered by a very low concentration of the drug.[38]

Because of concerns about the long term health risks of the antibiotic, the U.S. in 2001 joined the European Union (EU) in banning chloramphenicol use

in aquaculture, following the EU's rejection of Chinese shrimp imports due to chloramphenicol contamination.[39] In 2003, FDA lowered its detection level to 0.3 ppb, thus conforming to allowable levels established in Canada and the EU.[40] While several of the world's seafood exporting countries now claim to have eliminated chloramphenicol from their fish farming industries, proper testing and enforcement remain nearly impossible due to the massive annual influx of aquaculture products from tens-of-thousands of Southeast Asian suppliers.[41]

The other antibiotic being illegally used in aquaculture is the family of drugs known as nitrofurans.[42] Nitrofurans are a body of veterinary drugs that have been used to treat infections in animals.[43] FDA banned nitrofuran use in aquaculture in 2002[44] after having determined that the use of these drugs in food animals results in carcinogenic residues.[45] As the aquaculture industry attempts to reduce or eliminate its reliance on chloramphenicol, it may increasingly turn to nitrofurans as a substitute due to the difficulty in detecting the presence of nitrofurans.[46] While U.S. industry, represented by the National Fisheries Institute, has called upon FDA to better ensure that the U.S. Hazard Analysis and Critical Control Points (HACCP) standards are enforced against importers,[47] the illegal use of nitrofurans is suspected to be a problem both domestically[48] and in imported aquaculture.

Furthermore, new evidence has recently emerged regarding the use of a sea lice medication called Slice in Canadian aquaculture. Slice is administered in feed and, therefore, is not considered a pesticide.[49] While Slice was approved as an emergency drug by the Canadian Food Inspection Agency (CFIA), more than 170 million of Canada's farmed salmon were treated with Slice between 1999 and 2003,[50] and residues of emamectin benzoate, the active ingredient in Slice, have been discovered in Canadian farmed salmon by the CFIA.[51] The use of Slice in Canadian farmed salmon presents cause for concern as emamectin is known to "block a major inhibitory neural transmitter in the brain," and has been shown to cause behavioral and growth changes as well as pathological brain changes in animal studies.[52] Canada exports the vast majority of its farmed salmon, 95 percent of which are consumed by the U.S.,[53] and wild scallop beds in Maine have also been found to contain the drug in levels significantly higher than those permitted by the United States.[54] While Canada's current tolerance level of 50 parts per billion for emamectin vastly exceeds the two parts per billion allowable under U.S. EPA guidelines for meat, FDA does not currently monitor Canadian farmed salmon for this drug.[55]

Proper testing and enforcement remain nearly impossible due to the massive annual influx of aquaculture products from tens-of-thousands of Southeast Asian suppliers.

There are serious concerns that the use of antibiotics in food animals may lead to antibiotic resistance in bacteria that cause human illnesses. Antibiotic resistance is "a natural phenomenon developed by bacteria as a means to escape the antibiotic effect and to survive its contact . . . . [T]he use of antibiotics selects for resistant bacteria, allowing antibacterial resistant bacteria to survive and multiply."[56] The FAO, the World Health Organization (WHO), and the World Organization for Animal Health (OIE) reported that "Antimicrobial resistance is a consequence of antimicrobial use."[57] The expanding use of antibiotics in all agriculture, including aquaculture, is contributing to the increasing resistance of some bacteria to specific antibiotics. This growing resistance is undermining the effectiveness of antibiotics used to treat human illness. FDA stated that "disease-causing microbes that have become resistant to drug therapy are an increasing public health problem.

Tuberculosis, gonorrhea, malaria, and childhood ear infections are just a few of the diseases that have become hard to treat with antibiotic drugs."[58]

In reviewing the studies on drug resistance in fish pathogenic bacteria over the past 30 years, one researcher reported that there appears to be "a clear impact between use of antibacterial drugs in aquaculture and development of antibiotic resistance in fish pathogenic bacteria."[59] The researcher went on to explain that there also appears to be "an impact on the environmental bacterial flora surrounding fish farms where antibacterial drugs are being used."[60]

The American Society of Microbiology (ASM), Antibiotic Resistance Task Force, is concerned about the use of antibiotics in aquaculture and its contribution to the problem of antibiotic resistance.[61] The ASM explains that:

> **1.** Although aquaculture production is growing rapidly, disease prevention and treatment practices are far from standardized or regulated.[62]
> **2.** When antibiotics are used in aquaculture, the drugs typically remain in the open environment and may flow out of production facilities into open waterways or sewage systems, where they may also interact with other environmental contaminants.
> **3.** The antibiotics typically used are also important in treating human disease and infections.
> **4.** Impacts of all these factors on the emergence of antibiotic resistance are unknown. However, we do know the following:
>
> **a.** Studies demonstrate an increase in resistant bacteria in the intestines of fish receiving antibiotic drugs (citation omitted).
> **b.** Recent studies indicate the level of resistant bacteria in the gut of wild fish is affected during antibiotic treatment of farmed fish (citation omitted).
> . . .
> **d.** Prior to medication 0.6 to 1 percent of the fecal bacteria in wild fish were resistant to toxacillin and oxytetracycline, respectively (citation omitted).

The expanding use of antibiotics in all agriculture, including aquaculture, is contributing to increasing resistance of some bacteria to specific antibiotics.

The risk of humans contracting antibiotic-resistant bacteria is a serious concern. The Centers for Disease Control (CDC) found that bacteria from aquaculture ecosystems can be transferred directly to humans by the handling of fish.[64] CDC acknowledges that, "Bacteria on fish may also be transmitted to humans when the aquaculture fish are eaten, or when other foods, which have been cross-contaminated by bacteria from fish, are eaten."[65] Thus, current science has shown that the overuse of antibiotics, including those used in aquaculture, can contribute to the emergence of antibiotic-resistant bacteria that cause illness in humans.

MALACHITE GREEN

Malachite green, often used as a fabric dye, is used extensively in aquaculture around the world[66] to prevent fungal growth on fish eggs and as a topical treatment for parasitic infections in adult fish through direct input into the water.[67] Fish rapidly absorb malachite green from treated water and reduce it to leuco-malachite green.[68] The chemical then accumulates in the tissues and eggs of contaminated fish.[69] Humans are exposed to the chemical through consumption of these treated fish.[70]

Malachite green is banned for use on fish in several countries, including the U.S., but efforts to eradicate its use have proven unsuccessful as it is still routinely used throughout the world.[71] Malachite green has been widely used by the U.S. aquaculture industry since the 1930s and is likely still being used in some U.S. aquaculture facilities today due to its low cost, ready availability, and high efficacy.[72]

Two years after the United Kingdom banned the use of malachite green in aquaculture, the government discovered illegal levels of the chemical in salmon sold by a major supermarket.[73] In September 2004, a shipment of Chilean farmed salmon was rejected by Holland after the fish were found to contain illegal levels of malachite green residue.[74] Chile also outlawed malachite green in 1995, but enforcement is lax, and environmentalists argue that salmon farmers use the chemical extensively.[75]

Risks with Using Malachite Green

There are many possible human health consequences of eating fish contaminated with malachite green. First, both clinical and experimental studies show that malachite green is a toxin. It "decreases food intake, growth and fertility rates; causes damage to liver, spleen, kidney and heart; inflicts lesions on skin, eyes, lungs and bones; and produces teratogenic effects in rats and mice."[76]

Second, malachite green has been found to be mutagenic; that is, it increases genetic mutation by causing changes in DNA. Animal studies show that it is mutagenic in rats and mice and causes severe developmental abnormalities in pregnant New Zealand white rabbits.[77]

Third, malachite green is carcinogenic to the liver, thyroid, and other organs of experimental animals.[78] Studies also show an increased incidence of tumors in the lungs, breasts, and ovaries of rats exposed to malachite green.[79]

DYING FISH

Nearly all Atlantic salmon sold in the U.S. is farm-raised and virtually all of that is artificially colored with potentially dangerous dyes.

Despite the rapidly growing consumption of salmon in the U.S., most consumers are likely unaware of the presence of two artificial dyes, astaxanthin and canthaxanthin, in the majority of the salmon that they consume.[80] Due to the lack of availability of wild-caught Atlantic salmon, it is estimated that 95 percent of all Atlantic salmon (including most Chilean, Canadian, Scottish, Norwegian, Icelandic, Tasmanian, and Irish salmon) is farm-raised, and virtually all farmed salmon is artificially colored with astaxanthin or canthaxanthin.[81] While the flesh of wild salmon is naturally pink due to their diet of krill and other reddish prey, farmed salmon flesh is pale grey in color before it is dyed.[82] Ironically, the salmon-farming industry uses these unnecessary and potentially dangerous dyes to create the illusion of a more natural and appetizing product.[83]

Dangers of Dying Fish

Like the use of antibiotic drugs in aquaculture, FDA must also approve the use of color additives. Although FDA has approved the use of astaxanthin and canthaxanthin as color additives in salmon farming, there are human health concerns surrounding the use of these dyes that require further study. For example, a recent study performed at Southampton University in the UK suggests that there may be a connection between consumption of artificial food colorings and hyperactivity rates in young children.[84]

Furthermore, in 1995, the EU Scientific Committee on Food issued a report finding a link between canthaxanthin and retinal damage.[85] In response to these concerns, the European Commission decided to cut the amount of this additive permitted in salmon by decreasing the maximum permissible level from 80 mg per kilogram of salmon feed to 25 mg.[86] The U.S. has meanwhile maintained a permissible level of 80 mg per kilogram of feed for both canthaxanthin and astaxanthin.[87]

In addition to concerns about the direct human health impacts of these dyes, it also is worth noting the deceptive effects on consumers of the use of such dyes. The salmon-farming industry's use of dyes to make farmed salmon look identical to wild salmon also makes it difficult or impossible for consumers to distinguish between the two and to choose the type of fish they prefer.[88] Consumers may prefer to buy wild salmon instead of farmed salmon because of the extensive environmental problems involved in aquaculture practices, including harm caused to wild stocks from the transmission of diseases that propagate in fish farms, and pollution of coastal waters with nitrogenous fish waste, antibiotics, hormones and pesticides.[89]

Consumers may also choose wild salmon over farmed salmon due to evidence that farmed salmon may provide fewer health benefits and greater risks from contaminants. According to U.S. nutritionist Andrew Weil and The American Journal of Clinical Nutrition, "farmed salmon have two to three times fewer omega-3's than their wild counterparts. Meanwhile, the fat content of farmed fish ranges between 11 percent and 20 percent versus 7 percent for wild."[90]

CONTAMINANTS: PCBS, PBDES AND DIOXINS

Environmental Contaminants Found in Farmed Fish

Farm-raised salmon has been documented to have much higher concentrations of environmental contaminants than wild salmon.[91] Among these environmental contaminants are highly toxic PCBs, or polychlorinated biphenyls, (once widely used as lubricants and coolants but banned by Congress in the 1970s due to their myriad human health effects) and their close relative, dioxin (formed from the burning of chlorine-containing chemicals like plastics and found at high levels in the notorious defoliant Agent Orange). Although PCBs have been banned for many years, it is a long-living pollutant, like dioxin, that cycles through the ecosystem and persists in the environment today. Scientists also believe that PCBs are carried in the air from other countries where the chemicals are still being used.[92]

Farm-raised salmon has been shown to have much higher concentrations of environmental contaminants such as PCBs and dioxin.

