AUTHORIZATION TO DISCHARGE UNDER THE
NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

In compliance with the provisions of the Federal Clean Water Act as amended, (33 U.S.C. §§1251 et seq.; the "CWA"), and the Massachusetts Clean Waters Act, as amended, (M.G.L. Chap. 21, §§26-53),

Genzyme Corporation

is authorized to discharge from a facility located at

500 Soldiers Field Road
Allston, MA 02134

to the receiving water named the Charles River, a class B water, in accordance with effluent limitations, monitoring requirements, and other conditions set forth herein.

This permit shall become effective on the date of signature.

This permit and the authorization to discharge expire at midnight, five (5) years from the last day of the month preceding the effective date.

This permit supersedes the general permit for reverse osmosis reject water that was issued on December 17, 2002 and that expired on December 17, 2007.

This permit consists of 5 pages in Part I including effluent limitations and monitoring requirements and 25 pages in Part II, Standard Conditions.

Signed this 1st day of May, 2009

/S/ SIGNATURE ON FILE

_____
Director
Office of Ecosystem Protection
Environmental Protection Agency
Boston, MA

_____
Director
Division of Watershed Management
Department of Environmental Protection
Commonwealth of Massachusetts
Boston, MA

PART I.A. **Effluent Limitations and Monitoring Requirements**

1. During the period beginning on the effective date and lasting through expiration, the permittee is authorized to discharge reverse osmosis (RO) reject water from outfall serial number **001**. Such discharges shall be limited and monitored by the permittee as specified below:

EFFLUENT CHARACTERISTIC	EFFLUENT LIMITS		MONITORING REQUIREMENTS	
PARAMETER	**AVERAGE MONTHLY**	**MAXIMUM DAILY**	**MEASUREMENT FREQUENCY**	**SAMPLE[1] TYPE**
Flow[2]	66,000 GPD	120,000 GPD	Continuous	Recorder
pH Range[3]	6.5 – 9.0 s.u.		1/Week	Grab
Dissolved Oxygen[3]	Not less than 6.0 mg/l		1/Month	Grab
Total Suspended Solids	Report mg/l	Report mg/l	1/Quarter	Grab
Total Ammonia Nitrogen	Report ug/l	Report ug/l	1/Month	Grab
Total Residual Chlorine	Report ug/l	Report ug/l	1/Month	Grab
Copper, Total	Report ug/l	Report ug/l	1/Quarter	Grab

The discharge of wastewaters to the Charles River from any and all cleaning or backwashing of these RO units or any of their components is prohibited.

Footnotes:
1. Sampling shall be conducted at a point prior to discharge to Outfall 001 and prior to mixing with any other stream. Any change in sampling location must be reviewed and approved in writing by EPA and MassDEP. All samples shall be tested using the analytical methods found in 40 CFR §136, or alternative methods approved by EPA in accordance with the procedures in 40 CFR §136.
2. The flow shall be continuously measured and recorded using a flow meter.
3. Requirement for State Certification. For pH, the minimum and maximum values for each month shall be reported.

Part I.A.1. (continued)

a. The discharge shall not cause a violation of the water quality standards of the receiving waters.

b. The effluent pH shall be in the range of 6.5 through 9.0 standard units.

c. The discharge shall not cause objectionable discoloration of the receiving waters.

d. The effluent shall contain neither a visible oil sheen, foam, nor floating solids at any time.

e. The results of sampling for any parameter above its required frequency must also be reported.

3. Toxics Control

a. The permittee shall not discharge any pollutant or combination of pollutants in toxic amounts.

b. Any toxic components of the effluent shall not result in any demonstrable harm to aquatic life or violate any state or federal water quality standard which has been or may be promulgated. Upon promulgation of any such standard, this permit may be revised or amended in accordance with such standards.

4. Numerical Effluent Limitations for Toxicants

EPA or MassDEP may use the results of the chemical analyses conducted pursuant to this permit, as well as national water quality criteria developed pursuant to Section 304(a)(1) of the Clean Water Act (CWA), state water quality criteria, and any other appropriate information or data, to develop numerical effluent limitations for any pollutants, including but not limited to those pollutants listed in Appendix D of 40 CFR Part 122.

