January 8, 2003

Ms. Marta Jordan
Office of Water, Engineering and
Analysis Division (4303T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460

RE: THE CENTER FOR FOOD SAFETY’S COMMENTS DISSENTING FROM
THE AQUACULTURE EFFLUENT TASK FORCE SUBGROUP ON
DRUGS AND CHEMICALS

Dear Ms. Jordan:

The Center for Food Safety ("CFS") submits these comments as a
member of the Aquaculture Effluent Task Force Subgroup on Drugs and
Chemicals. Because these comments differ from the majority on this subgroup,
these comments are submitted as a dissent.

Although CFS’ comments were criticized by Dr. Scarfe from the American
Veterinary Medical Association, his comments are fundamentally flawed because
they are based on the incorrect assumption that there must be specific
undisputed evidence demonstrating that drugs and chemicals cause harm to
human health and the environment before EPA can regulate drugs and
chemicals used in aquaculture. This assumption is incorrect because regardless
of whether there is undisputed proof that drugs and chemicals cause harm, this
type of discharge is a pollutant under the Clean Water Act ("CWA") requiring a
National Pollution Discharge Elimination System permit ("NPDES").1
Furthermore, despite Dr. Scarfe’s attempts to minimize the scientific evidence,
this information shows that drug and chemical use may harm human health and
the environment and thus, these potential risks need to be mitigated by EPA by

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1 See infra at pp. 6-8.
CFS’ comments apply to all point source sectors of the aquaculture industry (including, ponds, raceways, and net pens). Establishing comprehensive national effluent guidelines is necessary in order for the states to set forth uniform standards, thereby decreasing the amount of pollutants entering the environment. This action is consistent with EPA’s statutory purpose under the CWA to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” 33 U.S.C. § 1251.

Within these comments, CFS explains why it is necessary for EPA to regulate drugs and chemicals under the national effluent guidelines. First, CFS presents scientific information demonstrating the potential human health and environmental concerns from the discharge of drugs and chemicals into the navigable waters. Next, CFS explains why fish farmers are legally required under the CWA to obtain a NPDES permit before discharging these pollutants. Finally, CFS provides recommendations for regulating drugs and chemicals in the national effluent guidelines.

I. Benefits from Regulating Antibiotics

The overuse of drugs in fish feed can cause serious public health problems. Antibiotics and other drugs are used in aquaculture to treat and prevent disease, control parasites, and affect reproduction and growth. The most common method of distributing antibiotics to farmed fish is through fish feed. However, diseased fish have a reduced appetite and as a result, much of the antibiotics enter the environment through uneaten fish feed. In addition, a large amount of the antibiotics that are consumed by the fish are not retained and thus, enter the environment through fish feces. It is predicted that 80% of most antibiotics are lost in the environment. The unused antibiotics accumulate in

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2 CFS encourages EPA to expand the number of facilities covered by the NPDES permitting requirements by modifying its regulation at 40 C.F.R. § 122.24, App. C. EPA’s current regulation is too lax because it exempts a large number of aquaculture facilities. Expanding the coverage of NPDES permits to include smaller dischargers is necessary to reduce even more pollution from fish farms.

3 Dr. Charles M. Brenbrook, Antibiotic Drug Use in U.S. Aquaculture, The Northwest Science and Environmental Policy Center 5 (Feb. 2002) [hereinafter Antibiotic Drug Use in U.S.] citing Food and Drug Administration, Fish and Fishery Products Hazards and Controls Guide (2006 ed. 2001). Dr. Scarfe attacks three of CFS articles for not being peer-reviewed yet the comments by the subgroup are filled with assertions completely lacking peer-reviewed literature or any other kind of citation.

4 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 antibiotic 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”]. Also, CFS strongly supports EPA’s regulation of total suspended solids, including feed management.

5 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.”).
wild fish and shellfish that feed on the food and feces of farmed fish. By eating farmed fish treated with antibiotics or even wild fish exposed to the antibiotics, humans will be ingesting antibiotics that may be harmful. For example, in one study, drug residues were found to exceed FDA levels. The researchers explained that

drug residues of up to at least 3.8 ppm were found in edible crab meat. In comparison, the US 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 (citation omitted), but exceeding maximum acceptable tissue residue levels as defined by public health authorities suggests the issue merits further attention.