A small study done in Canada examined the concentrations of environmental contaminants in farmed salmon and found that the levels of contaminants, such as PCBs and dioxins, were three to six times the levels recommended by the World Health Organization.[93] A sampling done in Scotland found "surprisingly high" levels of PCBs, and samplings in the UK found levels of DDT and chlordane in nearly all samples of farmed salmon.[94]

In the largest study ever to compare pollutants found in wild and farmed salmon, Ronald Hites sampled and analyzed over two metric tons of farmed and wild salmon from around the world.[95] The study found that farm-raised salmon contained significantly higher concentrations of environmental contaminants than those found in wild-caught salmon.[98] The study also reported that

farmed salmon obtained from Europe contained higher concentrations of contaminants than those farmed in North and South America.[97] Also, the authors of this study issued a new study in May 2005 that says to achieve a cancer risk in "the middle of the U.S. EPA's acceptable risk range," consumption of farmed salmon "must be effectively eliminated and consumption of wild salmon must be restricted generally to less than one meal per month.".[98]

Farm-raised fish contain much higher levels of environmental contaminants than do wild fish because they are fed a diet that is high in fish oils and fish meal that is primarily obtained from small pelagic fish. Small pelagic fish in polluted waters accumulate these chemicals in their fat.[99] Fish that are higher on the food chain, such as salmon, consume these contaminated fish and accumulate the chemicals in their fat. Fewer chemicals accumulate in wild salmon because their diet contains less of the contaminated fats and because they get more exercise, reducing their own fat levels.[100]

Other environmental contaminants have also been documented in high levels in farmed salmon. Some of these chemicals are toxaphene and dieldrin, two banned pesticides, and PBDEs (polybrominated diphenyl ether), a flame retardant.[101]

Methylmercury is yet another contaminant found in our coastal waters. Studies have shown that oil rigs discharge "one billion pounds of mercury-contaminated drilling muds or lubricating fluid" into the Gulf of Mexico each year.[102] The contamination of aquaculture fish may increase significantly if some members of Congress are successful at passing legislation that would allow the use of offshore oil and gas platforms for farmed fish production.[103] Exemplifying such practices, the Hubbs SeaWorld Research Institute has already announced plans for an aquaculture facility on a decommissioned oil platform off the California coastline.[104]

Hazards of Environmental Contaminants

High levels of environmental toxins such as toxaphene and dieldrin – two banned pesticides – are known to occur in farm-raised salmon.

Not surprisingly, there are significant human health risks in consuming toxic environmental contaminants. Environmental contaminants such as PCBs and dioxins are "considered among the most toxic of man-made chemicals and are thought to cause cancer, disrupt the endocrine system, cause developmental and reproductive problems, and other health problems."[105] In animal laboratory studies, PBDEs caused impaired development in fetuses and disrupted the hormone system.[106] Mercury has been shown to cause neurological disorders, especially in developing fetuses and young children.[107]

The Hites study mentioned above used health guidelines set by EPA to assess the health risks of environmental contaminants. EPA sets health guidance levels for PCBs in wild-caught fish, and FDA sets the limits for commercially-sold fish.[108] The Hites study found that the contaminant levels did not exceed FDA's limits but far exceeded EPA's levels. Hites' study relied upon EPA's standards, finding that EPA's approach is "designed to manage health risks by providing risk-based consumption advice regarding contaminated fish," whereas FDA's approaches "are not strictly health-based, do not address the health risks of concurrent exposure to more than one contaminant, and do not provide guidance for acceptable levels of toxaphene and dioxins in fish tissue."[109]

The Hites study concluded that the "consumption of farmed salmon may result in exposure to a variety of persistent bioaccumulative contaminants with

the potential for an elevation in attendant health risks."[110] ("Bioaccumulative" refers to contaminants that typically are stored in fat cells and accumulate and concentrate as they move up through the food chain, at the top of which sit humans.) Based upon these studies, seafood consumers face serious risks in consuming farm-raised salmon.

GENETICALLY ENGINEERED FISH

Genetically engineered fish are being developed to, among other things, grow faster and produce human insulin. To date, at least 35 species of fish and shellfish have been genetically engineered, including Atlantic salmon, tilapia, and oysters, but none are yet available on the market (*See Table 4, next page*).[111] The developers of a genetically engineered Atlantic salmon would like to change that and are currently seeking to commercialize their creation. FDA is reviewing this fish under its new animal drug regulations.

The engineered salmon contains a growth-hormone gene from a Chinook salmon and an antifreeze-protein gene promoter from an ocean pout that keeps the growth hormone active.[112] These transgenes are injected into fertilized eggs. As a result, the engineered fish is designed to grow as much as 10 to 30 times faster than normal salmon.[113]

Hazards of Genetically Engineered Fish

The novel nature of genetically engineered fish creates significant human health concerns, such as allergenicity, toxicity, and other unintended effects. The National Academy of Sciences looked at the human health impacts of consuming genetically engineered animals and found that novel genes may trigger severe allergic reactions in some people.[115] Additionally, FDA recognizes that the transgene cannot be "turned off" once it is inserted into the organism, and may lead to uncontrolled expression.[116] Over-expression of an existing protein leads to higher levels of exposure to that protein. As toxicity to humans may be determined by either the nature or the quantity of a substance, a higher concentration of a protein may create toxic results for some people.[117] Depending on where transgenes are inserted, they may also "affect the expression of other genes by disabling them or turning them on at an inappropriate time."[118]

Furthermore, the foreign growth hormone genetically inserted into salmon may increase production of other compounds such as insulin in the fish.[119] FDA also acknowledges that, "The incidental insertion of drug resistance genes from bacterial plasmids introduces further uncertainties as to food safety."[120]

The FDA acknowledges the uncertainties – "as to food safety" – that surround the insertion of foreign genes into salmon.

HORMONES

Hormones are used in aquaculture for "inducing or preventing reproductive maturation, for sex reversal and for promoting growth."[126] For example, chorionic gonado-tropin is used to promote spawning function in male and female fish.[127] The University of Hawaii's Institute of Marine Biology, in collaboration with the University of California's Sea Grant Program, is experimenting with growth hormones in the popular tilapia fish.[128] These scientists have found that tilapia injected with genetically engineered bovine growth hormone, or rBGH, grows close to twice the size of wild tilapia in just four weeks.[129] Researchers have not indicated whether they will seek FDA approval to put this fish on the market.

Table 4. **Examples of Genetically Engineered Fish**

Species	Foreign Gene	Purpose
Atlantic salmon	Anti-freeze protein gene (AFP)* AFP, salmon growth hormone (GH)	Cold Tolerance Added growth, feed efficiency
Coho salmon	Chinook salmon GH, AFP	At 1 year, 10-30 fold growth jump
Chinook salmon	AFP, salmon GH	Added growth, feed efficiency
Rainbow trout	AFP, salmon GH	Added growth, feed efficiency
Cutthroat trout	Chinook salmon GH, AFP	Added growth
Tilapia	AFP, salmon GH	Added growth, feed efficiency; stable inheritance
Tilapia	Tilapia GH	Added growth, stable inheritance
Tilapia	Modified tilapia insulin-producing gene	Produce human insulin
Salmon	Rainbow trout lysosome gene and flounder pleurocidin gene	Disease resistance, in development
Striped Bass	Insect genes	Disease resistance, in early stages of research
Mud Loach	Mud loach GH, mud loach and mouse promoter genes	Added growth, feed efficiency; 2-30 fold growth increase; inheritable transgene
Channel catfish	Growth hormone	33% growth improvement in culture conditions
Common Carp	Salmon and human GH	150% growth improvement in culture conditions; improved disease resistance; tolerance of low oxygen level
Indian Major Carp	Human growth hormone	Added growth
Goldfish	Growth hormone, AFP	Added growth
Abalone	Coho salmon GH, various promoters	Added growth
Oysters	Coho salmon GH, various promoters	Added growth
Arctic Char[121]	Growth hormone	Added growth
Flounder[122]	Ocean pout AFP gene promoter, Chinook salmon GH	Added growth
Japanese Medaka[123]	Salmon GH w/(Mt) promoter	Added growth
Zebrafish[124]	Sea coral gene	Phosphorescent red glow
Silver Sea Bream[125]	Rainbow trout GH with common carp b-actin promoter	Added growth

* From Arctic flatfish.

