

RESPONSE TO COMMENTS - DATED JANUARY 06, 2005
REISSUANCE OF NPDES PERMIT NO. NH0000710
NEW HAMPSHIRE FISH AND GAME DEPARTMENT'S
POWDER MILL FISH HATCHERY

The U.S. Environmental Protection Agency (EPA-New England) and the New Hampshire Department of Environmental Services, Water Division (NHDES-WD) solicited public comments from October 26, 2004, through November 24, 2004, on the draft National Pollutant Discharge Elimination System (NPDES) permit to be reissued to the New Hampshire Fish and Game Department (NHF&GD) for its fish hatchery in New Durham, New Hampshire. This permit is for the discharge of fish hatchery overflow (culture) water from several outfalls into the Merrymeeting River.

EPA-New England received one set of written comments during the public-notice (comment) period, that from the NHF&GD dated November 17, 2004. The following is a list of responses to those comments and any corrections made to the public-noticed permit as a result of those comments. In addition, EPA-New England made a series of minor changes to the issued permit for purposes of clarification.

These seven pages of responses and associated comments are complementary to the Fact Sheet and Draft Permit. For the reader to fully understand them, he or she should be familiar with the draft permit, the associated Fact Sheet, applicable federal National Pollutant Discharge Elimination System (NPDES) permit regulations and the State of New Hampshire's Water Quality Statutes, Administrative Rules and Surface Water Quality Regulations.

The effective date of this permit has been set at April 1, 2005, which is a little over 60 days from the anticipated date of issuance. The Agency's general rule for NPDES Permits with comments is to make them effective 60 days following the permit's effective date.

COMMENT NO. 1.

The department believes that FACT SHEET page 17 last paragraph referring to FDA instructions should be expanded to include application to ponds, which we follow, rather than limiting us to tanks and raceways directions:

“Every year during July through September cultured salmonid fish at Powder Mill Hatchery must sustain infections of the protozoan parasite *Ichthyophthirius multifiliis* commonly referred to as ICH. It is a difficult organism to control with the only FDA approved drug being a formalin solution. FDA instructions provide for allowable daily one hour treatments up to 170 mg/L for tanks and raceways @ above 50° F. to control ICH and 15 - 25 mg/L indefinitely for earthen ponds every other day regardless of temperature.

Since the rearing facilities at Powder Mill are a complex series of raceways and earthen ponds the latter described above is the method of choice for two reasons:

1. The higher concentrations allowed for raceways as described in the former method would require far more formalin for mitigation as compared to the latter thereby causing discharge concentrations to be far above 4.5 mg/L.
2. The later method using 20 mg/L has already proven to be effective for mitigation with discharge concentrations under 4.5 mg/L.”

Due to the large complexity of raceways and earthen ponds at Powder Mill we are following the “earthen pond” guidelines as designated in CFR 529.1030, which permits 15-25 microliters per liter indefinitely for earthen ponds thereby maintaining discharge concentrations under 4500 ppb.

The department uses 20 microliters per liter for 17 hours every other day (six days per week during a peak ICH period for two weeks in August) until mitigation of the parasite is achieved. Water flows from raceways to earthen ponds. [Copy of instructions attached]

IF the department were to follow a “one hour per day per raceway, tank and/or in-line settling pond” treatment: the discharge probably would exceed the concentration limit, however our treatment for 17 hours/42 “raceways, **earthen ponds**, circular tanks, or in-line earthen settling ponds” is effective at 0.4 hours per pond, does not exceed our concentration limit and is 59.5 % less than the one hour instructions would be, if we were to follow it.

The department needs to know, preferably in writing, whether it will be permitted to continue its’ SOP for treatment for Ichthyophthirus in accordance with the label instruction, or not. If not the alternative is a \$400,000+ capital expense on UV treatment, which cannot very well be justified unless the department has no other choice, by conditions of this permit language, and interpretation.

It was already disconcerting to have the word raceway re-defined to simplify the permit writing. Fish culturists define a raceway as an individual rectangular container for raising fish in. EPA has re-defined a whole series of raceways as a raceway.