The use of antibiotics in aquaculture can also exacerbate the significant problem of antibiotic resistant bacteria. In reviewing the studies on drug resistance in fish pathogenic bacteria over the past 30 years, a 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.” The researchers 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.”

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. Bacteria that are resistant

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7 Id.
8 Capone, supra note 4, at 73. There is also the serious problem regarding FDA’s inadequate seafood inspection system. See U.S. General Accounting Office, Federal Oversight of Seafood Does Not Sufficiently Protect Consumers (Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Jan 2001) (explaining that FDA is not adequately ensuring the safety of seafood).
9 Unable to refute the science, Dr. Scarfe admits that the use of antimicrobials “can potentially exacerbate the problem of antimicrobial resistant bacteria.” CFS recommends that EPA take a precautionary approach to the regulation of drugs and chemicals in order to maintain the chemical, physical, and biological integrity of the nation’s waters. This action is consistent with the agency’s mission under the CWA. 33 U.S.C. § 1251.
11 Id.
to antibiotics can harm human health by preventing the effective treatment of illness. The ASM explains that:

1. Although aquaculture production is growing rapidly, disease prevention and treatment practices are far from standardized or regulated.  
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 – 1 percent of the fecal bacteria in wild fish were resistant to oxacillin and oxytetracycline, respectively. (citation omitted). 

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 handling the fish. FDA acknowledges that “[b]acteria 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.” Due to the potential for humans to contract antibiotic resistant bacteria from farm-raised fish, it is imperative that the use of drugs in aquaculture facilities be monitored.

Currently, there is no public data indicating the precise amount of antibiotics used in aquaculture. However, it is estimated that 204,000 to 433,000

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13 Contrary to Dr. Scarfe’s assertions, 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. 
15 Memorandum from Frederick Angulo, D.V.M., Ph.D., Dep’t of Health and Human Services, to the record (Oct. 18, 1999). 
16 Id. 
17 Dr. Scarfe ignores the ASM recommendation for surveillance of antibiotic resistance in animals and instead attempts to misrepresents ASM’s recommendations by stating that studies are needed before deciding whether drug use monitoring is needed. Nowhere does ASM issue this statement. See ASM report, supra note 12, at 11.
pounds of antibiotics are used by the aquaculture industry.\textsuperscript{18} Despite the volume of drugs administered to diseased fish, a USDA survey of the catfish industry revealed that less than 60 percent of aquaculture facilities keep records on disease treatments.\textsuperscript{19} The lack of record keeping is a severe problem given the potential human health antibiotic resistance concerns. By requiring aquaculture facilities to keep accurate records on the amount of antibiotics used and report regularly to EPA, the agency and researchers will have a better opportunity to assess this severe problem and protect human health and the environment.

\section*{II. Benefits from Regulating Chemicals}

The use of chemicals in aquaculture also poses a risk to human health and the environment. For example, many salmon farmers use color additives to give the salmon its pink hue similar to wild fish, but it should not be assumed that these chemicals are safe. There are human health safety issues connected with the color additive canthaxanthin. Research has already found that this additive “can cause deposits of yellow particles on the human retina, which children’s eyes thought to be particularly vulnerable.”\textsuperscript{20} Other chemicals such as PCB’s, pesticides, and dioxins are found in farmed fish feed. As a result, there are high levels of chemicals in farmed fish leading researchers to report that there are food safety concerns in consuming farmed fish regularly.\textsuperscript{21} Pesticides are also being used to control diseases among fish, such as sea-lice infestations, and disinfectants are used to prevent the spread of the virus. By discharging these chemicals into the water, there are