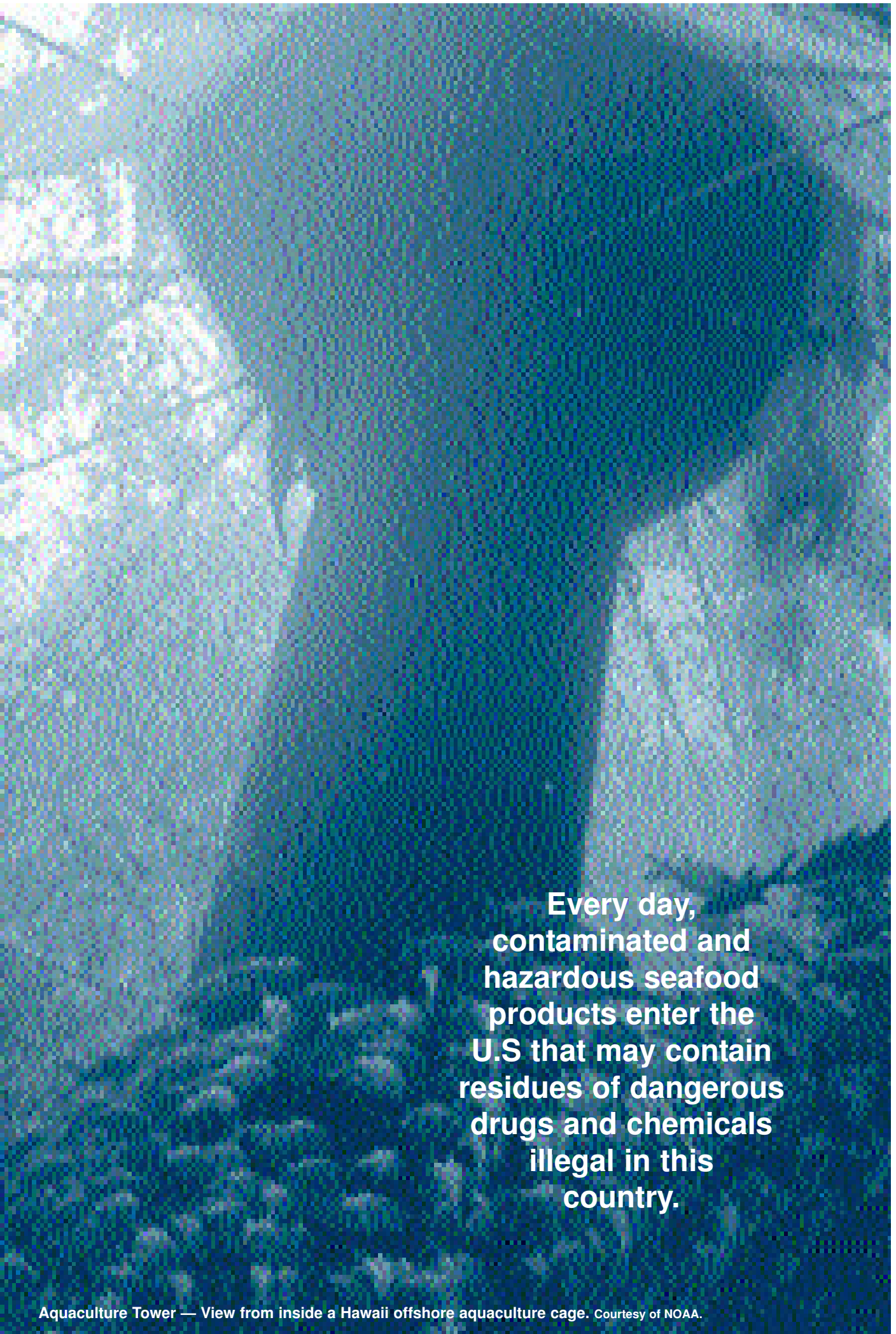
Source(s): Information on the first 17 species from Food and Agriculture Organization, available at ftp://ftp.fao.org/docrep/fao/003/x8002e/x8002e00.pdf. All other sources are individually footnoted.

Hazards of Hormones

The use of hormones in aquaculture is "not well documented and sometimes carried out without adequate understanding of the quantities needed and of their persistence in the environment or in aquaculture products once treatment is removed."[130] The unanswered questions surrounding the use of hormones in aquaculture are troubling given the potentially adverse health effects associated with some of them. For example, FDA's approval of rBGH to increase the production of milk in dairy cows was met with stiff opposition due to many concerns about the human health impacts of the hormone and the known adverse impacts on the health of cows, e.g., increases in cystic ovaries, disorders of the uterus, and other problems that lead to over use of antibiotics and other drugs. Furthermore, cows injected with rBGH face an increased risk for clinical mastitis, which leads to visibly abnormal milk.[131]

The NAS looked at the human health impacts of eating genetically engineered animals and found that novel genes may trigger severe allergic reactions.

Opponents also raised concerns about "elevated levels of insulin-like growth factor 1 (IGF-1) in milk from cows treated with rBGH. IGF-1 has been linked to tumor promotion in humans, specifically in prostate and breast cancers."[132] The debate about the human health impacts of rBGH and the possible presence of IGF-1 in dairy products from treated cows has prompted the European Union, Canada, Japan, Australia, and New Zealand to prohibit the domestic and imported use of rBGH in any dairy products.[133] Clearly the concerns raised by rBGH use in dairy cows should translate into equally significant concerns about its use in fish.



Every day, contaminated and hazardous seafood products enter the U.S that may contain residues of dangerous drugs and chemicals illegal in this country.

Aquaculture Tower — View from inside a Hawaii offshore aquaculture cage. Courtesy of NOAA.

The Regulators:
Current oversight & regulatory failures

4

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA is responsible for ensuring that both domestic and imported seafood is safe for consumers.[134] FDA approves certain drugs for use in domestic aquaculture and has implemented a system for ensuring that seafood producers comply with the rules. Despite FFDCA, significant gaps in the enforcement of safety laws leave consumers vulnerable to contaminated and hazardous seafood products, especially from imported seafood that may contain residues of dangerous drugs and chemicals that are illegal in the U.S.

Domestic Aquaculture

Drug and Chemical Use in Domestic Aquaculture

Under FFDCA, FDA is responsible for reviewing requests to market new animal drugs used in aquaculture and granting or denying their sale. (FDA has interpreted the term "drug" to include rBGH and rBGH-treated fish, and genetically engineered fish).[135] FDA's regulations for new animal drugs require drug producers to complete a new animal drug application before putting the drug on the market.[136] To be approved, the sponsor of the drug must demonstrate that the drug is safe and efficacious.[137]

FDA has approved six drugs for use in aquaculture: one anesthetic, one parasiticide, one spawning agent, and three antibiotics, all of which must be administered according to label instructions (*See Table 5*).

Oversight of Domestic Seafood Production

In 1997, FDA established a program of preventive controls designed to identify hazards during the seafood production process. The Hazard Analysis and Critical Control Points system (HACCP), requires seafood processors to identify harmful microbiological, chemical, and physical hazards that are reasonably likely to occur, including food safety hazards that may occur as a result of natural toxins, microbiological contamination, chemical contamination, pesticides, and drug residues.[138] Thus, the processor first determines whether contaminants

are reasonably likely to pose a significant food safety hazard; FDA Fish and Fisheries Products Hazards and Controls Guidance states that aquaculture drugs are reasonably likely to pose such a hazard.[139] The processor must establish critical control points (CCP) to determine at which processing steps it is necessary to implement controls.[140] For each step, the processor creates critical limits for each drug; FDA provides guidance for these levels in the Hazards and Controls Guidance. To enforce the critical limits, the processor may monitor producers in various ways, such as on-farm visits, residue drug testing, or a Quality Assurance program.[141]

FDA conducts unannounced inspections to assess processors' compliance with HACCP requirements.[142] As discussed below, FDA has been repeatedly criticized for failing to perform adequate inspections.

Domestic Undersight

FDA does not adequately protect consumers from unsafe seafood produced by the domestic aquaculture industry. For instance, HACCP is not being properly implemented. In a 2001 analysis, the Government Accountability Office found significant gaps in the enforcement of safety requirements under HACCP.[143]

First, although HACCP regulations apply to all seafood processing facilities, FDA is unable to identify all such facilities because there is no registration requirement for seafood firms. Furthermore, aquaculture facilities are not inspected through HACCP because they are not processing facilities.

Second, the GAO report revealed that FDA is not adequately enforcing even basic HACCP requirements. For example, the report showed that FDA failed to inspect many of the seafood products selected for inspection because they were not being processed on the day FDA personnel were on site, and inspectors did not return later to complete the inspection. The report found

Table 5. **Drugs & Chemicals Approved for Use in U.S. Aquaculture**

Drug/Chemical Name	Drug Type	Species	Indication
Tricaine methanesulfonate	Anesthetic	Finfish	Sedation/anesthesia
Formalin	Parasiticid	All finfish	Control protozoa
		All finfish eggs	Control fungi Saprolegniaceae
		Penaeid shrimp	Control protozoan parasites
Chorionic Gonadotropin	Spawning hormone	Male, female brood finfish	Aid in improving spawning function
Oxytetracycline monoalkyl trimethyl ammonium	Antibiotic	Pacific salmon	Mark skeletal tissue
		Salmon	Control ulcer disease, furunculosis, bacterial hemorrhagic septicemia, pseudomonas disease
		Catfish	Control bacterial hemorrhagic septicemia, pseudomonas disease
		Lobster	Control gaffkemia
Sulfadimethoxine, ormetoprim	Antibiotic	Salmon	Control furunculosis
		Catfish	Control enteric septicemia
Sulfamerazine	Antibiotic	Rainbow, brook, brown trout	Control furunculosis

Source: FDA, available at www.fda.gov/cvm/index/aquaculture/appendix a6.htm.

that in three FDA districts in fiscal year 1999, 48 percent of the products scheduled for inspection were not inspected because they were not being processed on the day of the inspection.[144]

Furthermore, the study found that 22 percent of seafood firms had not even filed a HACCP plan and, of those that did, more than half contained significant violations.[145]

The GAO report also found that when FDA did find serious deficiencies in HACCP plans, it failed to promptly issue warning letters to the firms in violation of the requirements. GAO also found that FDA does not have measurable data to assess its success in reducing safety hazards in domestic seafood production.[146]

FOREIGN AQUACULTURE

Drug and Chemical Use in Foreign Aquaculture

While the U.S. has an established animal drug approval system, drug approval and regulation regimes in other countries vary significantly. For example, different countries employ widely incongruent practices regarding antibiotic use in aquaculture.[147] Japan and many Southeast Asian countries approve a wider range of antibiotics for use in aquaculture than do North American and European countries.[148]

Although foreign producers exporting to the U.S. are required to meet standards equivalent to those of this country, many producers do not comply with these requirements. As a result, consumers may be exposed to residues of drugs and chemicals never approved by FDA.[149] Table 6 lists drugs not approved in the U.S. but identified by FDA as being used in foreign aquaculture practices.[150]

U.S. Oversight of Aquaculture Imports

As the large majority of aquaculture products consumed in the U.S. comes from foreign markets, FDA has an important obligation to ensure that imported seafood is safe for consumers. U.S. importers may receive seafood from countries that have entered into agreements with FDA that require seafood safety processes to meet U.S. standards.[151] Importers may also import from countries not party to an agreement with FDA so long as they obtain records documenting that the seafood was processed in compliance with the HACCP system.[152]

To enforce these requirements, FDA inspects some foreign producers and domestic importers to ensure their compliance with HACCP standards.[153] Under regulations promulgated under the Bioterrorism Act, foreign and domestic facilities must register with FDA. Also, importers are required to provide advance notice of shipments arriving in the U.S., including a description of the contents of the shipments.[154] FDA also conducts inspections of some seafood at U.S. ports-of-entry to confirm its safety.[155]

The GAO found that FDA failed to inspect many seafood products selected for inspection because they were not being processed on the day of the FDA visit.