A-series of 10 individual raceways: EPA designated the series as Raceway A
B-series of 6 individual raceways: EPA designated the series as Raceway B
C-series of 6 individual raceways: EPA designated the series as Raceway C
F-series of 8 individual raceways: EPA designated the series as Raceway F
G-series of 10 individual raceways: EPA designated the series as Raceway G
H-series of 10 individual raceways: EPA designated the series as Raceway H
I-series of 10 individual raceways: EPA designated the series as Raceway I

When instructions, or permit statements, refer to time per raceway, the definition of “raceway” could make the difference between whether an operation is in compliance or not. There can be no room for misinterpretation due to definitions of words, or only partial consideration of the label instructions, or how one chooses to follow label instructions. See instruction DIRECTIONS FOR

USE: 1. Parasiticide for Finfish section, and the METHODS OF APPLICATION section of the attachment. The department chose to follow instructions for ponds.

If that is ok, then the department can annually certify in writing that all Aquaculture Drugs and Chemicals used at this facility during the calendar year were ones approved by the USFDA and all applications were in accordance with label instructions. [Permit Page 12 of 19, 11. second paragraph.] If that is not ok, then the department has a problem, and should move forward on plans for ultra violet light treatment installation in place of using formalin.

RESPONSE NO. 1:

The permittee is correct in suggesting that the Formalin discussion in the Powder Mill's Fact Sheet's is inadequate particularly in reference to ponds. That will be corrected in future hatchery Fact Sheets (see paragraph in italics immediately below for planned revision), but for the purposes of this reissuance the first sentence in that paragraph is all encompassing as to the applicable Formalin regulations. The Agency states, "Formalin use should be consistent with U.S. Food and Drug Administration (FDA) labeling instructions as per 21 CFR Section 529.1030."

*Formalin use should be consistent with U.S. Food and Drug Administration (FDA) labeling instructions as per 21 CFR Section 529.1030. As an example of the formalin application rates for finfish to control external protozoa, such as the parasite Ichthyophthirius commonly referred to as ICH, FDA labeling instructions allow applications up to one hour a day with concentrations up to 170 mg/l for tanks and raceways at water temperatures above 50° Fahrenheit and every other day indefinitely with concentrations that range from 15 to 25 mg/l for earthen ponds regardless of water temperature. Finfish eggs may be treated up to 15 minutes per day with concentrations not to exceed 2,000 mg/l. **Note: These application rates are only presented as examples and any drug application should always be made in accordance with the container's labeling instructions.** While the prophylactic use of formalin (i.e., drugs and chemicals used to prevent specific disease(s) in the absence of their symptoms) is not mentioned in those FDA regulations, EPA-New England will only allow its use under the extralabel or INAD provisions of the Federal Food, Drug and Cosmetic Act as a "best management practice" to control the excessive use of drugs.*

EPA-New England and the NHDES-WD have compared the hatchery's method of PARASITE-S [Formalin (aqueous formaldehyde solution)] "drip method" of application with labeling instructions included with the hatchery's comments and have concluded that PARASITE-S application does not conform with FDA labeling instructions for all the hatchery's 7 Raceway Series and 27 Circular Tanks. Specifically, it's the **APPLICATION TO TANKS AND RACEWAYS** portion of the **METHODS OF APPLICATION** section that the hatchery has not followed. That part of the label states that the water supply to tanks and raceways shall be **turned off during the application and the fish shall be treated for up to 1 hour followed by the tank being drained and refilled.** The hatchery's approach of dripping PARASITE-S solution into the headworks box continuously for 17 hours with no stoppage of flow including the draining and refilling of rearing units appears not to be in compliance with the "turning off the water supply" as well as the "fish exposure time of up to one hour followed by the tank being drained and refilled" provisions of the label. By the Agency's calculation, a given fish in any individual raceway container is exposed to the PARASITE-S solution

for 17 continuous hours.

As to the three Show Ponds and the four Woods Ponds, the Agency is concerned that they also should be classified as tanks and raceways for the purposes of Formalin application because they have: (1) large inflow/outflow rates with respect to their individual pond volume; (2) small areal extent; and (3) water depths in the range of 2 to 3 feet which are more typical of raceway units than earthen ponds. Earthen ponds are deeper and have longer detention times (time to exchange one pond volume) than a typical raceway unit.