5. All existing manufacturing, commercial, mining, and silvicultural dischargers must notify the Director as soon as they know or have reason to believe:

a. That any activity has occurred or will occur which would result in the discharge, on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(1) One hundred micrograms per liter (100 ug/l);

(2) Two hundred micrograms per liter (200 ug/l) for acrolein and acrylonitrile; five hundred micrograms per liter (500 ug/l) for 2,4-dinitrophenol and for 2-methyl-4,6-dinitrophenol; and one milligram per liter (1 mg/l) for antimony;

(3) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or

(4) Any other notification level established by the Director in accordance with 40 C.F.R. §122.44(f).

b. That any activity has occurred or will occur which would result in the discharge, on a non-routine or infrequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(1) Five hundred micrograms per liter (500 ug/l);

(2) One milligram per liter (1 mg/l) for antimony;

(3) Ten (10) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or

(4) Any other notification level established by the Director in accordance with 40 C.F.R. §122.44(f).

c. That they have begun or expect to begin to use or manufacture as an intermediate or final product or byproduct any toxic pollutant which was not reported in the permit application.

6. This permit may be modified, or revoked and reissued, on the basis of new information in accordance with 40 CFR §122.62.

B. UNAUTHORIZED DISCHARGES

The permittee is authorized to discharge only in accordance with the terms and conditions of this permit and only from the outfall listed in Part I A.1. of this permit. Discharges of wastewater from any other point sources are not authorized by this permit and shall be reported in accordance with Section D.1.e. (1) of the General Requirements (Part II) of this permit (Twenty-four hour reporting).

C. MONITORING AND REPORTING

Reporting

Monitoring results obtained during each calendar month shall be summarized and reported on Discharge Monitoring Report Form(s) postmarked no later than the 15th day of the following month.

Signed and dated originals of these, and all other reports required herein, shall be submitted to the Director and the State at the following addresses:

Environmental Protection Agency
Water Technical Unit (SEW)
P.O. Box 8127
Boston, Massachusetts 02114

The State Agency is:

Massachusetts Department of Environmental Protection
Bureau of Waste Prevention
Northeast Regional Office
205B Lowell Street
Wilmington, MA 01887

Signed and dated Discharge Monitoring Report Forms required by this permit shall also be submitted to the State at:

Massachusetts Department of Environmental Protection
Division of Watershed Management
Surface Water Discharge Permit Program
627 Main Street, 2nd Floor
Worcester, Massachusetts 01608

D. STATE PERMIT CONDITIONS

This discharge permit is issued jointly by the U. S. Environmental Protection Agency (EPA) and the Massachusetts Department of Environmental Protection (MassDEP) under Federal and State law, respectively. As such, all the terms and conditions of this permit are hereby incorporated into and constitute a discharge permit issued by the Commissioner of the MassDEP pursuant to M.G.L. Chapter 21, §43.

Each Agency shall have the independent right to enforce the terms and conditions of this permit. Any modification, suspension or revocation of this permit shall be effective only with respect to the Agency taking such action, and shall not affect the validity or status of this permit as issued by the other Agency, unless and until each Agency has concurred in writing with such modification, suspension or revocation. In the event any portion of this permit is declared, invalid, illegal or otherwise issued in violation of State law such permit shall remain in full force and effect under Federal law as an NPDES permit issued by the U.S. Environmental Protection Agency. In the event this permit is declared invalid, illegal or otherwise issued in violation of Federal law, this permit shall remain in full force and effect under State law as a permit issued by the Commonwealth of Massachusetts.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND - REGION I
ONE CONGRESS STREET, SUITE 1100
BOSTON, MASSACHUSETTS 02114-2023

FACT SHEET

DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) PERMIT TO DISCHARGE TO WATERS OF THE UNITED STATES PURSUANT TO THE CLEAN WATER ACT (CWA)

NPDES PERMIT NUMBER: MA0040291

NAME AND MAILING ADDRESS OF APPLICANT:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

RECEIVING WATER(S): Charles River
(USGS Hydrologic Code #01090001 – Charles River Basin)

RECEIVING WATER CLASSIFICATION(S): Class B - Warm water fishery, Restrictions: Combined Sewer Overflows (CSO)

SIC CODE: 2834

Table of Contents

I. Proposed Action, Type of Facility and Discharge Location

The Genzyme Corporation, or "Genzyme" operates a biopharmaceutical manufacturing facility in Allston, Massachusetts. This facility is engaged in the production of therapeutic proteins for enzyme replacement. The facility was authorized to discharge reverse osmosis (RO) reject water on May 18, 2004 to the Charles River through Outfall 001, in accordance with the general permit for RO reject water (ROGP) that was issued on December 17, 2002. Genzyme initiated this discharge on May 25, 2005. Prior to this authorization, the permittee had discharged this water to the Massachusetts Water Resources Authority (MWRA) sewer, in accordance with a MWRA Sewer Use Discharge Permit.