Gaps in Oversight of Seafood Imports

The U.S. seafood inspection program suffers from several serious flaws: failure to adopt or enforce equivalency agreements with exporting countries, failure to communicate safety hazards to port-of-entry personnel, inadequate numbers of

Table 6. **FDA Testing for Drugs & Chemicals Used in Foreign Aquaculture**

Drug or Chemical	FDA Testing	Drug or Chemical	FDA Testing
Acriflavine	None	**Lincomycin**	None
Amoxicillin	None	**Malachite Green** (fungicide)	Catfish None in Salmon
Ampicillin	None	**Methyldihydro-testosterone**	None
Benzocaine	None	**Methylene Blue**	None
Bicozamycin	None	**Miroxisacin**	None
Chloramphenico (antibiotic)	Shrimp	**Nalidixic acid**	None
Colistin Sulfate	None	**Nitrofurantoin**	None
Doxycycline	None	**Novobiocin**	None
Erythromycin	None	**Oleandomycin**	None
Florfenicol	None	**Oxolinic acid** (pesticide)	Catfish, Salmon, Shrimp
Flumequine (antibiotic)	Shrimp, Catfish	**Oxytetracycline** (antibiotic)	Shrimp
Fosfomycin	None	**Piromidic Acid** (antimicrobial)	Shrimp
Fruluphenicol	None	**Nifurstyrenate**	None
Furanace	None	**Spiramycin**	None
Furazolidone	None	**Sulfonamides**	None
Josamycin	None	**Thiamphenicol**	None
Kanaymin	None		
Kitasamycin	None		

Source: FDA, available at www.fda.gov/cvm/index/vmac/young_files/young_text.htm

inspectors, and failure to test for many drugs used illegally in foreign aquaculture industries.

In 2004, GAO released a report focusing on FDA's imported seafood program. The GAO report found that FDA's programs had made some improvements but warned that the improvements did not sufficiently protect consumers from unsafe imported seafood.[156] First, GAO severely criticized FDA for failing to adopt seafood safety equivalency agreements with all countries exporting to the U.S. Without equivalency agreements, FDA must rely on an importers' documentation that the seafood was produced in compliance with U.S. standards, and many importers do not have adequate documentation. Furthermore, equivalency agreements allow FDA to focus more resources on inspecting imports from countries with less advanced safety processes.[157]

GAO also found that once FDA had identified safety hazards, it did little to immediately stop the importation of seafood from that source by notifying the port-of-entry personnel. For instance, in 2002, FDA discovered serious safety deficiencies involving six foreign seafood suppliers. The agency took an average of 348 days to notify port-of-entry personnel of the problem, leaving a significant window of time during which unsafe seafood from those exporters may have been purchased by U.S. consumers.[158]

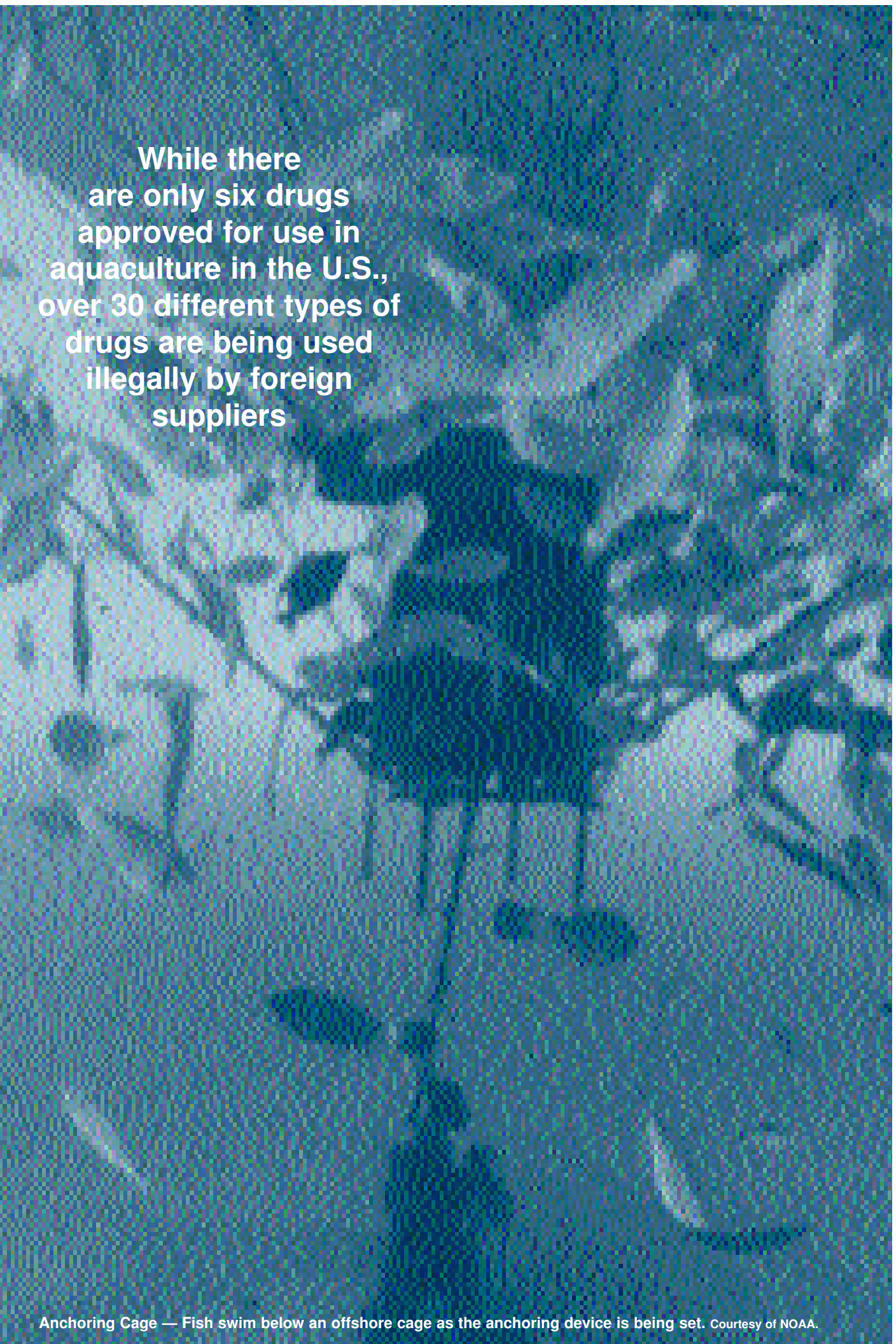
A lack of inspectors exacerbates an already dangerous problem: Fewer than 200 FDA inspectors screen the nearly 10 billion pounds of domestic and imported seafood consumed in the United States each year.[159] The 2004 GAO study found that FDA tested less than 1 percent of all seafood imported during fiscal year 1999 and only fared slightly better in 2002, testing 1.2 percent.[160]

Furthermore, when testing does occur, FDA does not test for the numerous drugs used illegally in aquaculture. While there are only six drugs approved for use in aquaculture in the U.S., there are over 30 different types of drugs being used illegally by foreign suppliers (*See Table 6*). However, of these illegal drugs and chemicals, FDA tests only for six, and then only in certain fish. For example, FDA tests for one illegal drug in salmon and for five illegal drugs in shrimp.[161] By contrast, the USDA tests for more than 50 drugs in imported meat and poultry.[162]

Fewer than 200 FDA inspectors screen the nearly 10 billion pounds of domestic & imported seafood consumed in the United States each year.

Many of these testing and inspection problems can be rectified by identifying and adopting regulatory actions taken by other countries. Also, European countries have taken a far more proactive approach to ensuring the safety of their imported seafood. For example, the Netherlands and England have repeatedly banned shipments of salmon from Chile found to contain malachite green.[163] About half of the salmon sold in the U.S. is from Chile.[164] If European countries are receiving tainted salmon, then it is highly likely that the U.S. also is receiving salmon tainted with illegal malachite green. In fact, at least two of the Chilean aquaculture companies that had salmon seized in Europe also export to the U.S."[165] Despite documents dating back to 1996 showing that FDA officials have suspected malachite green of causing cancer, FDA does not test for malachite green in salmon.[166]

Japan is another country with more stringent testing for illegal drugs and chemicals. Regulators in that country recently banned shipments of Chilean salmon after it tested positive for excessively high levels of the antibiotic oxytetracycline.[167] As with malachite green, FDA's inspection program fails to test for this antibiotic in salmon. The agency's failure to inspect for malachite green and oxytetracyclene places U.S. consumers at greater risk than consumers in other industrialized countries.



Anchoring Cage — Fish swim below an offshore cage as the anchoring device is being set. Courtesy of NOAA.

Looking Forward:
Recommendations for safe seafood

5

Numerous drugs and chemicals used in both domestic and foreign aquaculture place consumers at risk of exposure to residues of these substances, many of which are known to pose threats to human health. FDA's regulation of both domestic and imported seafood fails to adequately protect seafood consumers from these potential risks. As consumption of farm-raised seafood increases in this country, it becomes ever more critical that both FDA and the public take action to ensure consumer health and safety. The following is a list of recommendations to do just that:

IMPROVE ENFORCEMENT

FDA must dramatically increase its enforcement of existing seafood safety regulations, including HACCP and import regulations.

HACCP

FDA cannot ensure the safety of domestically produced seafood without more effectively implementing the HACCP program. A first step would be for FDA to inspect all seafood processing facilities and aquaculture facilities in the U.S. The agency should also require inspectors to revisit firms on the days when seafood products selected for inspection are being processed and conduct in-depth audits of firms to ensure that they properly meet HACCP requirements. Finally, FDA should promptly issue warning letters and create baseline information to accurately assess HACCP's progress in protecting consumers from unsafe seafood products.

Imports

FDA must focus greater attention on seafood imported into the U.S. by first establishing equivalency agreements with a greater number of importing countries. These agreements would help ensure safer processes in those countries and shift some of the burden of enforcing compliance to those governments and aquaculture firms. Also, when FDA identifies a source of potentially dan-

gerous imported seafood, it should immediately notify port-of-entry personnel to ensure that seafood from that source does not enter the U.S. market.

IMPROVE TESTING

Under the Bioterrorism Act, Congress directed FDA to better protect our nation's food supply.[168] FDA reacted to this Act by entering into a memorandum of understanding with the U.S. Customs and Border Protection.[169] By entering into this agreement, FDA is able to work with thousands of U.S. Customs inspectors to examine imported foods. Now that the agency has adequate resources, CFS recommends that FDA devote some of these resources to ensuring the safety of our seafood by testing a larger percentage of imported seafood and by testing for more illegal drugs and chemicals in more fish species.

The same testing regime should apply to domestic seafood producers as well, and FDA should require under HACCP that processors test for illegal drugs and chemicals that are reasonably likely to pose a significant risk to public safety. Because each of the drugs and chemicals discussed in this report poses a hazard to human health, FDA has an obligation to more rigorously test for them in both domestic and imported seafood.

Furthermore, as there are currently no methods for detecting hormones used in seafood production,[170] FDA should work to develop the means to detect hormones in imported products.

IMPLEMENT NEW REGULATORY PROGRAMS

FDA should implement new regulatory programs to address largely unregulated sources of potential harm, such as consumption of fish from fish farms sited near oil rigs, which are known to contaminate the marine environment with methylmercury. It is possible that those rigs could pose significant risks of contamination to nearby aquaculture facilities.