Furthermore, the Agency disagrees with the hatchery's assertion that Formalin applications for the entire hatchery can be performed under the "earthen pond" FDA guideline even though the hatchery contains a mixture of raceways, tanks and earthen ponds. The hatchery made the assertion in its comments stating that, "Due to the large complexity of raceways and earthen ponds at Powder Mill we are following the "earthen pond" guidelines as designated in CFR 529.1030, which permits 15-25 microliters per liter indefinitely for earthen ponds thereby maintaining discharge concentrations under 4500 ppb." To the contrary, the Agency believes that formalin applications should be tailored to the specific type of individual rearing unit rather than to the hatchery as a whole.

Both Agencies understand the operational reasoning/need behind the drip method (i.e., lower concentration over a longer time versus a high dose for a short time period) due to the hatchery's inability to shut off its water supply during PARASITE-S applications for ICH control. However, under the newly promulgated effluent limitations guidelines and new source performance standards for the concentrated aquatic animal production (CAAP) point source category (See 40 CFR Part 451), the Agency has no authority to allow drug and chemical usage other than that which is in conformance with FDA labeling instruction, extralabel use, INAD or new animal drug use provisions as prescribed under the authority of a qualified veterinarian or directives from the USFDA.

It appears to both Agencies that the hatchery's SOP (i.e., "drip method" for the control of ICH) would likely qualify under extralabel drug use for that usage covers any drug approved under the Federal Food, Drug and Cosmetic Act. The hatchery's use of PARASITE-S for ICH control is approved by the USFDA; however, this Agency believes the hatchery is just not applying it according to the labeling instructions. Furthermore, this Agency believes this use of the extralabel provision would require the NHF&GD to consult with a veterinarian for applications to the tanks and raceways sector of the hatchery.

Given this critical difference of opinion, the Agency recommends that the NHF&GD contact the USFDA to seek their opinion on this matter. To that end, the Agency understands that NHF&GD has written a letter dated December 10th to the USFDA's Office of Surveillance and Compliance requesting a determination whether the hatchery's SOP ("drip method") for the treatment of ICH is in accordance with label instructions. The Agency wants to reiterate that it will abide by the decision issued by the USFDA on this matter.

EPA-New England also reworded the permit language in Part I.A.11. of the draft permit to be clearer. The second and third sentences of the first paragraph were eliminated because the Agency believed they were in direct conflict with provisions of extralabel, INAD or new animal drug application provisions of the USFDA. For the purposes of 40 CFR Part 451, drugs and chemicals usage at CAAP facilities are considered appropriate only when in conformance with labeling instructions, extralabel, INAD or new animal drug application provisions of the USFDA. Furthermore, EPA-New England has revised its permitting approach towards prophylactic use (i.e., drugs and chemicals used to prevent specific disease(s) in the absence of their symptoms). The draft permit prohibited prophylactic use; however, the final permit allows its use if specifically allowed under the labeling instructions, or justified under the extralabel or INAD provisions of the Federal Food, Drug and Cosmetic Act. Keeping the annual certification of proper drug usage is also another way of ensuring that the applicator reads, thoroughly understands and abide's by FDA's labeling instructions. Below in quotes is the revised Part I.A11. as shown in the issued permit.

“The permittee shall use only those Aquaculture Drugs and Chemicals approved by the U.S. Food and Drug Administration (USFDA) and in accordance with labeling instructions or as allowed in **Part B.1. Drug Usage** immediately below. EPA-New England will defer to the expertise of the USFDA regarding whether or not a particular drug and/or chemical is used in accordance with appropriate USFDA requirements.

In addition, each year with the December Discharge Monitoring Report (to be submitted by January 15th) the permittee shall certify in writing that all Aquaculture Drugs and Chemicals used at this facility during the calendar year (specify the calendar year) were ones approved by the USFDA and were used in accordance with FDA labeling or as allowed under **Part B.1. Drug Usage** in Powder Mill's NPDES permit.”

EPA-New England understands the need to be specific and clear to avoid future misinterpretations, particularly in regards to enforcement as to the definition of raceways. Therefore, for each of the raceways listed in the draft permit (Raceways A, B, C, F, G, H and I Series) EPA-New England added to the end of footnote 1 on page 9/10 of the issued permit a detailed description of how many individual raceway units each raceway series contains to avoid any future misinterpretations. Furthermore, on pages 2 and 4 through 6 in the paragraph at the top of each of those effluent pages, EPA-New England changed the description ofRaceways X, Y and Zin the draft permit to readRaceways X, Y and Z Seriesin the issued permit.

