

**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: MA0040321

NAME AND MAILING ADDRESS OF APPLICANT:

**Shire Human Genetic Therapies, Inc.
700 Main Street
Cambridge, MA 02139**

NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:

**Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138**

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

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

SIC CODE: 2834

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I. Proposed Action, Type of Facility and Discharge Location

Shire Human Genetic Therapies, Inc. or “Shire”, formerly Transkaryotic Therapies, Inc., operates a biopharmaceutical facility in Cambridge, Massachusetts. This facility is engaged in the development, commercialization and manufacturing of therapeutic proteins for gene therapy applications. The facility was authorized to discharge reverse osmosis (RO) reject water on June 3, 2004 to Alewife Brook through Outfall 001, in accordance with the general permit for RO reject water (ROGP) that was issued on December 17, 2002. Shire initiated this discharge on February 1, 2005. The permittee had previously discharged this reject water to the MWRA and still has the option to divert this flow to the MWRA if it experiences an upset or other circumstance which may result in NPDES permit violations.

The ROGP expired on December 17, 2007 and EPA has decided not to reissue it. Therefore, this RO reject water discharge will be authorized under this individual permit. As such, the previous NPDES ROGP# of MAG450002 has been changed to the individual NPDES permit #MA0040321. The permittee was instructed to file an individual permit application and it did so on March 23, 2009 along with supplemental information on April 17, 2009.

The reissued permit will authorize the discharge RO reject water from Outfall 001 at up to a daily maximum flow of 30,000 gallons per day (GPD) to Alewife Brook. The effluent is routed to a storm drain connection which travels for about a 1/2 mile, before discharging to the Wheeler Street outfall (001) to Alewife Brook. See **Table 1** for a summary of Outfall 001 monitoring data, **Figure 1** for a map of the facility and the outfall location, and **Figure 2** for a water flow schematic.

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, Shire employs two reverse osmosis (RO) units to treat the incoming water, which is supplied by the City of Cambridge. The outputs of these RO units are 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 by a recorder at each of the RO units and all other parameters are sampled at the sampling port which contains the combined flow from both RO units prior to discharge to the storm sewer line and eventually to outfall 001.

Since the City of Cambridge source water contains some residual chlorine and other chlorination byproducts, this water is passed through a carbon pre-treatment bed since chlorine is detrimental to the operation of RO units. There is also multi-media filtration and an ultraviolet disinfection system to treat the source water for solids and bacteria

prior to entering the RO units. Any backwash from the multi-media filters is discharged to the MWRA sanitary sewer is prohibited from being discharged through Outfall 001.

For routine and preventative maintenance, the RO units are taken off line annually and cleaned. These pieces are cleaned with a disinfecting solution and the discharge from this cleaning operation is discharged to the MWRA sewer, thus resulting in no discharge to Outfall 001. Prior to operating the RO units, the permittee samples the combined effluent to assure that it will meet the NPDES permit limits. At that point, the flow is diverted back to Outfall 001. The discharge of wastewaters to the Alewife Brook from any cleaning of RO system components or the backwashing of carbon or multi-media filters associated with the RO unit operations has not been authorized by this permit.

III. Receiving Water Description

Under the state water use classification system, MassDEP has designated Alewife Brook (Segment MA71-04), as a Class B water (314 CMR 4.00), with existing variances for CSO discharges. 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 does not always meet the state water quality standards prescribed for Class B waters, especially after wet weather.

Alewife Brook is on the MassDEP's 2008 303(d) list of impaired waters for metals, nutrients, organic enrichment/low dissolved oxygen, pathogens, oil and grease, taste, odor and color, and objectionable deposits.

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 WQS 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 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 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 City of Cambridge is often above 8.3 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.

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 Shire 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 10,000 to 30,000 gallons per day (GPD). The permittee has requested flow limits based on its operational needs of a monthly average of 20,000 GPD and a daily maximum of 30,000 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. In an e-mail from Kathleen Keohane of the MassDEP to Betsy Davis of the USEPA on 11/25/03, a dilution factor of 17.95 was estimated for this discharge, based on an estimated 7Q10 flow of 0.39 MGD in Alewife Brook and a facility RO reject water flow of 23,000 GPD. The 7Q10 flow is the 7 day mean low flow, measured in cubic feet per second (cfs), at a 10 year recurrence interval and is typically used in permits to establish certain permit limits. The Alewife Brook 7Q10 estimate was provided by the United States Geological Survey (USGS) Streamstats program. Therefore, the ROGP was based on the 10 to 99 dilution range, which included limits 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