Antibiotic Use

There is an urgent need to review the current usage patterns of antimicrobials in aquaculture to identify looming hazards in food safety and infectious disease control in humans. The Center for Food Safety urges FDA to require the aquaculture industry to report the type and amount of aquaculture drugs being used. By requiring aquaculture facilities to keep accurate records on the type and amount of antibiotics used and report regularly to FDA, the agency and researchers will have a better opportunity to assess this severe problem and protect human health.

Genetically Engineered and Hormone-Treated Fish

FDA needs to establish a comprehensive and transparent regulatory framework for genetically engineered fish and fish treated with growth hormones.[171] For example, the agency should rigorously examine allergenicity, toxicity, and unintended effects of genetically engineered fish before allowing these fish to be sold to the public. Also, FDA should test the human health effects of using growth hormones on fish in light of potential links between these hormones and cancer.

Due to the numerous human health uncertainties in consuming these fish, CFS recommends that FDA impose an immediate moratorium on the sale of

genetically engineered and rBGH-treated fish until it has sufficiently demonstrated that such fish do not pose a health risk to consumers. Although FDA generally permits extralabel use of drugs with a veterinary prescription, it has prohibited the extralabel use of certain drugs, such as fluoroquinolone and glycopeptide antibiotics.[172] Similarly, FDA should prohibit extralabel use of rBGH in aquaculture until it has specifically approved the hormone for use in this context.

TIGHTEN STANDARDS

CFS encourages FDA to proactively reduce the use of antibiotics in aquaculture by withholding new approvals of antibiotics for such use. The agency also should follow the European Commission's lead in lowering the amount of dye allowed in feed. Due to the potential human health effects, FDA should look at the updated science and follow this precautionary approach.

Furthermore, the agency should update its health limits on contaminants such as PCBs so that they are consistent with EPA's. FDA's standards should reflect the most up-to-date science.

DEVELOP INCENTIVE PROGRAMS

FDA should encourage aquaculture producers to eliminate the unnecessary use of antibiotics by implementing practices that decrease their reliance on antibiotics. In Norway, for example, aquaculture producers diminished antibiotic use by more than 90 percent in a very short period of time by changing production practices and increasing use of vaccines.[173] FDA should issue guidelines or Good Manufacturing Practice statements in order to educate and encourage aquaculture producers to adopt such practices that would diminish their reliance on antibiotics.

PROVIDE CONSUMER INFORMATION

Information on Contaminants

FDA should provide the most up-to-date information to the public on the presence of potentially harmful drugs and chemicals in our seafood, including recommended numbers of servings per week for adults, children, and pregnant women. The agency has worked with EPA to issue advisories regarding safe consumption levels of fish containing mercury and should adopt similar practices for other contaminants.[174]

Regarding genetically engineered fish, FDA should adopt regulations that include measures to notify the public when a genetically engineered fish application is received and give the public an opportunity to comment before any genetically engineered fish is approved. FDA also should ensure that importers notify FDA of genetically engineered fish sent to the U.S. and follow the same regulatory requirements as domestic producers.

Labeling

Labeling is another critical method of conveying health information to consumers. First, FDA should enforce current labeling requirements. For example, the agency should address the failure of suppliers to label farmed salmon containing astaxanthin or canthaxanthin as required under the Federal Food, Drug, and Cosmetic Act.[175] As discussed above, poor labeling practices allow con-

sumers to believe they are actually buying wild salmon. It is imperative that FDA improve enforcement of labeling requirements and vigorously pursue claims of inadequate labeling.

One important labeling regime that USDA is responsible for implementing is Country of Origin Labeling (COOL). USDA's final rule on COOL became effective in April 2005.[176] COOL designates the country of origin and the method of production, "farmed" or "wild," of fish and shellfish, allowing consumers to make informed choices about the seafood products that they purchase.

FDA should require similar labeling for genetically engineered and rBGH-injected fish. If tilapia treated with growth hormones were imported into the U.S., consumers would likely be unaware that they are consuming hormone-injected fish as FDA does not require labeling of such foods. If rBGH fish become commercially available, the agency should, at a minimum, allow companies to follow a labeling regime similar to that used for dairy products. Companies that do not use milk from cows treated with rBGH may voluntarily label their products with this information, so long as they include a statement that "no significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows."[177] This label will provide consumers with important information regarding the possible health effects of seafood purchases.

ADVICE FOR CONSUMERS

Look for Labels

First, consumers can act to ensure that the seafood they purchase is safe by looking for seafood labels. Consumers can use Country of Origin Labeling to choose seafood products imported from countries that have good reputations for safe seafood production and avoid seafood from those that do not. For example, as inspections in Europe and Japan have discovered antibiotics and malachite green in salmon imported from Chile, consumers may wish to avoid Chilean imports.

Also, consumers can avoid many of the above drugs and chemicals, including antibiotics, environmental contaminants, malachite green, fish dyes, and the numerous other unapproved drugs being used in aquaculture, by purchasing seafood products labeled as "wild."

Another label that will help consumers is the USDA certified organic label for fish. Standards for organic fish have not yet been established, but if the standards are similar to those for terrestrial animals, the use of the drugs and chemicals mentioned above will be banned. Compliance with these standards will be assessed by accredited certifying agents.

Monitor FDA

Consumers can work to ensure that FDA enforces its own labeling requirements. For example, on April 23, 2003, class action lawsuits were filed against the nation's three largest grocery store chains—Safeway, Albertsons, and The Kroger Family—arguing that these stores failed to comply with FDA labeling requirements.[178] Smith and Lowney, the law firm bringing the case, sought a court order requiring retailers to conform to federal law in labeling their artificially colored salmon products, as well as civil penalties and damages for consumers.[179]

Pressured by litigation, these grocery stores complied with FDA requirement and as a result, consumers are likely seeing more and more grocery stores

identifying these color additives in their farmed fish.[180] Consumers should look for such labels when buying seafood and should demand that retailers ensure that their suppliers are accurately labeling seafood products.

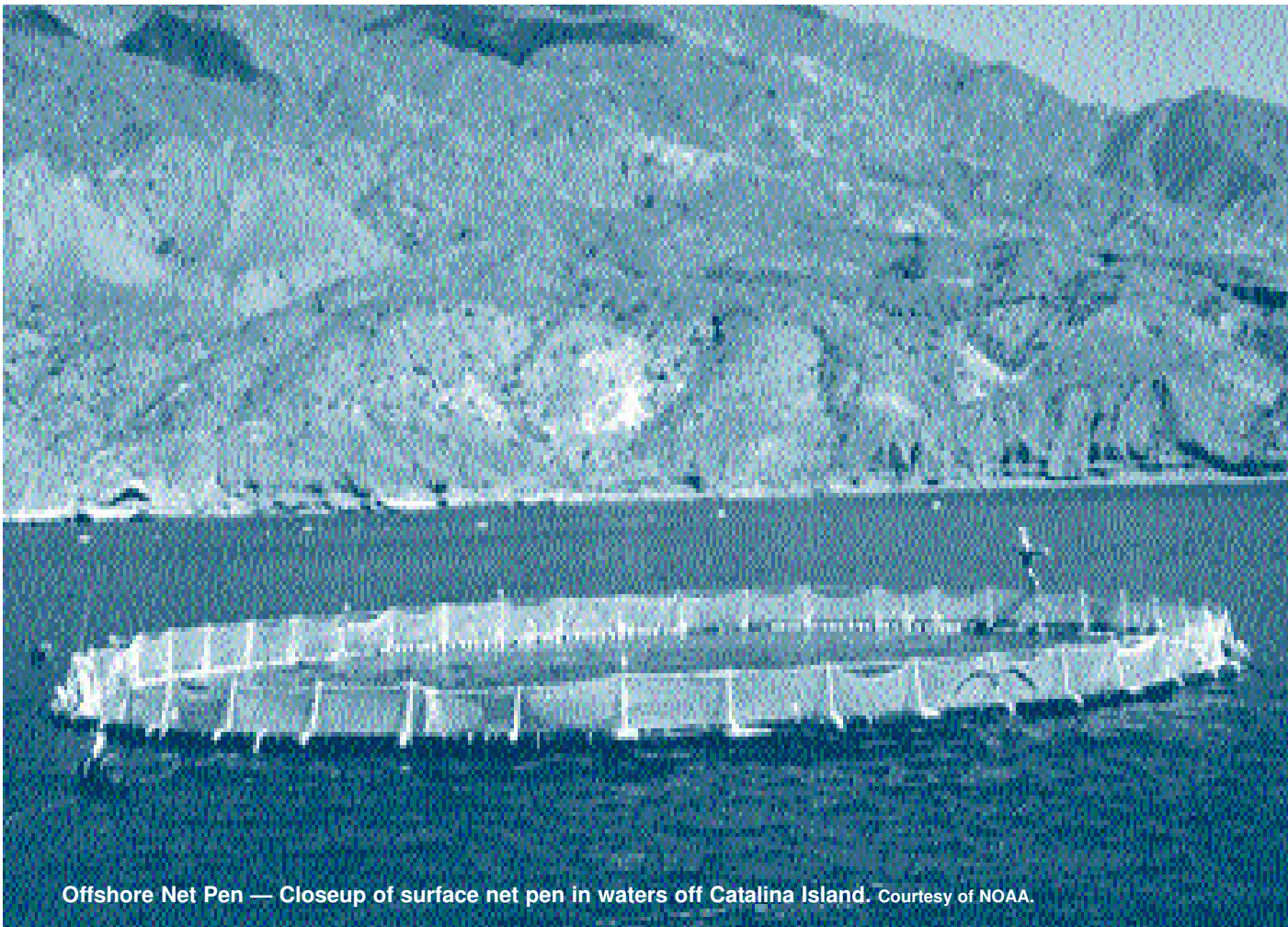
Similarly, consumers can demand that local markets provide safe seafood by, for example, requesting that their supermarkets carry seafood that does not contain antibiotics.

