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FISH

Harmful Aquaculture Chemicals and Waste Slip Through Regulatory Cracks

Backgrounder • November 2009

With many wild fish resources depleted worldwide, offshore aquaculture is billed by some as the only way to increase future fish production. However, this industry is plagued with various problems, including the regular use of chemicals and antibiotics — many of which are associated with serious health risks and potential for disrupting the natural environment.

Offshore aquaculture (also known as ocean fish farming and open water aquaculture) is the mass production of finfish in huge, often overcrowded cages in open ocean waters. In recent years, Congress has been pushed to approve federal legislation that would allow this industry in U.S. federal waters (from about 3 miles offshore out to 200 miles, except off Texas and west Florida, where federal waters begin at about 9 miles from shore). Thus far, no bills have come to pass, largely due to massive public opposition. But industry enthusiasts– including our own National Oceanic and Atmospheric Administration (NOAA), the very agency tasked with conservation and management of U.S. ocean resources — have continued to feverishly push the development of offshore aquaculture in the U.S. Both regional plans and state projects have moved forward, and new federal legislation is expected to be introduced in Congress that will promote a standardized national program for offshore aquaculture. Unfortunately, there still has not been a bill or plan to address the many potential negative effects on the environment, consumers, fishing businesses and coastal communities from a nationwide offshore aquaculture industry.

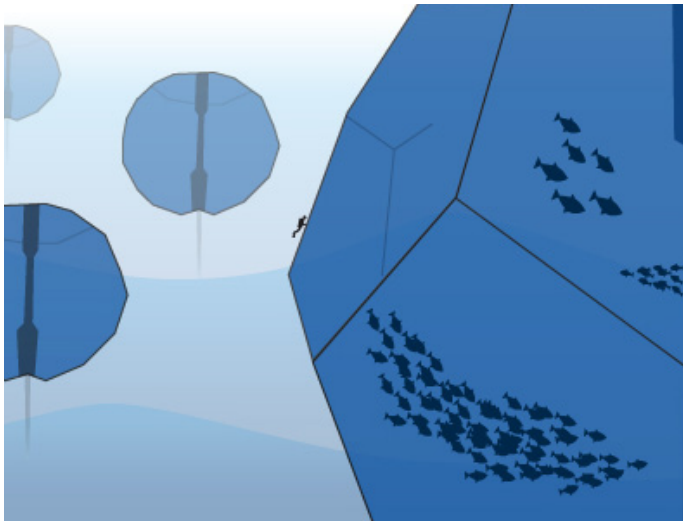

Illustration of proposed aquaculture cages off the coast of Hawaii.

One of the very serious human health and ecological concerns with offshore aquaculture, detailed below, is the use of chemicals and drugs, for which there is not a sufficiently strong regulatory system in place.

Problems associated with using drugs and chemicals in the open ocean

A recent article published in *Clinical Infectious Diseases* describes how the use of antimicrobial agents in aquaculture leads to the creation of drug-resistant bacteria, from which resistance genes may transfer to human pathogens. In other words, "drug-resistant pathogens from the aquatic environment may reach humans directly." Resistance of human pathogens to antimicrobial agents used in aquaculture "severely limits the therapeutic options in human infection."[1]

Marine organisms can be harmed by irresponsible use of chemicals. For example, research published in the *ICES Journal of Marine Science* found that "chemicals used in the treatment of sea-lice infestations are lethal to shrimp and lobsters." Moreover, lobsters exposed to concentrations of the drug not strong enough to kill them "had decreased reproductive success compared to control lobsters."[2]

An offshore aquaculture cage off the coast of Hawaii. Photo by the National Oceanic & Atmospheric Administration (NOAA).

Aquaculture Drugs in the United States

There are eight types of drugs approved for use in aquaculture in the U.S.[3] Four are antibiotics, one is used for antibacterial purposes, one is used to combat parasites, one is a hormone used in spawning, and one is used to temporarily immobilize fish. Of these, only three (the hormone, the parasiticide, and one of the antibiotics) are explicitly approved for all types of finfish that could be grown in ocean fish farming. Plus, one antibiotic is only explicitly approved for fry or fingerlings, and the hormone for broodfish.[4] This could easily give the impression that regulation of aquaculture drugs in the United States takes a very precautionary stance. Indeed, proponents of ocean fish farming argue that the United States is a safer place to practice offshore aquaculture because chemicals and drugs are regulated more extensively than in other countries. However, due to regulatory categories, a policy on "extra-label" drug use, and Investigational New Animal Drugs (INADs), it is possible for additional, and possibly very dangerous, drugs and chemicals to be used in U.S. offshore aquaculture.