The ROGP expired on December 17, 2007 and EPA has decided not to reissue the ROGP. Therefore, this RO reject water discharge will be authorized under this individual permit. As such, the previous ROGP# of MAG450001 has been changed to the individual NPDES permit #MA0040291. The permittee was instructed to file an individual permit application and it did so on April 1, 2008.

The reissued permit will authorize the discharge RO reject water from Outfall 001 at up to a daily maximum flow of 120,000 gallons per day (GPD) to the Charles River. The effluent is routed under the Genzyme property and connects to the Boston Water & Sewer Commission (BWSC) storm drain system at the Massachusetts Turnpike ramp, which is directed under Cambridge Street to the BWSC storm water outfall (#SDO034) to the Charles River. See **Figure 1** for a map of the facility and the outfall location.

II. Description of Treatment System and Discharges

Outfall 001 – Reverse Osmosis Reject Water

To achieve the required level of water purity for its pharmaceutical production, Genzyme employs three reverse osmosis (RO) units to treat the incoming municipal drinking water, which is supplied by the MWRA. See **Figure 2** for a water flow schematic of this process. The output of these RO units is a purified water which is used in production and the RO reject water, which is discharged to Outfall 001. This reject water contains the typical parameters which are found in drinking water, except at higher concentrations.

Flow is measured onsite prior to discharge to outfall 001. The flow meter is read daily and records are kept on-site. Grab samples for pH and DO are taken on a monthly basis from a sample port on the discharge line prior to discharge to Outfall 001. Sampling for TSS is taken at the same point, but as a 24 hr composite sample. The pH is monitored continuously and also measured in grab samples at this same sampling port.

Since the MWRA water contains some residual chlorine, this water is dechlorinated at the site via carbon pre-treatment beds, since chlorine is detrimental to the operation of RO units. There are also sand and media filtration steps prior to the water being treated in the RO units. Any backwash from any of these filters is discharged to the MWRA sanitary sewer and not allowed to be discharged to Outfall 001.

In 2005, the DMRs reported levels of TRC between 20 and 80 ug/l. The permittee has noted that these detected levels were likely the result of the permittee's own in-house sanitization of the RO filters. Because of these readings, the permittee discontinued the practice of in-house sanitization. For routine and preventative maintenance, the units are taken off line, and are cleaned piece by piece, as necessary. The RO unit filters are sent off-site for cleaning, so no chemicals are added to the RO system at the facility. These pieces are cleaned with a disinfection solution which is composed primarily of hydrogen peroxide. This solution is discharged to an on-site waste water treatment facility and eventually to the MWRA sewer, thus resulting in no discharge to Outfall 001. Prior to reinstallation onto the RO units, the cleaned components are triple rinsed with purified water which is also discharged to the MWRA sewer. The discharge of wastewaters to the Charles River from any and all cleaning or backwashing of these RO units or any of its components has not been authorized by this permit. TRC has not been detected in the permittee's effluent since 2005.

III. Receiving Water Description

Under the state water use classification system, MassDEP has designated this segment of the Charles River, which runs from the Watertown Dam to the Science Museum in Boston (Segment MA72-08), as a Class B water (314 CMR 4.00), with CSO restrictions. Class B waters are designated as a habitat for fish, other aquatic life, and wildlife and for primary and secondary contact recreation. These waters are to be suitable for public water supply following appropriate treatment, irrigation and other agricultural uses, and compatible industrial cooling and process uses. The waters shall have consistently good aesthetic value. This segment of the Charles River does not always meet the state water quality standards prescribed for Class B waters, especially after wet weather. This segment is on the MassDEP's 2006 303(d) list of impaired waters for unknown toxicity, priority organics, metals, nutrients, organic enrichment/low dissolved oxygen, pathogens, oil and grease, taste, odor and color, noxious aquatic plants and turbidity.

Although the 303(d) listed this segment of the Charles River for non-attainment for metals, it did not list any specific metals. If a specific metal had been listed, then any discharges containing this metal could not be afforded the benefit of any dilution calculation when determining whether a permit limit was necessary, as is typically allowed. In order to determine whether this segment of the Charles River is impaired for copper, EPA compared instream levels of copper with ambient water quality criteria for copper. Data from the Clean Charles 2005 Initiative collected by EPA between 1999 and 2004 shows that water column levels of dissolved copper in the vicinity of the discharge are below ambient acute and chronic water quality criteria in 69 of the 72 samples taken upstream and downstream of the facility in dry and wet weather. This sampling data may be found at http://www.epa.gov/region1/charles/2005.html, within the Clean Charles 2005 Water Quality Reports. Based on this data, EPA believes that the Charles River in the vicinity of this discharge is not impaired for copper and therefore, a dilution factor may be used to determine whether any permit limit is warranted. EPA has applied a dilution factor to this discharge for copper as shown in Section VI below and has found

that there is no reasonable potential for copper in the effluent to cause or contribute to water quality standards violations. Consequently, this draft permit has eliminated the prior effluent copper limit of the ROGP and has established a monitor only requirement for copper.