Provide Information to FDA and Congress

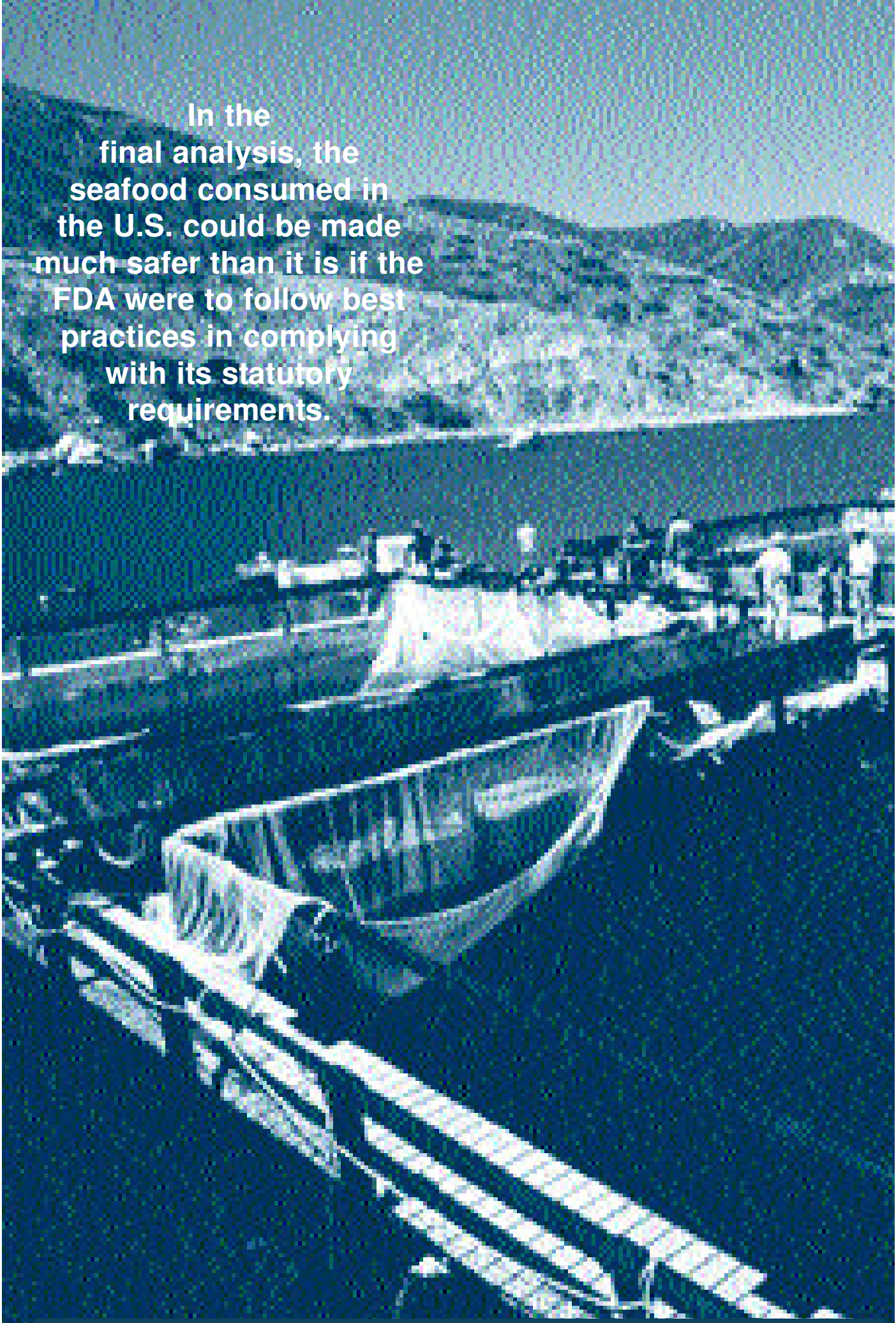
Finally, consumers can take the important action of informing Congress and FDA of their concerns about seafood safety.

Consumers should also demand that FDA regularly issue risk-based consumption limits for environmental contaminants by identifying the amount of fish a person can safely eat per month. Similarly, consumers should demand that FDA inform them when the agency receives an application for a genetically-modified fish, allow consumers time to comment on the application, and provide for proper labeling of such products.

Consumers that would like to urge FDA to implement mandatory labeling for genetically engineered foods can do so by sending an e-mail to the agency at www.centerforfoodsafety.org/action4.cfm. To demand that FDA impose a moratorium on genetically engineered fish until research demonstrates their safety, consumers can send comments to the agency at www.centerforfoodsafety.org/action2.cfm.



Offshore Net Pen — Closeup of surface net pen in waters off Catalina Island. Courtesy of NOAA.



In the final analysis, the seafood consumed in the U.S. could be made much safer than it is if the FDA were to follow best practices in complying with its statutory requirements.

Surface Net Pen — Net pen being used for experimental project on raising bluefin tuna. Courtesy of NOAA.

Bottom Line:

Necessary steps for FDA

6

In the final analysis, the seafood consumed in the U.S. could be made much safer than it is if the Food and Drug Administration were to follow best practices in complying with its statutory requirements. These practices include the recommendations discussed in the preceding chapter and summarized below:

Improve Enforcement

- Work to improve enforcement of the HACCP program to ensure the safety of domestic aquaculture products.
- Take steps to more effectively protect consumers against unsafe imported seafood by establishing equivalency agreements with exporting countries.

Improve Testing

- Expand its range of testing to detect all potentially harmful drugs and chemicals and to test for these drugs and chemicals in more species of fish.
- Require the domestic and foreign aquaculture industry to report the type and amount of aquaculture drugs used, then monitor compliance.
- Test for PCBs and other environmental contaminants.

Implement New Regulatory Programs

- Impose a moratorium on the sale of genetically engineered fish and fish treated with growth hormones until the agency establishes a transparent and comprehensive regulatory framework.
- Examine allergenicity, toxicity, and unintended effects of genetically engineered fish before allowing these fish to be sold to the public.
- Require importers to notify the agency if importing genetically engineered fish into the U.S. and require importers to fully follow the agency's regulatory requirements.

Tighten Standards

- Update the health limits for environmental contaminants such as PCBs so that they are consistent with the EPA's risk-based consumption standards.

Develop Incentive Programs

- Develop incentive programs to reduce the unnecessary use of drugs and chemicals in aquaculture.

Provide Information to Consumers

- Provide information to the public regarding the presence of drugs and chemicals in seafood.
- Require that retailers and producers provide consumers with information to help them make informed choices about their seafood purchases. Develop and enforce labeling standards for aquaculture products.

FOR CONSUMERS

Consumers can also act to ensure that they are purchasing the healthiest seafood for themselves and their families. The Center for Food Safety recommends that consumers:

Look for Labels

- Look for the Country of Origin Labeling (COOL) to distinguish between farmed and wild salmon and to identify the country in which the fish were caught or farmed.
- Urge the USDA to establish organic standards for aquaculture, and provide input for creation of these standards.

Monitor FDA

- Demand that FDA enforce its labeling requirements and that retailers ensure their suppliers are accurately labeling seafood products.
- Request that local markets carry seafood that does not contain antibiotics.

Provide Information to FDA

- Demand that FDA regularly issue risk-based consumption limits for environmental contaminants, identifying the amount of fish a person can safely eat per month.
- Let FDA know that the public should (1) be notified when a genetically engineered fish application is received, (2) have an opportunity to comment, and (3) be made aware of genetically engineered fish products in the market place through proper labeling.
- Check the Center for Food Safety's Web site for the latest information on fish farming www.centerforfoodsafety.org.

References:

1 U.S. Gen. Accounting Office, FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed, GAO-04-246 (Jan 2004) [hereinafter "GAO 2004"], available at www.gao.gov/new.items/do4246.pdf.

2 Food & Agric. Org. of the U.N., 1995a. Aquaculture Production Statistics, Rome 186 (1984-1993).

3 See Rebecca J. Goldburg et al., Pew Oceans Comm'n, Marine Aquaculture in the United States: Environmental Impacts and Policy Options (2001), available at www.pewoceans.org/reports/137PEWAquacultureF.pdf.

4 Food & Agric. Org. of the U.N., The State of the World Fisheries and Aquaculture (2002), available at www.fao.org/docrep/005/y7300e/y7300e04.htm#P1204_5310.

5 Id.

6 Kim R. Young, U.S. Food & Drug Admin., Aquaculture: A Need for Import Tolerances (Jan. 24, 2002), available at www.fda.gov/ohrms/dockets/ac/02/slides/3816s1_05_young/index.htm [hereinafter "Import Tolerances"].

7 Id.

8 Econ. Research Serv., U.S. Dep't of Agric., Briefing Room - Aquaculture: Overview [hereinafter "USDA Briefing Room"], available at www.ers.usda.gov/briefing/aquaculture/overview.htm (last visited Sept. 14, 2004).

9 Nat'l Oceanic & Atmospheric Admin., Seafood Consumption Rose Again in 2003 (Sept. 27, 2004), available at www.noaanews.noaa.gov/stories2004/s2322.htm.

10 Import Tolerances, supra note 6.

11 Id.

12 Id.

13 USDA Briefing Room, supra note 8.

14 Id.

15 Id.

16 Memorandum from Frederick Angulo, D.V.M., Ph.D., Medical Epidemiologist, Foodborne & Diarrheal Diseases Branches, Division of Bacterial & Mycotic Diseases, National Center for Infectious Diseases, to the record [hereinafter "Memorandum"].

17 Bruce Nicholson, Fish Diseases in Aquaculture (Univ. of Maine, Orono, Maine), Jan. 11, 2000, available at www.umaine.edu/mainesci/Archives/MolecularBiology/salmon-diseases.htm.

18 Charles M. Benbrook, Antibiotic Drug Use in U.S. Aquaculture, The Northwest Sci. & Envtl. Policy Ctr. 5 (Feb. 2002) [hereinafter "Antibiotic Drug Use in U.S."]; Sara Graslund & Bengt-Erik Bengtsson, Chemicals and Biological Products Used in South-East Asian Shrimp Farming, and Their Potential Impact on the Environment - A Review, 280 Sci. Total Env't 93, 114 (2001).

19 Ctr. for Food Safety & Applied Nutrition, Food & Drug Admin., Aquaculture Drugs (A Chemical Hazard), Fish & Fisheries Products Hazards & Controls Guidance: Third Edition (Jun. 2001) [hereinafter "Hazards & Controls Guidance"], available at www.cfsan.fda.gov/~comm/haccp4k.html.

20 Antibiotic Drug Use in U.S., supra note 18, at 3.

21 Id.

22 Id. at 5 (explaining that given the lack of data collection, it's likely that "short-term spikes in antibiotic use would not be detected by government regulatory officials or public health experts"). For a different calculation on the amount of drugs used in aquaculture, see Drugs Used in the US Aquaculture Industry (Nov. 2003) [hereinafter "Drugs Used in the U.S. Aquaculture Industry"], available at www.aquanic.org/asap/white_pages/drugs.pdf.

23 Antibiotic Drug Use in U.S., supra note 18, at 8.

24 Sarah K. Cox, Raincoast Conservation Society, Diminishing Returns: An Investigation into the Five Multinational Corporations that Control British Columbia's Salmon Farming Industry 28 (Dec. 2004), available at www.raincoast.org/files/DiminishingReturns_final.pdf.

25 Id. at vi-vii.

26 Id. at 3.

27 Warren Bell, Human Health Risks Associated With Salmon Farming, presented to the Federal Standing Committee on Fisheries & Oceans on behalf of Friends of Clayoquot Sound (May 7, 2002), available at www.watershed-watch.org/ww/publications/sf/PaoneBellBriefSCFO.PDF.