Drugs of low regulatory priority

The Food and Drug Administration (FDA) has regulatory priority guidelines for drugs, classifying some as "high regulatory priority," and others as "low regulatory priority."[5] FDA is unlikely to object to use of drugs in the latter category. Two drugs, copper sulfate and potassium permanganate, have had their status deferred, pending further study. **These chemicals are known to be potentially dangerous to humans: exposure to copper sulfate can cause liver and kidney damage,[6] and potassium permanganate can cause nausea, vomiting, abdominal pain, and kidney damage.**[7] Since they have not been designated in a regulatory category, **there are no set standards for their use, which leaves aquaculture operators the freedom to use them as they see fit.**

INADs and Extra-label use

Fish farming operations can also use approved drugs for unapproved purposes under "extra-label" policies. With the supervision of a veterinarian, drugs can be administered for purposes beyond what is listed on their label.[8] This gives fish farmers access to additional drugs, and also means that two types of antibiotics, Romet and Terramycin, which are only approved in aquaculture for certain types of fish, could actually be used for any fish in an ocean fish farm.[9] Because FDA does not inspect aquaculture facilities, there is little oversight to ensure that prescribed extra-label directions are being followed.

Even more disturbing is that under existing regulations, fish farmers can legally use unapproved drugs by participating in what are called Investigational New Animal Drug (INAD) studies. INADs are drugs that are in the process to be approved, but have not yet been thoroughly tested for safety and effectiveness.[10] The drug companies that wish to market these drugs get an exemption from FDA to allow their drugs to

be used without approval, as long as it is part of "a study."[11] Because this is considered confidential business information, FDA does not keep records of these so-called studies, but relies on the drug company to do so.[12] This means that potentially dangerous substances are used legally in aquaculture facilities without FDA supervision. The example of SLICE (see side box) illustrates the problems associated with INADS.

SLICE: A Case Study of a Dangerous Aquaculture Chemical

Emamectin benzoate is a chemical often used in aquaculture. Commonly known as SLICE because of its use in treating sea lice infections, it is administered through fish feed, and therefore can be considered a veterinary drug rather than a pesticide. However, its use is unsafe because emamectin has been shown to "block a major inhibitory neural transmitter in the brain" and to "cause behavioral and growth changes as well as pathologic brain changes in animal studies."[13] The Pesticide Action Network asserts that its toxicities to humans include carcinogenicity, reproductive and developmental toxicity, neurotoxicity, and acute toxicity.[14] SLICE is a dangerous chemical to risk releasing into the marine environment or to apply to fish that will become food. For this reason, FDA does not approve it for use in the United States, and it is not a registered pesticide with EPA (EPA has two registered products containing emamectin benzoate, but neither are used in aquaculture.) Nonetheless, records from the Maine Department of Environmental Protection show that aquaculture facilities are currently using SLICE in the United States, and moreover, it does not appear to be considered illegal. A document produced by the Association of Aquaculture Veterinarians of British Colombia explains that SLICE is permitted for use in food fish in Maine under the Investigational New Animal Drug process.[15] Under the INAD process, sponsors of a New Animal Drug are permitted to run trials of medications in the field.[16] Similarly, the Federal Insecticide, Fungicide and Rodenticide Act allows EPA to permit field-testing of investigational pesticides.[17] A system that allows dangerous unapproved drugs like SLICE to be used in the field cannot be trusted to protect consumers and the environment from dangerous drugs in the future.

EPA regulations: insufficient oversight of cumulative effects of drugs and chemicals