As part of the permit application, the permittee also provided the results of effluent sampling for other metals, and they were not detected. Therefore, no further consideration was given to effluent limits for any other metals.

IV. Limitations and Conditions

The effluent limitations and all other requirements described in Part VI of this Fact Sheet may be found in the draft permit.

V. Permit Basis: Statutory and Regulatory Authority

General Requirements

The Clean Water Act (CWA) prohibits the discharge of pollutants to waters of the United States without a National Pollutant Discharge Elimination System (NPDES) permit unless such a discharge is otherwise authorized by the CWA. The NPDES permit is the mechanism used to implement technology and water quality-based effluent limitations and other requirements including monitoring and reporting. This draft NPDES permit was developed in accordance with various statutory and regulatory requirements established pursuant to the CWA and any applicable State regulations. The regulations governing the EPA NPDES permit program are generally found at 40 CFR Parts 122, 124, 125, and 136.

When developing permit limits, EPA must consider the most recent technology-based treatment and water quality-based requirements. Subpart A of 40 CFR Part 125 establishes criteria and standards for the imposition of technology-based treatment requirements in permits under Section 301(b) of the CWA, including the application of EPA-promulgated effluent limitations and case-by-case determinations of effluent limitations under Section 402(a)(1) of the CWA. EPA is required to consider technology and water quality-based requirements as well as all limitations and requirements in the existing permit when developing permit limits.

Technology-Based Requirements

Technology-based treatment requirements represent the minimum level of control that must be imposed under Sections 301(b) and 402 of the CWA (see 40 CFR §125 Subpart A) to meet best practicable control technology currently available (BPT) for conventional pollutants and some metals, best conventional control technology (BCT) for conventional pollutants, and best available technology economically achievable (BAT) for toxic and non-conventional pollutants. There are no effluent limitations guidelines which are applicable to this facility.

In general, the statutory deadline for non-POTW, technology-based effluent limitations must be complied with as expeditiously as practicable but in no case later than three years after the date such limitations are established and in no case later than March 31, 1989 (see 40 CFR §125.3(a)(2)). Compliance schedules and deadlines not in accordance with the statutory provisions of the CWA can not be authorized by a NPDES permit.

In the absence of published technology-based effluent guidelines, the permit writer is authorized under Section 402(a)(1)(B) of the CWA to establish effluent limitations on a case-by-case basis using best professional judgment (BPJ).

The effluent monitoring requirements have been established to yield data representative of the discharges under the authority of Section 308(a) of the Clean Water Act, according to regulations set forth at 40 CFR § 122.41(j), 122.44(i) and 122.48. The monitoring program in the permit specifies routine sampling and analysis which will provide continuous information on the reliability and effectiveness of the installed pollution abatement equipment. The approved analytical procedures are to be found in 40 CFR 136 unless other procedures are explicitly required in the permit.

Water Quality-Based Requirements

Water quality-based limitations are required in NPDES permits when EPA and the State determine that effluent limits more stringent than technology-based limits are necessary to maintain or achieve state or federal water quality standards (WQS). See Section 301(b)(1)(C) of the CWA.

Receiving water requirements are established according to numerical and narrative standards adopted under state law for each water quality classification. When using chemical-specific numeric criteria to develop permit limits, both the acute and chronic aquatic-life criteria, expressed in terms of maximum allowable in-stream pollutant concentration, are used. Acute aquatic-life criteria are considered applicable to daily time periods (maximum daily limit) and chronic aquatic-life criteria are considered applicable to monthly time periods (average monthly limit). Chemical-specific limits are allowed under 40 CFR § 122.44(d)(1) and are implemented under 40 CFR § 122.45(d). The Region has established, pursuant to 40 CFR 122.45(d)(2), a maximum daily limit and average monthly discharge limits for specific chemical pollutants.

A facility's design flow is used when deriving constituent limits for daily and monthly time periods as well as weekly periods where appropriate. Also, the dilution provided by the receiving water is factored into this process where appropriate. Narrative criteria from the state's water quality standards are often used to limit toxicity in discharges where (a) a specific pollutant can be identified as causing or contributing to the toxicity but the state has no numeric standard; or (b) toxicity cannot be traced to a specific pollutant.