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 52 ug/l and a daily maximum of 73 ug/l for those discharges in the 10 – 99 dilution range. The permittee has reported total copper values of between non-detect and 4 ug/l since obtaining coverage under the ROGP. The copper limits that would apply for this discharge are hardness dependent and have been calculated below to reflect the water quality criteria published in the Federal Register on December 10, 1998 (National Recommended Water Quality Criteria, December 10, 1998, FR Vol. 63, No.237) 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 X is the chronic coefficient for dissolved fractions of a particular metal;
 Y is the acute coefficient for dissolved fractions of a particular metal;
 h is the hardness of the receiving water; ln is the natural logarithm

The following is the calculation of the applicable water quality based copper limits for this discharge:

Chronic: $X = 0.8545$ $Y = -1.702$

Acute $X = 0.9422$ $Y = -1.70$

Estimated hardness = 50 mg/l as CaCO₃¹

Thus;

$$e^{(0.8545 [(\ln 50)] - 1.702)} \qquad e^{(0.9422 [(\ln 50)] - 1.70)} =$$

$$5.2 \text{ ug/l} \qquad \qquad \qquad 7.3 \text{ ug/l}$$

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

Alewife Brook 7Q10 flow in Cambridge (from USGS Streamstats): **0.39 MGD**

Average Flow = 20,000 GPD or **0.02 MGD**; Maximum Flow = **0.03 MGD**

average flow dilution: $\frac{0.39 + 0.02}{0.02} = \mathbf{20}$ maximum flow dilution: $\frac{0.39 + 0.03}{0.03} = \mathbf{14}$

Monthly Average (chronic)
20 (5.2) = **100 ug/l**

Daily Maximum (acute)
14 (7.3) = **100 ug/l**

These values must be divided by a conversion factor to attain the applicable total recoverable metal limits. The chronic value corresponds to a monthly average limit and the acute to a daily maximum limit.

Monthly average: $100 \text{ ug/l} / 0.96 = \mathbf{104 \text{ ug/l}}$; Daily Maximum: $100 \text{ ug/l} / 0.96 = \mathbf{104 \text{ ug/l}}$

Since the ROGP copper limits are more stringent than those based on the actual dilution, the ROGP's total recoverable copper limits of 52 and 73 ug/l will remain in this permit due to anti-backsliding and since the permittee has demonstrated that it can comply with these limits. This permit has reduced the monitoring frequency from monthly to quarterly due to the low levels present in the discharge. In addition, 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 over a 24 hour period.

1. Estimated value based on City of Cambridge drinking water hardness values reported in 2006 ranging from 50 – 60 mg/l. Drinking water source of Fresh Pond is in close proximity to this discharge.

Other Metals

As part of the permit application, the permittee also provided the results of effluent sampling for other metals. Total aluminum was detected at 90.2 ug/l. The chronic and acute WQC for aluminum are 87 ug/l and 750 ug/l, respectively. These criteria are not hardness dependent. Based on the dilution available, it has not been determined that any limit on aluminum should be established at this time. However, in order to ensure that the discharge of aluminum does not cause or contribute to WQS violations, a quarterly monitoring requirement has been established for total aluminum. No other metals were detected at a level that would be believed to cause or contribute to water quality standards violations. Therefore, no further consideration was given to monitoring requirements for any other metals.

pH

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 8.3 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 6.6 to 9.3 s.u.

EPA has determined that the upper range of the pH shall be limited at 9.0 s.u. This is the highest level that is typically allowed in EPA's technology guidelines. EPA expects that the instream state WQS of 8.3 s.u. would still be met, due to the 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.

Total Suspended Solids (TSS)

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 at levels below 10 mg/l and often not detected. In order to assure that the filtering steps employed prior to the RO system are working properly and that suspended solids do not pass through to the effluent, the limits and monthly monitoring requirement have been retained in the draft permit. 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. In addition, the permittee no longer needs to report the mass of TSS associated with the detected concentration.

Dissolved Oxygen (DO)

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 6.2 to 15.4 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.