The Environmental Protection Agency (EPA) also has a hand in regulating certain aspects of aquaculture. It is charged with ensuring that aquaculture operations follow the Clean Water Act. Unfortunately, as the Marine Aquaculture Task Force has pointed out, EPA's regulatory approach does not appear to take future growth in aquaculture into account. Its approach "allows neither meaningful assessment nor mitigation of cumulative impacts from aquaculture operations."[18] EPA relies on

qualitative, rather than numerical, standards to limit the discharge of pollutants, including drugs and chemicals, into the waters. Fish farms are required to develop and implement Best Management Practices[19] that should help to "eliminate spillages of drugs, pesticides, and feed, and establish safe storage methods."[20] Unfortunately, in essence, this allows industry to set its own standards for management practices. EPA also requires fish farms to report drug, chemical and feed spills and the use of certain drugs, but it does not require operators to report use of approved drugs, INADs, or extra-label use of drugs if they have already been approved for use in similar conditions.[21] Not having complete records of all the drugs used on an ocean fish farm means that EPA has no method for analyzing the overall environmental impact of aquaculture drugs in a given region. Pesticides are also exempted from EPA reporting requirements.[22]

Conclusion

The crowded, stressed conditions present in fish farms frequently lead to disease, infection, and the use of drugs and chemicals to prevent or treat disease and infections. If drug and other chemical use is not carefully regulated, human health and the marine environment could be seriously harmed. The U.S. FDA and EPA supposedly regulate which – and how – chemicals and drugs are used in aquaculture, and the industry's effects on the environment, but neither agency currently has sufficient regulations in place to keep our seafood safe and our environment healthy. Building a better regulatory system would require more research and significant sums of money and time. Rather than put all these resources into limiting the serious potential negative impacts of aquaculture drugs/chemicals used in ocean fish farms (which would still do nothing to solve the other concerns associated with ocean fish farming), our administration would do better to encourage the growth of an alternative method of aquaculture: land-based recirculating aquaculture systems (RAS), which require less and often no chemical inputs and are entirely self-contained systems, with no free flow of contaminants into open waters.

Appendix: Aquaculture Drugs Already in use in the U.S. and Potential Related Effects

Approved Aquaculture Drugs	Purposes	Potential Effects
Florfenicol - Aquaflor	Antibiotic	May cause allergic reactions in susceptible individuals; may cause slight eye irritation, constipation, changes in blood cell counts, changes in stool, or liver effects; may cause developmental effects or effects to male reproductive organs[23]
Formalin – sold as Parasite-S, Formalin-F, Formacide-B and Paracide - F	Kills fungus, parasiticides	Potential Carcinogen[25]
Sulfadimethoxine & Ormetoprim – sold as Romet 30 and Romet TC	Antibiotic	Allergic reactions, blood system effects, birth defects[26]
Oxytetracycline Hydrochloride – sold as Oxytetracycline HCL Soluble Powder – 343; Terramycin-343; Tetroxy Aquatic Soluble Powder	Antibiotic	Carcinogenicity and effects on fertility in animal studies[27]; antimicrobial resistance
Oxytetracycline Dihydrate – Terramycin 200 for Fish	Antibiotic	Antimicrobial resistance
Tricaine Methanesulfonate – sold as Finquel and Tricaine-S	Temporary immobilization	Unknown – chemical, physical, and toxicological properties and toxicity to the environment have not been fully explored.[28]
Special Category Drugs	**Purposes**	**Potential Effects**
Copper Sulfate	Algaecide/antibacterial/ antifungal	Liver and kidney damage[29]
Potassium Permanganate	Algicide/antibacterial/ antifungal/parasiticide	Nausea, vomiting, abdominal pain, and kidney damage[30]
Example of INAD in Use	**Purposes**	**Potential Effects**
Emamectin Benzoate AKA SLICE	Pesticide used to treat sea lice infections	Carcinogenicity, reproductive and developmental toxicity, neurotoxicity, and acute toxicity[31]

Endnotes

1 Heuer, Ole. E et al. "Human health consequences of use of antimicrobial agents in aquaculture." *Clinical Infectious Diseases* vol.49, iss.8, October 2009 at 1248-1253.

2 Haya, K. et al. "Environmental impact of chemical wastes produced by the salmon aquaculture industry." *ICES Journal of Marine Science* vol.58, no.2, 2001, 492-496.

3 Approved drugs for use in aquaculture: florfenicol, hydrogen peroxide, chorionic gonadotropoin, formalin, sulfadimethoxine & ormetroprim, oxytetracycline hydrochloride, oxytetracycline dihydrate, and tricaine methanesulfonate.

4 Approved Drugs for Use in Aquaculture, poster produced by USFWS AADAP Program, AFS Fish Culture Section, AFS Fish Health Section, and FDA Center for Veterinary Medicine, December 2008.

5 "Enforcement Priorities for Drug Use in Aquaculture." Center for Veterinary Medicine Program Policies and Procedures Manual 1240.4200, U.S. Food and Drug Administration, revised April 2007.