EPA regulations require NPDES permits to contain effluent limits more stringent than technology-based limits where more stringent limits are necessary to maintain or achieve state or federal WQS. The permit must address any pollutant or pollutant parameter (conventional, non-conventional, toxic and whole effluent toxicity) that is or may be discharged at a level that causes or has "reasonable potential" to cause or contribute to an excursion above any water quality criterion. See 40 CFR Section 122.44(d)(1). An excursion occurs if the projected or actual in-stream concentration exceeds the applicable criterion. In determining reasonable potential, EPA considers (a) existing controls on point and non-point sources of pollution; (b) pollutant concentration and variability in the effluent and receiving water as determined from the permit application, Monthly Discharge Monitoring Reports (DMRs), and State and Federal Water Quality Reports; (c) sensitivity of the species to toxicity testing; (d) known water quality impacts of processes on wastewater; and, where appropriate, (e) dilution of the effluent in the receiving water.

WQS consist of three parts: (a) beneficial designated uses for a water body or a segment of a water body; (b) numeric and/or narrative water quality criteria sufficient to protect the assigned designated use(s); and (c) antidegradation requirements to ensure that once a use is attained it will not be degraded. The Massachusetts Surface Water Quality Standards (MA SWQS), found at 314 CMR 4.00, include these elements. The state will limit or prohibit discharges of pollutants to surface waters to assure that surface water quality standards of the receiving waters are protected and maintained or attained. These standards also include requirements for the regulation and control of toxic constituents and require that EPA criteria, established pursuant to Section 304(a) of the CWA, shall be used unless a site-specific criterion is established. The conditions of the permit reflect the goal of the CWA and EPA to achieve and then to maintain WQS.

Antibacksliding

A permit may not be renewed, reissued or modified with less stringent limitations or conditions than those contained in the previous permit unless in compliance with the anti-backsliding requirements of the CWA [see Sections 402(o) and 303(d)(4) of the CWA and 40 CFR §122.44(l)(1 and 2)]. EPA's antibacksliding provisions prohibit the relaxation of permit limits, standards, and conditions except under certain circumstances. Effluent limits based on BPJ, water quality, and state certification requirements must also meet the antibacksliding provisions found at Section 402(o) and 303(d)(4) of the CWA.

The regulations at 40 CFR §122.44(l)(2)(i)(B)(1) offer an exception to the antibacksliding provisions based on information that was not available at the time of permit issuance and which would have justified the application of a less stringent effluent limitation. This exception is also referred to as "new information". The results of the monitoring for copper, or "new information", indicate that effluent levels based on revised dilution factors are well below the chronic and acute water quality based standards and that effluent levels of total copper would not be expected to cause or contribute to instream WQS violations. See discussion and calculations in Section VI below. Therefore, the copper limit has been changed to a quarterly monitoring requirement.

Regarding pH, the upper end of the pH range has been changed from 8.3 standard units (s.u.) to 9.0 s.u. This change is based on new information that shows that the permittee's source water from the MWRA is often above 9.0 s.u. and that with the dilution available to the discharge, it would not be expected that the discharge would cause or contribute to a violation of the instream State pH range requirement of 6.5 – 8.3 s.u.

For Total Suspended Solids (TSS), since all prior monitoring has not detected TSS in the effluent, the effluent limits of 30 mg/l as a monthly average and 45 mg/l as a daily maximum have been eliminated. However, this permit has established a quarterly monitoring requirement for TSS to assure that the filtering mechanism of the RO system is working properly and that suspended solids do not pass through to the effluent. This change is being allowed according to the "new information" exception.

Antidegradation

Federal regulations found at 40 CFR Section 131.12 require states to develop and adopt a statewide antidegradation policy which maintains and protects existing instream water uses and the level of water quality necessary to protect the existing uses, and maintains the quality of waters which exceed levels necessary to support propagation of fish, shellfish, and wildlife and to support recreation in and on the water. The Massachusetts Antidegradation Regulations are found at Title 314 CMR 4.04. This draft permit is being reissued with similar limits that were established in the ROGP. Therefore, EPA and MassDEP have determined that there is no evaluation that needs to be conducted relative to antidegradation since the permittee is not increasing its permitted flow or adding any new or increased levels of any pollutants.

State Certification

Under Section 401 of the CWA, EPA is required to obtain certification from the state in which the discharge is located that all water quality standards or other applicable requirements of state law, in accordance with Section 301(b)(1)(C) of the CWA, are satisfied. EPA permits are to include any conditions required in the state's certification as being necessary to ensure compliance with state water quality standards or other applicable requirements of state law. (See CWA Section 401(a) and 40 CFR §124.53(e).) Regulations governing state certification are set out at 40 CFR §124.53 and §124.55. EPA regulations pertaining to permit limits based upon water quality standards and state requirements are contained in 40 CFR §122.44(d).