COMMENT NO. 2.

Permit page 13 of 19, Drug Usage, c. remove “s” after the word label.

RESPONSE NO. 2:

The permittee is correct in pointing out in the draft permit that a “s” should be removed from the word “extralabels” on the first line of Drug Usage, Item c. on page 13. Accordingly, Part I.B.1.c. on page 13 of the issued permit has been changed to reflect this correction.

COMMENT NO. 3.

In the “proposed action, type of facility and discharge location” document, third paragraph, there is an error. Fish are raised in two of the three “show pools” for stocking purposes. Most of the show fish in the other one are for show, but they could be stocked as well.

RESPONSE NO. 3:

The permittee’s comment refers to a sentence written in the public document notifying the public of the Agency’s desire to reissue Powder Mill’s NPDES permit. It also appears on page 3 of the Fact Sheet accompanying the draft permit.

Comment noted, however, it’s an EPA regulation that the Fact Sheet supports the draft public-noticed version of the permit, and, therefore, is not revised at final issuance. However, the permittee’s clarification serves to correct page 3 of the Fact Sheet for future reference.

Other Changes Made to Draft Permit

EPA-NEW ENGLAND’S CHANGE NO. 1.

The Agency edited pages 2 through 8 of the draft permit to remove the reporting requirements for average monthly loads and concentrations for the parameters TSS, BOD₅, Total Phosphorus and Total Nitrogen in the issued permit for it is inappropriate to compute average monthly values based on a single quarterly sampling. In addition, for clarification purposes, footnote 3 was moved from referencing “1/Quarter” in the draft permit to “24-Hour Composite” in the issued permit and footnote 4 was moved from referencing “1/Quarter” in the issued permit to the “Total Phosphorus as P” in the issued permit.

EPA-NEW ENGLAND’S CHANGE NO. 2.

The Agency edited page 9 of the draft permit to remove a “s” and to capitalize the “P” in “pond” under “Discharging Unit” for “Outfall 005”. The issued permit now reads Woods Pond #2.

EPA-NEW ENGLAND’S CHANGE NO. 3.

The Agency edited footnote 4 on page 10 of the draft permit to add “/l” (meaning per liter) to “μg” to read “μg/l” at two places, one each in the first and second sentences of that footnote. Those sentences in the issued permit now read:

For purposes of analysis and reporting of Total Phosphorus, the permittee shall use the minimum quantification level (ML) of 10 micrograms per liter (μg/l). (A ML of less than 10 μg/l is also acceptable.)

EPA-NEW ENGLAND’S CHANGE NO. 4.

The Agency added a sentence to footnote 5 on page 10 of the draft permit for purposes of clarification and streamlining of record keeping. The sentence in italics shown below was added between the last two sentences. Below in quotes is the corrected footnote as shown in the issued permit.

“The permittee shall submit a written report with its monthly DMR of any significant import and/or export of fingerling or greater size fish which occurred during the reporting month. The report shall include the dates and quantities of each import and/or export. *In lieu of a written report, the permittee is allowed to submit a copy of their in house “monthly reports form” as long as that form contains the relevant information.* This report excludes any fish mortality data as that is covered separately under **Part I.A.6.**”

EPA-NEW ENGLAND’S CHANGE NO. 5.

The Agency edited the first paragraph of the Best Management Practices (BMP) Plan on page 14 of the draft permit (See Part I.B.4) for clarification purposes. Specific edits were to the 1st sentence (2nd line) where the phrase or word shown in italics was changed from “....this section (*Item 4*) will.. ..” to “... this section *below* will....” and in the 2nd sentence (5th line) where the phrase shown in italics was added between “the” and “BMP” to read “The permittee shall implement the *intent of the* BMP requirements.....”. Below in quotes is the corrected paragraph as shown in the issued permit.

“The permittee must develop, implement and maintain a BMP Plan on site, hereinafter referred to as the **PLAN**, that describes how the requirements listed under this section below will be achieved and will make the current version of that **PLAN** available to EPA-New England and/or the NHDES-WD upon request. The permittee shall implement the intent of the BMP requirements described below upon the permit’s effective date; however, the permittee has **180 days following the permit’s effective date** to certify in writing to EPA-New England and the NHDES-WD that a written **PLAN** has been developed in accordance with requirements listed in this part and must submit that certification with the appropriate DMR.”