\textsuperscript{18} Antibiotic Use in U.S., \textit{supra} note 3, 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.”). This is a significant discharge of pollutants that needs to be regulated by EPA in national effluent standards.
\textsuperscript{19} Id. at 8.
\textsuperscript{20} How the King of Fish is being farmed to death, Observer, available at \url{www.intl-ecogen.com/newspaper.html} (Jan. 7, 2001); See Alejandro Espaillat et al., Canthaxanthine Retinopathy 117 Archives of Ophthalmology 412 (1999); Also see 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.”).
\textsuperscript{21} M.D.L. Easton et al., Preliminary examination of contaminant loadings in farmed salmon, wild salmon and commercial salmon feed 46 Chemosphere 1053, 1062, 1069 (2002)(finding that farmed salmon contain up to ten times more PCBs than wild salmon and increases the risk of adverse health effects by consuming more than 1-3 portions of farmed salmon a week). Easton’s study has been criticized because of the small sample size yet Easton used as many samples as the Canadian food inspection agency uses to determine whether fish are safe for human consumption. Frank Fuller, Farmed salmon study raises cancer questions, Anchorage Press, available at \url{http://www.intl-ecogen.com/newspaper.html} (Aug 1, 2001).
potential impacts to human health and aquatic organisms. Even EPA recognizes that PCBs and other chemicals found in fish feed represent a “potential source of contamination” in fish feed. In fact, EPA is requesting that FDA review the new information showing that “elevated levels of dioxins, PCBs, and possibly other contaminants may exist in fish-based feed used in salmon aquaculture and other animal culture.”

Cypermethrin, a drug used to treat salmon for sea lice, is another chemical that has been found to be toxic to aquatic organisms. In the NPDES permit issued in Maine, the use of cypermethrin was prohibited. FDA conducted an environmental review of this drug based on information gathered through an Investigational New Animal Drug (“INAD”) application. Based on this information, EPA found that the use of this drug is lethal for organisms passing through the mixing zone and to sensitive organisms beyond the mixing zone. FDA has not yet approved this drug and due to the potential environmental impacts, this drug should not be permitted for any aquaculture use.

In light of the potentially harmful human health and environmental effects from using chemicals in aquaculture, it is critical that EPA require the aquaculture industry to maintain records and report the amount of chemicals used. Only by maintaining these records and reporting to EPA, will it be possible to study the potential threats to human health and the environment.

III. Drugs and Chemicals are Pollutants Discharged into Navigable Waters

EPA must be guided by its statutory responsibilities under the CWA - to reduce pollution discharged from point sources into the nation’s waters. 33 U.S.C. § 1311(a). The agency should not be persuaded by the industry to ignore this duty under the CWA.

To fulfill EPA’s statutory obligation under the CWA, EPA must determine whether drugs and chemicals are “pollutants” added to navigable waters from a point source. If drugs and chemicals fit within this statutory requirement, then

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22 K. Haya, et al., Environmental impact of chemical wastes produced by the salmon aquaculture industry, 58 ICES J. of Marine Science 492 (2001); See I.M. Davies et al., Environmental risk of ivermectin to sediment dwelling organisms, 163 Aquaculture 29 (1998)(finding that the use of ivermectin to treat sea lice may significantly harm benthic organisms in the immediate vicinity of the salmon farm).
23 Acadia permit, infra note 27, at 30.
24 Id. at 31.
25 Id. at 28.
26 The CWA broadly defines “navigable waters” as “the waters of the United States, including the territorial seas.” 33 U.S.C. § 1362(7). EPA has determined that “aquatic animal production facilities” that fall within the definition of “concentrated aquatic animal production facilities” are point sources. 40 C.F.R. §122.24, App. C. When CFS refers to “aquaculture facilities,” throughout these comments, we are referring to the facilities that fall within the point source definition.
EPA must issue a NPDES permits regardless of whether there is clear proof that a pollutant causes harm. See United States Public Interest Research Group v. Atlantic Salmon of Maine, 215 F. Supp 2d 239, 246, n.3 (D. ME 2002)(explaining that “Although USPIRG introduces into the record numerous facts relating to the harm certain substances may have on the environment or to humans, the Act does not require proof that the pollutant causes harm.”).

Under the CWA, “the discharge of any pollutant by any person is unlawful.” 33 U.S.C. § 1311(a). The only time a discharge of a pollutant is permitted is when a NPDES permit has been obtained. See e.g. EPA v. Cal. Ex Rel. State Water Res. Control Bd., 426 U.S. 200, 205 n.14 (1976). Under the CWA, the term “pollutant”

Means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical waste, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water. 33 U.S.C. § 1362(6).