VI. Explanation of Permit's Effluent Limitations

Outfall 001

The ROGP for Genzyme had required flow monitoring with no limit. The permittee has noted that the effluent flows vary with production needs and DMRs have shown effluent flows of RO reject water to be in the range of 2,300 to 90,000 gallons per day (GPD). The permittee has requested flow limits based on its operational needs of a monthly

average of 66,000 GPD and a daily maximum of 120,000 GPD and these have been established as the draft permit limits.

The ROGP had 2 sets of limits, one for discharges with a dilution factor of 10 to 99 and another for a dilution factor of 100 to 1000. The permittee estimated a dilution factor of 256 for this discharge and the ROGP for Genzyme established the limits based on the latter dilution range, which included limits for Total Suspended Solids (TSS), Total Residual Chlorine (TRC), pH, Total Copper and Dissolved Oxygen. There were also monitoring requirements for flow and ammonia. For this individual draft permit, EPA has evaluated whether these previous limits and monitoring requirements are still appropriate based on past discharge monitoring results and also considered whether any other requirements need to be included, based on the recently submitted individual permit application.

Copper may be toxic to aquatic life at low concentrations, so the ROGP contained numerical limits for total recoverable copper and specified an appropriate method of analysis. Total copper limits in the ROGP were established at a monthly average of 516 ug/l and a daily maximum of 730 ug/l for those discharges in the 100 – 1000 dilution range. The permittee has reported total copper values of between non-detect and 39 ug/l since obtaining coverage under the ROGP. The copper limits that would apply for this discharge have been calculated below to reflect the water quality criteria published in the Federal Register on December 10, 1998 and dilution factors based on revised plant flows.

Water Quality-Based Total Copper limits that would apply to this discharge

$$e\,(X\,[\ln(h)] + Y)$$

Where:	Chronic	Acute
X=	0.8545	0.9422
Y=	-1.702	- 1.70

ln = natural logarithm
Estimated hardness = 50 mg/l as CaCO3

Thus;

$e(.8545\,[(\ln 50)] - 1.702)$ = 5.2 ug/l

$e(.9422\,[(\ln 50)] - 1.70)$ = 7.3 ug/l

To achieve the applicable effluent limits, the following dilution factors were used:

Charles River 7Q10 flow at Waltham (USGS gage# 0110450): **9.2 MGD**

Average Flow = 66,000 GPD or **0.066 MGD**; Maximum Flow = **0.12 MGD**

average flow dilution: $\frac{9.2 + 0.066}{0.066}$ = **140** maximum flow dilution: $\frac{9.2 + 0.12}{0.12}$ = **78**

Water Quality Based Effluent Limitations:

Monthly Average (chronic)	Daily Maximum (acute)
140 (5.2) = **0.73 mg/l**	78 (7.3) = **0.57 mg/l**

The DMRs have shown effluent total copper levels in the range of non-detect to 39 ug/l. Based on these results, there is not a reasonable potential that this discharge will violate either one of these values. Therefore, a quarterly, monitor only requirement has been established for total copper to verify that the actual effluent levels remain well below these values. The sample type has been changed from a 24 hour composite to a grab sample, because there is not expected to be significant variability in the discharge of effluent copper through a 24 hour period.

The pH range in the ROGP was previously limited to the Class B range of 6.5 to 8.3 s. u. which is the range required by state WQS and which can be found at 314 CMR 4.05. The permittee has demonstrated that its source water is often above 9.0 s.u. and that the effluent could not always be within this permitted range without pH adjustment. The DMRs have reported effluent pH in the range of 6.5 to 9.3 s.u. In August of 2008, the permittee installed a pH treatment system which uses a carbon dioxide injection system for pH adjustment. The permittee had previously installed an automatic diversion system that would divert flow from outfall 001 back to the MWRA if the pH level was above the permitted level. The permittee has noted that this diversion option is no longer available.

EPA has determined that the upper range of the pH shall be limited at 9.0 s.u. This is the highest level allowed in EPA technology guidelines. EPA expects that the instream State WQS of 8.3 s.u. would still be met, due to the significant amount of dilution available to this discharge. The draft permit continues to require weekly grab samples for pH and a reporting of the monthly pH range in the DMRs.