6 "Copper and Compounds." Department of the Environment and Water Resources, Australian Government, May 2007. Available at: www.npi.gov. au/database/substance-info/profiles/27.html

7 "Material Safety Data Sheet: Potassium Permanganate." Libox Chem. (India) Pvt. Ltd. Available at: http://liboxgoa.googlepages.com/materialsafetydatasheet%28msds%29ofpotassium

8 "Extralabel Use of Approved Drugs in Aquaculture." Center for Veterinary Medicine Program Policy and Procedures Manual 1240.4210, U.S. Food and Drug Administration, October 1997.

9 "Extralabel Use of Approved Drugs in Aquaculture." Center for Veterinary Medicine Program Policy and Procedures Manual 1240.4210, U.S. Food and Drug Administration, October 1997, Revised February 2008.

10 21 CFR § 511 (2002) New Animal Drugs for Investigational Use

11 Ibid

12 "Fish and Fisheries Products Hazards and Controls Guidance: Third Edition." Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, June 2001. Available at www.cfsan.fda.gov/~comm/haccp4k.html Accessed (Dec 12, 2007)

13 "The Catch with Seafood: Human Health Impacts of Drugs &Chemicals used by the Aquaculture Industry." The Center for Food Safety, Washington, DC, 2005. Quoting: Rothenbush, Theresa. "Report Shows Health Canada Allowing Widespread use of Emergency Drug in Farmed Salmon." Press Release, Raincoast Conservation Society, December 13, 2004.

14 Kegley, S., Hill, B., and Orme, S. "Emamectin, benzoate, pesticide use statistics for 2005." PAN Pesticides Database, Pesticide Action Network. Available at: www.pesticideinfo.org/Detail_ChemUse.jsp?Rec_Id=PC37430

15 "SLICE (Emamectin Benzoate)." Association of Aquaculture Veterinarians of British Colombia, December 14, 2004. Available at: www.agf.gov.bc.ca/AHC/fish_health/Sealice/AAVBC_Slice_Info.pdf

16 21, CFR § 511.1 (2002).

17 Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category, 40 C.F.R. § 451(VI)(D), 2004.

18 "Sustainable Marine Aquaculture: Fulfilling the Promise; Managing the Risks." Marine Aquaculture Task Force, January 2007, p. 80. Available at: www.whoi.edu/cms/files/mcarlowicz/2007/1/Sustainable_Marine_Aquaculture_final_1_02_07_17244.pdf

19 Technical Development Document for the Final Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category, EPA-821-R-04-012, 2004, p. 7-1. Available at: www.epa.gov/guide/aquaculture/tdd/

20 Op. cit. 40 C.F.R. § 451(VI)(C), 2004.

21 Op. cit. 40 C.F.R. § 451(VI)(C) and (D), 2004.

22 Op. cit. 40 C.F.R. § 451(VI)(D), 2004.

23 Material Safety Data Sheet. Aquaflor, Schering-Plough, Pointe Claire, Quebec, Feb. 2004.

25 Material Safety Data Sheet, Formalin, 10%, Mallinckrodt Baker, Inc, Phillipsburg, NJ; Material Safety Data Sheet, Parasite-S, Hexxon, Feb. 2009.

26 Material Safety Data Sheet. Romet 30, Pharmaq, March 2006 and Material Safety Data Sheet, Romet TC, Pharmaq, March 2006.

27 Material Safety Data Sheet. Terramycin-343, Pfizer, July 1999; Material Data Safety Sheet. Terramycin, Pfizer, July 1999; and

28 Material Safety Data Sheet. Tricaine-S, Western Chemical Inc.

29 "Copper and Compounds." Department of the Environment and Water Resources, Australian Government, May 2007. Available at: www.npi.gov. au/database/substance-info/profiles/27.html

30 "Material Safety Data Sheet: Potassium Permanganate." Libox Chem. (India) Pvt. Ltd. Available at: http://liboxgoa.googlepages.com/materialsafetydatasheet%28msds%29ofpotassium

31 Kegley, S., Hill, B., and Orme, S. "Emamectin, benzoate, pesticide use statistics for 2005." PAN Pesticides Database, Pesticide Action Network. Available at: www.pesticideinfo.org/Detail_ChemUse.jsp?Rec_Id=PC37430

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