Courts have explained that this term includes substances that are not specifically listed but subsumed under the broad generic terms. USPIRG, 215 F. Supp 2d at 246; see e.g. Sierra Club, Lone Star Ch. v. Cedar Point Oil Co., 73 F.3d 546, 566-568 (5th Cir. 1996)(explaining that the meaning of pollutant is intended to “leave out very little”).

In the USPIRG case in the District Court of Maine, the court explains that the defendant salmon farm distributes feed into its net pens containing the drugs and chemicals canthaxanthin, astaxanthin, and oxytetracycline. USPIRG, 215 F. Supp. 2d at 248. The uneaten feed flows out of the pens or falls through the pens to the ocean floor. The court finds that these drugs and chemicals are “chemical waste” that fit within the meaning of “pollutant” under the CWA. Id. Similarly, the court identifies the chemicals used to treat salmon for sea lice, including cypermethrin, as chemical waste and therefore, also finds that this is a pollutant under the CWA. Id. Finally, the court explains that the net pens are treated with an antifoulant containing copper that is discharged from the net pens into the water. Id. Copper is specifically listed by EPA as “toxic pollutant” in 40 C.F.R. § 401.15(22) and therefore, is a pollutant under the CWA. Id.

After holding that drugs and chemicals used by the salmon aquaculture industry are pollutants under the CWA, the court further explains that these items do not naturally occur in the water, but rather are put in the water by the company as part of its operation. Id. at 248-9. Therefore, the discharge of drugs and chemicals are “additions” to the water. See Catskill Mountains Ch. Of Trout Unlimited v. City of N.Y., 273 F.3d 481, 491 (2nd Cir. 2001)(finding that “for there to be an ‘addition,’ a ‘point source must introduce the pollutant into navigable water from the outside world.’”).
The USPIRG case clearly shows that drugs and chemicals are pollutants that are added to the water from the aquaculture industry as part of their operations. Therefore, fish farmers must receive a permit from EPA to discharge any drugs and chemicals into the marine environment. In order to set minimum standards to protect the environment, uniform effluent standards should be adopted by EPA. Otherwise, there will be different standards among all the states for regulating drug and chemical use resulting in inconsistent environmental protections.

IV. Recommendations

In order for the states issuing NPDES permits to implement uniform standards, it is essential that EPA establish comprehensive national effluent guidelines for aquaculture facilities regarding the use of drugs and chemicals. 

EPA established important groundwork for industry-wide effluent standards in issuing an NPDES permit on February 21, 2002, to the Acadia Aquaculture facility in Blue Hill Bay within the Maine coastal waters. CFS recommends that many of the conditions stipulated in the permit be incorporated into national effluent standards for aquaculture operations. In order to protect the aquatic environment from drugs and chemicals discharged from aquaculture facilities, the EPA should use these standards in establishing national effluent standards for all aquaculture facilities that discharge into navigable waters, not just for the Acadia facility in Maine.

1. Reporting/Record Keeping for ALL Drugs and Chemicals Discharged From Aquaculture Facilities

EPA’s proposed rule includes reporting/record keeping for extra label drug use and INAD use. Although many within the aquaculture industry are advocating that EPA remove this provision, it is essential that EPA retain this provision in the proposed rule, especially since these drugs have not been approved by FDA for the intended use. While FDA is responsible for the approval of drugs, this statutory authority does not alleviate EPA from its responsibilities under the CWA for preventing the discharge of pollutants into the marine environment. In Maine, EPA explained that

EPA does have the responsibility to ensure that there are no adverse impacts to the aquatic environment due to discharges

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27 Letter from Steph J. Silva, Director, EPA’s Maine Program to Erick Swanson, Acadia Aquaculture LLC. (Feb. 21, 2002) (approving NPDES Permit No. ME0036234) [hereinafter “Acadia permit”].

28 Id. at 30. Regardless of whether a pollutant causes harm, fish farmers are responsible for obtaining an NPDES permit before discharging drugs and chemicals into the nation’s waters. In addition, fish farmers who discharge drugs and chemicals must meet state water quality standards (the establishment of national effluent standards are minimum standards that can be adjusted to meet more stringent state water quality standards). 40 C.F.R. § 131 et seq.
associated with drug applications. Where a product label's minimum effective dosage has been developed to not only ensure the drug's efficacy, but also to minimize adverse impacts to the aquatic environment, a decision to increase dosage over the label's minimum effective dosage could have environmental implications.²⁹

For EPA to delete this provision for reporting/record keeping for extra label and INAD uses, EPA would be ignoring its statutory duties to protect the environment. Therefore, CFS recommends that the national guidelines require all aquaculture facilities to report to EPA before discharging any extra label drugs or INADs and keep records of extra label drug or INAD discharges.