Since RO systems concentrate solids in the intake water, the previous ROGP had established permit limits of 30 mg/l (monthly average) and 45 mg/l (daily maximum) for TSS as well as a monitoring requirement for the mass of TSS discharged. All monitoring results with the ROGP have shown TSS levels to be consistently non-detect. Therefore, the TSS limit has been removed and the monthly monitoring requirement has been changed to a quarterly monitoring requirement to assure that the filtering portion of the RO system is working properly and that suspended solids do not pass through to the effluent. The sample type has been changed from a 24 hour composite to a grab sample, because there is not expected to be significant variability in the discharge of TSS through a 24 hour period.

Consistent with the Class B State WQS, there is also a minimum dissolved oxygen (DO) level of 6.0 mg/l required, to be monitored once per week. Previous DMRs have shown the DO to be within the range of 7.6 to 22 mg/l. Therefore, since the minimum limit of

6.0 has always been met, this parameter's monitoring frequency has been changed from weekly to monthly.

Although the ROGP has a limit for Total Residual Chlorine (TRC), the permittee will not be using any chlorine based chemical for cleaning purposes and all discharges associated with the cleaning of the RO units will be discharged to the MWRA's system. TRC has not been detected in the effluent since September 2005. Although the permittee dechlorinates the intake water prior to putting it through the RO system with carbon filters, there will remain a monthly monitoring requirement for TRC in this permit to assure that TRC levels are not present in the discharge and that the carbon units are working as intended and removing residual chlorine in the source water prior to being sent through the RO units and eventually discharged to Outfall 001.

When RO units are bleached or cleaned with hypochlorite or other chlorine based compounds, chloromines are created, resulting in the reject water containing ammonia. Therefore, Total Ammonia Nitrogen (TAN) monitoring was required in the ROGP. The permittee now conducts cleaning of its RO system components off-site and then triple rinses these components with purified water which is then directed to the MWRA sewer. A review of past DMRs has found that TAN has been detected at levels of 551 and 528 ug/l, with several non-detect samples. However, since this segment of the Charles River is impaired for nutrients and these recent levels appear to be above typical background levels, this monthly monitoring requirement has been maintained in this draft permit.

VII. Essential Fish Habitat Determination (EFH)

Under the 1996 Amendments (PL 104-267) to the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. § 1801 et seq. (1998)), EPA is required to consult with the National Marine Fisheries Services (NMFS) if EPA's action or proposed actions that it funds, permits, or undertakes, may adversely impact any essential fish habitat such as: waters and substrate necessary to fish for spawning, breeding, feeding, or growth to maturity (16 U.S.C. § 1802 (10)). Adversely impact means any impact which reduces the quality and/or quantity of EFH (50 C.F.R. § 600.910 (a)). Adverse effects may include direct (e.g., contamination or physical disruption), indirect (e.g., loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions.

EFH is only designated for species for which federal fisheries management plans exist (16 U.S.C. § 1855(b) (1) (A)). EFH designations for New England were approved by the U.S. Department of Commerce on March 3, 1999. The following is a list of the EFH species and applicable lifestage(s) for the area that includes Massachusetts Bay, to which the Charles River discharges:

Species	Eggs	Larvae	Juveniles	Adults
Atlantic cod (*Gadus morhua*)	X	X	X	X
haddock (*Melanogrammus aeglefinus*)	X	X		

pollock (*Pollachius virens*)	X	X	X	X
whiting (*Merluccius bilinearis*)	X	X	X	X
Red hake (*Urophycis chuss*)	X	X	X	X
white hake (*Urophycis tenuis*)	X	X	X	X
winter flounder (*Pseudopleuronectes americanus*)	X	X	X	X
yellowtail flounder (*Pleuronectes ferruginea*)	X	X	X	X
windowpane flounder (*Scopthalmus aquosus*)	X	X	X	X
American plaice (*Hippoglossoides platessoides*)	X	X	X	X
ocean pout (*Macrozoarces americanus*)	X	X	X	X
Atlantic halibut (*Hippoglossus hippoglossus*)	X	X	X	X
Atlantic sea scallop (*Placopecten magellanicus*)	X	X	X	X
Atlantic sea herring (*Clupea harengus*)		X	X	X
long finned squid (*Loligo pealei*)	n/a	n/a	X	X
short finned squid (*Illex illecebrosus*)	n/a	n/a	X	X
Atlantic butterfish (*Peprilus triacanthus*)	X	X	X	X
Atlantic mackerel (*Scomber scombrus*)	X	X	X	X
summer flounder (*Paralicthys dentatus*)				X
scup (*Stenotomus chrysops*)	n/a	n/a	X	X
black sea bass (*Centropristus striata*)	n/a		X	X
surf clam (*Spisula solidissima*)	n/a	n/a	X	X
bluefin tuna (*Thunnus thynnus*)			X	X