28 Antibiotic Drug Use in U.S., supra note 18, at 3.

29 See Douglas G. Capone et al., Antibacterial Residues in Marine Sediments and Invertebrates Following Chemotherapy in Aquaculture, 145 Aquaculture 55, 56 (1996) (explaining that "a large fraction of some antibacterial agents supplied to the culture animal, typically in the form of feed additives, is not absorbed and retained by the animal, but is released to the environment . . . ") [hereinafter "Capone"].

30 Ruth-Anne Sandaa et al., Transferable Drug Resistance in Bacteria from Fish-Farm Sediments, 38 Can. J. Microbiol. 1061, 1063, 1065 (1992) (concluding that "fish pathogens can survive in marine environments . . . bacteria with transferable resistant plasmids and fish pathogenic bacteria in sediments creates situations where transfer of resistance to the pathogenic bacteria is possible").

31 Rebecca Goldberg & Tracy Triplett, Murky Waters: Environmental Effects of Aquaculture in the U.S., Environmental Defense Fund 44 (1997).

32 Id.

33 Capone, supra note 29, at 73.

34 Hazards & Controls Guidance, supra note 19.

35 Ctr. for Veterinary Med., U.S. Food & Drug Admin., Extralabel Use of Approved Drugs in Aquaculture, Program Policy & Procedures Manual, Guide 1240.4210 (Oct. 29, 1997).

36 Dan McGovern, Can Global Standards Calm Chemical Residue Concerns?, Intrafish 8-9 (Jan. 2004), available at www.intrafish.com/pdf/download/3877e184a05bee565d25191ab086ee8d/2004/1/08.pdf and www.intrafish.com/pdf/download/3877e184a05bee565d25191ab086ee8d/2004/1/09.pdf.

37 Press Release, Food & Drug Admin., FDA Increases Sampling of Imported Shrimp and Crayfish (Crawfish) (Jun. 14, 2002), available at www.fda.gov/bbs/topics/NEWS/2002/NEW00815.html.

38 Public Citizen, Chemical Cocktail: The Health Impacts of Eating Farm-Raised Shrimp, 6 (Dec. 2004).

39 McGovern, supra note 36, at 8.

40 Steven Hedlund, CBS Report Fails to Dampen Shrimp Sales, SeaFood Business, Nov. 2004.

41 Id.

42 Nitrofurans, including the drugs nitrofurazone and furazolidone, are antibiotics that, despite their carcinogenic nature, were at one time approved by the FDA for certain limited uses in food-producing animals. 67 Fed. Reg. 5470 (Feb. 6, 2002) (codified at 21 C.F.R. pt. 530). In light of new evidence indicating that nitrofuran residues may be present in edible tissues of animals who are only treated topically with nitrofurans, the FDA has declared that "no nitrofuran product may be legally used in food-producing animals." Id. at 5471.

43 Food Standards Agency, Eating Safely at Home: Nitrofurans, available at www.food.gov.uk/healthiereating/asktheexpert/eatingsafely/nitrofuransaskexpert (last visited Oct 15, 2004).

44 McGovern, supra note 36, at 8.

45 67 Fed. Reg. 5470.

46 McGovern, supra note 36, at 8.

47 U.S. Newswire, Seafood Industry Calls for Additional Safeguards on Imports; Pilot Program Would Target Antibiotic Residues (Aug. 9, 2004) (explaining that the National Fisheries Institute has established guidance documents to help assist foreign fish producers under HACCP), available at http://releases.usnewswire.com/GetRelease.asp?id=34485.

48 Conversation with a concerned consumer (Sept. 23, 2004) (reporting that a fish feed facility in Mississippi is illegally using nitrofurans).

49 Cox, supra note 24, at 24.

50 Id.

51 Id. at 23.

52 Theresa Rothenbush, Press Release, Raincoast Conservation Society, Report Shows Health Canada Allowing Widespread Use of Emergency Drug in Farmed Salmon (Dec. 13, 2004), available at www.raincoast.org/news_releases/emergency_drug.htm.

53 Id.

54 Cox, supra note 24, at 25.

55 Rothenbush, supra note 52.

56 Background Document for the Joint WHO/FAO/OIE Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment, Geneva, Switzerland, 1-5 (Dec. 2003), available at www.who.int/salmsurv/links/en/background.pdf.

57 Id. at 2. The term "antimicrobial" is used as a synonym for antibiotic. Id. at 5.

58 US Food and Drug Administration, Antibiotic Resistance (2003), available at www.fda.gov/oc/opacom/hottopics/anti_resist.html.

59 Henning Sorum, Antibiotic Resistance in Aquaculture, 92 Acta Vet. Scand. Suppl. 29, 34 (1999).

60 Id.

61 American Society for Microbiology, Report of the ASM Task Force on Antibiotic Resistance (July 4, 1994) [hereinafter "ASM report"], available at www.asm.org/ASM/files/CCPAGECONTENT/DOCFILENAME/0000005962/antibiot[1].pdf.

62 There is a lack of federal standards regarding drug use in aquaculture. FDA decides whether or not to approve a drug for aquaculture use but does not impose a mandatory reporting/monitoring requirement for the use of drugs by fish farmers.

63 Antibiotic Drug Use in U.S., supra note 18 (citing ASM Report, supra note 42).

64 Memorandum, supra note 16, at 2.

65 Id.

66 S.J. Culp & F.A. Beland, Malachite Green: A Toxicological Review, 15 J. Am. Coll. Toxicol. 219, 222 (1996).

67 Id.

68 Shivaji Srvastava et al., Toxicological Effects of Malachite Green, 66 Aquatic Toxicol. 319, 324 (2004) [hereinafter "Toxicological Efects"] (citing D.J. Alderman, Malachite Green and Alternatives as Therapeutic Agents, 16 Eur. Aquacult. Soc. Bredene 235 (1992)).

69 Bongsup P. Cho et al., Synthesis and Characterization of 4'-Amino and 4'-Nitro Derivatives of 4-N, N-Dimethylaminotriphenylmethane as Precusors for a Proximate Malachite Green Metabolite, 56 Tetrahedron 7379, 7379 (2000).

70 Culp & Beland, supra note 66, at 220.

71 Toxicological Effects, supra note 53, at 320 (citing R.A. Schnick, The Impetus to Register New Therapeutants for Aquaculture, 50 Prog. Fish-Cult. 190 (1988)).

72 Culp & Beland, supra note 66, at 220.

73 Sean Poulter, Cancer-Link Chemical Found in Store Salmon, The Daily Mail, Aug. 10, 2004.

74 Cox, supra note 24, at 28.

75 Dan McGovern, Chilean Salmon Farming Industry Using Cancerous Minerals to Clean Fish, Worldcatch (May 23, 2002).

76 Toxicological effects, supra note 53, at 324; see also National Toxicology Program, U.S. Department of Health & Human Services, NTP Technical Report on the Toxicity Studies of Malachite Green Chloride and Leucomalachite Green Administered in Feed to F344/N Rats and B6C3F1 Mice (June 2004) (discussing study on rats and mice), available at http://ehp.niehs.nih.gov/ntp/members/tox71/tox71-full.pdf.

77 Id.

78 Id.

79 Id.

80 See Press Release, Smith & Lowney, P.L.L.C., Buyer Beware: Something Fishy about Farm Raised Salmon (Apr. 23, 2003) [hereinafter "Smith & Lowney"], available at www.smithandlowney.com/salmon/pressrelease/.

81 Linda Joyce Forristal, The Great Salmon Scam, Insight on the News, June 12, 2000, available at www.findarticles.com/p/articles/mi_m1571/is_22_16/ai_62741745.

82 Smith & Lowney, supra note 80.

83 Stewart Anderson, International Institute of Fisheries Economics & Trade, Salmon Color and the Consumer "Eye Appeal is Buy Appeal" (2000), available at http://oregonstate.edu/Dept/IIFET/2000/abstracts/andersons.html.

84 B. Bateman et al., The Effects of a Double Blind, Placebo Controlled, Artificial Food Colourings and Benzoate Preservative Challenge on Hyperactivity in a General Population Sample of Preschool Children, 89 Arch. Dis. Child. 506 (June 2004), discussed in Ban Artificial Food Colourings, BBC News, May 25, 2004, available at http://newssearch.bbc.co.uk/1/hi/health/3742423.stm.

85 Press Release, European Union, Brighter Eyesight or Brighter Salmon? Commission Decides New Rules on Coluring Feed Additive (Jan. 27, 2003), available at: http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/123&format=HTML&a; see Alejandro Espaillat et al., Canthaxanthine Retinopathy, 117 Archives of Opthamology 412 (1999); see also European Commission, Health & Consumer Protection Directorate-General, Opinion of the Scientific Committee on Animal Nutrition on the Use of Canthaxanthin in Feedingstuffs for Salmon and Trout, Laying Hens, and Other Poultry, 18 (adopted Apr. 2002) (explaining that the "use of canthaxanthin in salmonids production leads to residues in the flesh that could expose some human consumers to amounts of canthaxanthin in excess of the ADI").

86 Press Release, WorldSeafoodMarket, EC Adopts Regulation Cutting Canthaxanthin in Salmon and Poultry Feed (Jan. 29, 2003) (citing the Commissioner for Health & Consumer Protection as saying that "scientific assessments have shown that a high intake of Canthaxanthin produces an accumulation of pigments in the retina, affecting the sight").

87 FDA Listing of Color Additives Exempt from Certification, 21 C.F.R. § 73.75 (2004).

88 Anderson, supra note 83.

89 Forristal, supra note 81.

90 Nick Jans, Farmed Salmon Can't Beat Wild, USA Today, Oct. 6, 2002, available at http://www.usatoday.com/news/opinion/editorials/2002-10-06-oplede_x.htm.

91 Ronald A. Hites et al., Global Assessment of Organic Contaminants in Farmed Salmon, 303 Science 226 (Jan. 9, 2004) [hereinafter "Organic Contaminants"], available at http://www.pewtrusts.com/pdf/salmon_study.pdf.

92 Robert McClure & Lisa Stiffler, Sound's Salmon Carry High PCB Levels but State Says Health Benefits of Eating the Fish Outweigh Risks, Seattle Post-Intelligencer, Jan. 15, 2004.

93 Michael Weber, What Price Farmed Fish, 28, SeaWeb, (2003) (citing M.D.L. Easton et al., Preliminary Examination of Contaminant Loadings in Farmed Salmon, Wild Salmon and Commercial Salmon Feed, 46 (7) Chemosphere 1053 (Feb. 2002)), available at www.seaweb.org/resources/sac/pdf/WhatPriceFarmedFish_low.pdf.

94 Id.

95 Organic Contaminants, supra note 91, at 226.

96 Id. at 227.

97 Id. at 228.

98 Jeffery A. Foran, "Risk-Based Consumption Advice For Farmed Atlantic and Wild Pacific Salmon Contained with Dioxins and Dioxin-like Compounds": Envtl. Health Persp. 552-6 (May 2005). Foran JA, et al.