Total Residual Chlorine (TRC)

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. However, the City of Cambridge’s water supply, the source of the water used at this facility, is chlorinated and TRC has been detected in the effluent in the range of ND to 0.22 mg/l, with the high value being the only violation of the daily maximum limit of 0.20 mg/l. The following calculation shows what the TRC limit would be based on the actual dilution:

Water Quality Criteria: Freshwater – Chronic: 0.011 mg/l ; Acute: 0.019 mg/l

Effluent Limitations:

<u>Monthly Average:</u>	<u>Daily Maximum:</u>
$20 (.011 \text{ mg/l}) = \mathbf{0.22 \text{ mg/l}}$	$14 (0.019 \text{ mg/l}) = \mathbf{0.27 \text{ mg/l}}$

Since the ROGP’s TRC limits are more stringent than those based on the actual dilution, the ROGP’s limits of 0.11 mg/l as a monthly average and 0.20 mg/l as a daily maximum will remain in this permit due to anti-backsliding and since the permittee has demonstrated that it can comply with these limits. Therefore, a monthly monitoring requirement for TRC has been retained in this draft 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.

Total Ammonia Nitrogen (TAN)

When RO units are bleached or cleaned with hypochlorite or other chlorine based compounds, chloramines are created, resulting in the reject water containing ammonia. Therefore, Total Ammonia Nitrogen (TAN) monitoring was required in the ROGP.

Although the permittee conducts cleaning of its RO system components on-site and does not use chlorine-based cleaning compounds, all rinse water from this cleaning operation is diverted to the MWRA sewer, as previously described. A review of past DMRs has found that TAN has been detected at levels up to 1200 ug/l, with some non-detect samples. However, since Alewife Brook 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 Alewife Brook discharges:

Species	Eggs	Larvae	Juveniles	Adults
Atlantic cod (<i>Gadus morhua</i>)	X	X	X	X
haddock (<i>Melanogrammus aeglefinus</i>)	X	X		
pollock (<i>Pollachius virens</i>)	X	X	X	X
whiting (<i>Merluccius bilinearis</i>)	X	X	X	X
Red hake (<i>Urophycis chuss</i>)	X	X	X	X
white hake (<i>Urophycis tenuis</i>)	X	X	X	X
winter flounder (<i>Pseudopleuronectes americanus</i>)	X	X	X	X
yellowtail flounder (<i>Pleuronectes ferruginea</i>)	X	X	X	X
windowpane flounder (<i>Scophthalmus aquosus</i>)	X	X	X	X
American plaice (<i>Hippoglossoides platessoides</i>)	X	X	X	X
ocean pout (<i>Macrozoarces americanus</i>)	X	X	X	X
Atlantic halibut (<i>Hippoglossus hippoglossus</i>)	X	X	X	X
Atlantic sea scallop (<i>Placopecten magellanicus</i>)	X	X	X	X
Atlantic sea herring (<i>Clupea harengus</i>)		X	X	X
long finned squid (<i>Loligo pealei</i>)	n/a	n/a	X	X
short finned squid (<i>Illex illecebrosus</i>)	n/a	n/a	X	X

Atlantic butterfish (<i>Peprilus triacanthus</i>)	X	X	X	X
Atlantic mackerel (<i>Scomber scombrus</i>)	X	X	X	X
summer flounder (<i>Paralichthys dentatus</i>)				X
scup (<i>Stenotomus chrysops</i>)	n/a	n/a	X	X
black sea bass (<i>Centropristus striata</i>)	n/a		X	X
surf clam (<i>Spisula solidissima</i>)	n/a	n/a	X	X
bluefin tuna (<i>Thunnus thynnus</i>)			X	X

A review of the relevant essential fish habitat information provided by NMFS indicates that EFH has been designated for 23 managed species within the NMFS boundaries encompassing Massachusetts Bay. It is possible that a number of these species utilize these receiving waters for spawning, while others are present seasonally.

Based on the available information, EPA has determined that Shire'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 Alewife Brook. 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 Alewife Brook. During the public comment period, EPA has provided a copy of the Draft Permit and Fact Sheet to NMFS for consultation with NMFS under Section 305(b)(2) of the Magnuson-Stevens Act for EFH.

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 through 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
Boston, MA 02114-2023
Telephone: (617) 918-1579 FAX: (617) 918-1505

Paul Hogan, Massachusetts Department of Environmental Protection
Division of Watershed Management, Surface Water Discharge Permit Program
627 Main Street, 2nd Floor, Worcester, Massachusetts 01608
Telephone: (508) 767-2796 FAX: (508) 791-4131

May 20, 2009
Date

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