A review of the 23 species in this table for the Mirant Kendall Station draft permit (MA0004868) in 2004 revealed that the life stages of concern were present in the seawater salinity zone (salinity > 25.0 parts per thousand) or the mixing water/brackish salinity zone (0.5 < salinity < 25.0 parts per thousand) only. No life stage was identified as inhabiting the tidal freshwater salinity zone. Although there is some seasonal salt water intrusion into the Lower Basin of the Charles River (that segment below the Boston University Bridge), the freshwater of the Charles River in the vicinity of Genzyme's discharge does not experience appreciable mixing with the saline Boston Harbor water.

Based on the available information, EPA has determined that Genzyme's operation, as restricted by the draft permit conditions, will not directly or indirectly cause adverse

effects to EFH species or their habitat, because the draft permit contains limits that are protective of the aquatic species in the Charles River. For the RO reject water discharge, appropriate limits have been established and all cleaning wastewaters will be discharged to the MWRA's sewer system and not directly to the Chares River.

VIII. Endangered Species Act (ESA)

Section 7(a) of the Endangered Species Act of 1973, as amended (ESA) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical (a "critical habitat"). The ESA requires every Federal agency, in consultation with and with the assistance of the Secretary of Interior, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. The United States Fish and Wildlife Service (USFWS) typically administer Section 7 consultations for bird, terrestrial, and freshwater aquatic species. The NMFS typically administers Section 7 consultations for marine species and anadromous fish.

EPA has reviewed the federal endangered or threatened species of fish, wildlife, and plants to see if any such listed species might potentially be impacted by the reissuance of this NPDES permit and has not found any such listed species. EPA has determined that there are no species of concern present in the vicinity of the outfall from this Facility. Therefore, EPA does not need to formally consult with NMFS or USFWS in regard to the provisions of the ESA.

EPA has structured the proposed limits to be sufficiently stringent to assure that Water Quality Standards will be met. The effluent limits established in this permit ensure the protection of aquatic life and maintenance of the receiving water as an aquatic habitat. During the public comment period, EPA has provided a copy of the Draft Permit and Fact Sheet to both NMFS and USFWS.

Other Conditions

The remaining conditions of the permit are based on the NPDES regulations, 40 CFR Parts 122 though 125, and consist primarily of management requirements common to all permits.

IX. State Certification Requirements

EPA may not issue a permit unless the State Water Pollution Control Agency with jurisdiction over the receiving waters certifies that the effluent limitations contained in the permit are stringent enough to assure that the discharge will not cause the receiving water to violate State WQS. The staff of MassDEP has reviewed the draft permit and advised EPA that the limitations are adequate to protect water quality. EPA has requested permit certification by the State pursuant to 40 CFR 124.53 and expects that the draft permit will be certified.

X. Public Comment Period, Public Hearing, and Procedures for Final Decision

All persons, including applicants, who believe any condition of the draft permit is inappropriate must raise all issues and submit all available arguments and all supporting material for their arguments in full by the close of the public comment period, to the U.S. EPA, Massachusetts Office of Ecosystem Protection (CIP), 1 Congress Street, Suite 1100, Boston, Massachusetts 02114-2023. Any person, prior to such date, may submit a request in writing for a public hearing to consider the draft permit to EPA and MassDEP. Such requests shall state the nature of the issues proposed to be raised in the hearing. A public hearing may be held after at least thirty days public notice whenever the Regional Administrator finds that response to this notice indicates significant public interest. In reaching a final decision on the draft permit the Regional Administrator will respond to all significant comments and make these responses available to the public at EPA's Boston office.

Following the close of the comment period, and after a public hearing, if such hearing is held, the Regional Administrator will issue a final permit decision and forward a copy of the final decision to the applicant and each person who has submitted written comments or requested notice. Within 30 days following the notice of the final permit decision, any interested person may submit a request for a formal hearing to reconsider or contest the final decision. Requests for formal hearings must satisfy the requirements of 40 CFR 124.74, 48 Fed. Reg. 14279-14280 (April 1, 1983).

XI. EPA and MassDEP Contacts

Additional information concerning the draft permit may be obtained between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays, from the EPA and MassDEP contacts below:

George Papadopoulos, Massachusetts Office of Ecosystem Protection
One Congress Street Suite 1100 - Mailcode CIP
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Paul Hogan, Massachusetts Department of Environmental Protection
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February 17, 2009
Date

Stephen S. Perkins, Director
Office of Ecosystem Protection
U.S. Environmental Protection Agency