99 Id.

100 See Gina Kolata, Farmed Salmon Have More Contaminants Than Wild Ones, Study Finds, NY Times, Jan. 9, 2004; Juliet Eilperin, Farmed Salmon Raise Concerns, Wash. Post, Aug. 11, 2004, at A03 [hereinafter "Farmed Salmon Raise Concerns"].

101 Id.

102 Gulf Restoration Network, The Threat of Mercury from Discharges from Oil and Gas Platforms (2002), available at www.gulfrestorationnetwork.org/mercury/issues.htm.

103 Rigs to Reefs Act of 2003, H.R. 2654, 108th Cong. (2003).

104 Cox, supra note 24, at 10.

105 Weber, supra note 93, at 28 (citing J.K. Huwe, Dioxins in Food: A Modern Agricultural Perspective, 50 J. Agric. Food Chem. 1739 (2002)).

106 Farmed Salmon Raise Concerns, supra note 100.

107 U.S. Dep't of Health & Human Services & U.S. Envtl. Prot. Agency, What You Need to Know about Mercury in Fish and Shellfish (Mar. 2004), available at http://vm.cfsan.fda.gov/~dms/admehg3.html.

108 Environmental Working Group, PCBs in Farmed Salmon (EPA's standards were updated in 1999 based upon the most up to date science whereas FDA has not updated its limits since 1984. The limits set by each agency are dramatically different. EPA's limits are 500 times more protective than the limits set by FDA.), available at http://www.ewg.org/reports/farmedPCBs (last visited Sept. 22, 2004).

109 Organic Contaminants, supra note 91, at 228 (citing EPA, 2 Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories: Risk Assessment and Fish Consumption Limits (2000), available at www.epa.gov/ost/fishadvice/volume2/index.html); Ctr. for Food Safety & Applied Nutrition, Food & Drug Admin., Fish and Fisheries Products Hazards and Controls Guidance, available at www.cfsan.fda.gov/~acrobat/haccpc09.pdf (last visited Oct. 1, 2004).

110 Organic Contaminants, supra note 91, at 229.

111 Tony Reichhardt, Will Souped Up Salmon Sink or Swim?, 406 Nature 10 (July 6, 2000), available at www.med.harvard.edu/chge/textbook/newtopics/aquaculture/salmon.pdf.

112 Choy L. Hew & Garth Fletcher, Transgenic Fish for Aquaculture, Chemistry & Industry (1997).

113 Id.

114 In addition to food safety concerns, there are also serious environmental risks with genetically engineered fish. See Ctr. for Food Safety, Petition Seeking a Moratorium on the Domestic Marketing and Importation of Transgenic Fish (May 2001) [hereinafter "Center for Food Safety Petition"], available at http://www.gefish.org.

115 Nat'l Acad. of Sci., Animal Biotechnology: Science Based Concerns, 70 (2002).

116 John Matheson, Food & Drug Admin., Will Transgenic Fish Be the First Ag-Biotech Food-Producing Animals?, 9 FDA Veterinarian (May/June 1999), available at www.fda.gov/cvm/index/fdavet/1999/may.html#transgenics.

117 See AquaBounty, Faster Growing Salmon Could Give Growers Competitive Edge (adapted from Prince Edward Island Dep't of Fisheries & Env't, Aquaculture Review (1997)), available at www.aquabounty.com/peidof.htm.

118 See, e.g., Zhang P., Institute of Oceanology, Chinese Academy of Sciences, Genetic Manipulation of Olive Flounder (discussing the fast-growing transgenic flounder and the all-female flounder), available at www.imbc.gr/biblio_serv/aquachallenge/zhang.html (last visited Oct. 4, 2004); A/F Protein Inc., Winter Flouder (discussing use of the flounder's antifreeze protein in other organisms), available at www.afprotein.com/flounder.htm (last visited Oct. 1, 2004).

119 Richard Howard, Genetically Modified Male Mating Advantage and the Trojan Gene Effect in a Fish, ISB News Report (Apr. 2004) (discussing salmon growth hormone gene (sGH) driven by a metallothionine (Mt) promoter), available at www.gene.ch/genet/2004/Apr/msg00028.html.

120 Andrew Pollack, Gene-Altering Revolution Nears the Pet Store: Glow-in-the-Dark Fish, N.Y. Times, Nov. 22, 2003, available at www.nytimes.com/2003/11/22/science/22FISH.html.

121 See J.K. Lu et al., Production of Transgenic Silver Sea Bream (Sparus sarba) by Different Gene Transfer Methods, 4 (3) Marine Biotechnology 328-37 (June 2002), available at www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14961266.

122 See Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 46 (Jan. 2001) [hereinafter "Elements of Precaution"].

123 Matheson, supra note 116; Elements of Precaution, supra note 122, at 87-89 (explaining that unintended genetic changes in fish is

the rule rather than the exception, and includes changes in enzyme activity, gross anatomy, behavior, and hormonal activity).

124 See Elements of Precaution, supra note 122, at 89.

125 Id. at 87-89.

126 Food & Agric. Org. of the U.N., Technical Guidelines for Responsible Fisheries Aquaculture Development - 5 30 (1997), available at ftp://ftp.fao.org/docrep/fao/003/W4493e/W4493e00.pdf.

127 21 C.F.R. § 522.1081 (2001).

128 Brett Wilkison, Tilapia Growth Hormone Test, 19 Cal. Coast & Ocean 24 (2003-2004). The study was partly funded by the Monsanto Company ($80,000) and by Sea Grant ($100,000). Monsanto developed and patented the rBGH drug POSILAC.

129 Id.

130 Food & Agric. Org. of the U.N. (1997), supra note 112, at 30.

131 Monsanto Company, POLISAC (1993) (on file with author).

132 Wilkison, supra note 128, at 25-26.

133 Id. at 26.

134 21 U.S.C. § 301 et seq.

135 See, e.g., Carol Lewis, A New Kind of Fish Story: The Coming of Biotech Animals, FDA Consumer (Food & Drug Admin., Rockville, Md.), Jan.-Feb. 2001, available at www.fda.gov/fdac/features/2001/101_fish.html.

136 FDA New Animal Drug Applications, 21 C.F.R. § 514.1 (2004).

137 21 U.S.C. § 360b(b)(1)(A) (2004).

138 FDA Fish & Fishery Products, 21 C.F.R. § 123.6 (2004).

139 Hazards & Controls Guidance, supra note 19.

140 FDA Fish & Fishery Products, 21 C.F.R §§ 123.6, 123.8 (2004).

141 Hazards and Controls Guidance, supra note 19.

142 GAO 2004, supra note 8.

143 U.S. Gen. Accounting Office, Federal Oversight of Seafood Does Not Sufficiently Protect Consumers, GAO-01-204 (Jan. 2001) [hereinafter "GAO 2001"], available at http://www.gao.gov/new.items/d01204.pdf.

144 Id. at 17.

145 Id. at 18.

146 Id. at 5-6.

147 Drugs Used in the U.S. Aquaculture Industry, supra note 22.

148 World Health Org., Technical Report Series No. 883, Food Safety Issues Associated with Products from Aquaculture 23 (1999).

149 R.A. Schnick, U.S. Joint Subcomm. on Aquaculture, World Aquaculture Drug and Vaccine Registration Progress, available at http://ag.ansc.purdue.edu/aquanic/jsa/aquadrugs/publications/world_drug_progress_9-20-99.htm (last visited Sept. 17, 2004).

150 Import Tolerances, supra note 5.

151 FDA Fish & Fishery Products, 21 C.F.R. § 123.12 (2004); see GAO 2004, supra note 6, at 2.

152 GAO 2004, supra note 8, at 2.

153 Id.

154 Press Release, U.S. Food & Drug Admin., HHS Issues New Rules To Enhance Security of the U.S. Food Supply (Oct. 9, 2003), available at www.hhs.gov/news/press/2003pres/20031009.html.

155 7 U.S.C. § 136 et seq. EPA is responsible for licensing pesticides. EPA and FDA set "action levels" for pesticides such as DDT.

156 GAO 2004, supra note 8.

157 Id. at 16 (FDA required importers to document compliance with U.S. requirements rather than entering into equivalency agreements. GAO found that importers are far from complying with U.S. requirements, estimating that importers had 48 percent of the required documentation.).

158 Id. at 5.

159 Michael Milstein, Imported Seafood Goes Untested, The Oregonian (Sept. 14, 2003), available at www.eurocbc.org/usa_imported_seafood_untested_14sept2003page1269.html.

160 GAO 2004, supra note 8, at 4.

161 Import Tolerances, supra note 6.

162 Milstein, supra note 159.

163 Id.

164 Id.

165 Id.

166 Id.

167 Id.

168 Public Health Security & Bioterrorism Preparedness & Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in scattered sections of 21 U.S.C.).

169 Press Release, U.S. Food & Drug Admin., FDA and CBP Bolster Safeguards on Imported Food (Dec. 3, 2003), available at www.fda.gov/bbs/topics/NEWS/2003/NEW00988.html.

170 Id.

171 See Center for Food Safety Petition, supra note 114 (outlining detailed recommendations to FDA on regulatory framework for genetically engineered fish).

172 Ctr. For Veterinary Med., U.S. Food & Drug Admin., CVM Makes the Analysis of Comments on the Fluoroquinolone and Glycopeptide Prohibition Available to the Public (Jan. 15, 1998), available at www.fda.gov/cvm/index/updates/fqcomanalup.html.

173 World Health Org., Use of Antimicrobials Outside Human Medicine and Resultant Antimicrobial Resistance in Humans (Jan. 2002), available at www.who.int/mediacentre/factsheets/fs268/en/.

174 Dep't of Health & Human Services & Envtl. Prot. Agency, What You Need to Know About Mercury in Fish and Shellfish (Mar. 2004), available at www.cfsan.fda.gov/~dms/admehg3.html.

175 See Smith & Lowney, supra note 80.

176 68 Fed. Reg. 61944 (proposed Oct. 30, 2003). USDA issued an interim final rule to delay implementation for six months. USDA, Interim Final Rule - Country of Origin Labeling of Fish and Shellfish (Sept. 30, 2004), available at www.ams.usda.gov/cool.

177 Interim Guidance on the Voluntary Labeling of Milk & Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).

178 Lori Thomas v. Albertson's, Inc., Heather Dolin et al. v. Safeway, Inc., Cristopher Krupp et al. v. Kroger Co., Fred Meyer Stores, Inc., & QFC Sub. Inc. (Wash. Super. Ct. filed Apr. 23, 2003).

179 See Smith & Lowney, supra note 80.

180 Mary E. Alexander, Salmon to Dye For, June 23, 2003, available at, www.lauflaw.com/editorialarchives/salmon.htm (last visited Sept. 26, 2004).

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