In addition, CFS recommends that EPA go one step further from its proposed rule by requiring all aquaculture facilities to regularly report/maintain records on the discharges of ALL drugs and chemicals discharged into the water and maintain these records for at least five years. This reporting requirement is mandatory in the Acadia permit and should also be incorporated into the national effluent guidelines.³⁰

Regardless of whether FDA has approved a drug, EPA must ensure that the biological, physical, and chemical integrity of the nation’s water is protected.³¹ In the Acadia permit, “EPA acknowledges the need to track the discharge of antibiotics and other drugs, and has included in the final permit a monthly reporting requirement for the facility to identify the type and amount of drugs used.”³² Specifically, the Acadia permit requires that any discharge of drugs be reported to EPA and include the following: “1) date and time of treatment; 2) drug used; 3) concentration of drug administered and total quantity used, including amount of feed used if applied through feed; 4) approximate number of fish, as well as number of pens treated; 5) route of administration; 6) predominant current direction during treatment.”³³

Establishing national effluent guidelines for reporting/record keeping for all drugs discharged into navigable waters will further EPA's responsibility to protect the nation’s waters. Therefore, CFS recommends that the national effluent guidelines require all aquaculture facilities to report/maintain records of all monthly discharges of drugs and chemicals similar to the Acadia permit.³⁴

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²⁹ Id. at 34.
³⁰ The Maine permit refers to drugs broadly to include any reference to the “discharge of chemicals intended to treat cultured salmon for disease or parasites.” Id. at 33.
³² Acadia permit, supra note 27 at 29.
³³ Id. at 22/Part I.
³⁴ Maintaining records of drug use should not be found to be overly burdensome. In fact, commenters from the effluent task force subgroup on drugs and chemicals stated that “[m]aintaining use records as part of a BMP and annual reporting does not seem onerous.”
(2) Mandatory Best Management Practices to Minimize the Use of Drugs and Chemicals

Mandatory Best Management Practices ("BMPs") for drugs and chemicals should also be part of the national effluent guidelines.\textsuperscript{35} Adopting BMPs aimed at protecting fish health will aid in limiting the use of drugs and chemicals. This goal is not only consistent with EPA’s statutory duties under the CWA, but also furthers the FAO’s code of conduct for aquaculture. Under section 9.4.4, the FAO encourages states to “promote effective farm and fish health management practices favouring hygienic measures and vaccines. Safe, effective, and minimal use of therapeutants, hormones and drugs, antibiotics and other disease control chemicals should be ensured.”\textsuperscript{36}

In the Acadia permit, EPA identifies as a BMP, the use of vaccines to control disease.\textsuperscript{37} Other measures to control disease include decreasing stress by reducing stock density.\textsuperscript{38} Both of these measures should be mandatory BMPs for all aquaculture facilities because they work to protect the health of farmed fish and decrease the amount of pollutants entering the environment. Therefore, CFS recommends that EPA incorporate mandatory BMPs into the national effluent guidelines that seek to protect fish health by controlling disease through the use of vaccines and decreasing stress by limiting stock density.

Conclusion

In conclusion, CFS has demonstrated that: (1) drugs and chemicals are “pollutants” that may harm human health and the environment, and (2) regardless of whether there is undisputed proof that drugs and chemicals cause harm, the discharge of these pollutant requires an NPDES permit under the CWA. In order for the regulation of these pollutants to be consistent among the 50 states, CFS recommends the adoption of national effluent guidelines for drug and chemical use. Moreover, there should be no question whether these standards are attainable because they are already being implemented by the aquaculture industry in Maine.

\textsuperscript{35} EPA should adopt BMPs that are part of the national effluent guidelines rather than letting the industry set individual standards. Consistent standards throughout the aquaculture industry will aid in reducing the pollution discharged into the environment.


\textsuperscript{37} Acadia permit, supra note 27, at 22/Part I.

Sincerely,

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