

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION II  
290 Broadway - 24th Floor  
New York, New York 10007-1866

FACT SHEET  
DRAFT NPDES PERMIT TO DISCHARGE  
INTO THE WATERS OF THE UNITED STATES

NPDES Application No. PR0026695

Name of Permit Writer: Khalid Chowdhry

Date: July 7, 2010

Name and Address of Applicant:

Amgen Manufacturing Limited (AML)  
P.O. Box 4060  
Juncos, Puerto Rico 00777

Name and Address of Facility  
where Discharge Occurs:

AML Wastewater Treatment Plant  
State Road PR-31, Km 24.6  
Juncos, Puerto Rico 00777

Receiving Water:

Rio Gurabo River

Classification: SD

I. LOCATION OF DISCHARGE

The above-named applicant has applied for a National Pollutant Discharge Elimination System (NPDES) permit to the U.S. Environmental Protection Agency (EPA) to discharge into the designated receiving water. The location of the discharge, outfall 001 P, is described by the following U.S.G.S coordinates:

<u>Discharge</u>	<u>Latitude</u>	<u>Longitude</u>
001	18° 14' 33"	65° 54' 15"

A map showing the location of the facility is found in Attachment I.

## II. DESCRIPTION OF APPLICANT'S FACILITY AND DISCHARGE

Amgen Manufacturing Limited (AML) is a biotechnology manufacturing company with its facilities in Juncos. AML proposes to discharge a daily maximum of 3,028 m<sup>3</sup> (0.8 MGD) as treated process wastewater, blowdown and other wastewaters after tertiary treatment at this wastewater treatment plant (WWTP). The point of discharge, designated as Outfall 001 P discharges to Gurabo River. The receiving water has been classified SD by the Puerto Rico Environmental Quality Board (EQB).

A description of the type and quantity of pollutants which are to be discharged is listed in Table A-1 of the draft permit.

## III. DESCRIPTION OF LIMITATIONS AND CONDITIONS

A brief summary of the basis of each effluent limitation and other conditions in the draft permit is provided in Attachment II.

## IV. STATE CERTIFICATION REQUIREMENTS

State Certification requirements, based upon an Intent to Issue a Water Quality Certificate (WQC) issued by EQB, are described in Attachment III. Review and appeals of limitations and conditions attributable to this certification shall be made through the applicable procedures of the Commonwealth of Puerto Rico and may not be through EPA procedures.

## V. PROCEDURES FOR REACHING A FINAL DECISION ON THE DRAFT PERMIT

These procedures, which are set forth in 40 CFR 124, are described in the public notice of preparation of this draft permit. Included in the public notice are requirements for the submission of comments by a specified date, procedures for requesting a hearing and the nature of the hearing, and other procedures for participation in the final agency decision.

## VI. EPA CONTACT

Additional information concerning the draft permit may be obtained between the hours of 8:00 A.M. and 4:30 P.M., Monday through Friday from:

Jeffrey F. Gratz, Chief  
Clean Water Regulatory Branch  
U.S. Environmental Protection Agency  
290 Broadway, 24<sup>th</sup> Floor  
New York, NY 10007-1866  
(212) 637-3876

Carl-Axel Soderberg, Director  
U.S. Environmental Protection Agency  
Caribbean Environmental Protection Division  
EDIF Centro Europa Apt 417  
1492 Avenida Ponce De Leon  
San Juan, PR 00907-4127  
(787) 977-5814

## ATTACHMENT II

### DESCRIPTION OF DRAFT PERMIT CONDITIONS FOR OUTFALL 001

The effluent limitations, monitoring requirements, and other conditions of this permit are described in the draft permit. The effluent limitations in the permit are equivalent to the most stringent values specified in the applicable technology-based guidelines or water quality-based limitations. All anti-backsliding decisions are made in accordance with EPA Region II Antibacksliding Policy.

#### Table A-1 Effluents and Monitoring Requirements

All effluent limitations and monitoring requirements of parameters listed in Table A-1 are as imposed in the Intent to Issue a WQC issued by EQB, dated June 30, 2010. The Intent to Issue a WQC was issued by EQB for the purpose of assuring compliance with EQB's water quality standards and compliance with other appropriate requirements of State law as provided by Section 401(d) of the Clean Water Act.

#### Technology Based Effluent Limitations

The Technology Based effluent limits are included as required by 40 CFR Part 439.45: Pharmaceutical Manufacturing Point Source Category: Subpart D: Mixing, Compounding, and Formulation. EPA has included both monthly average and daily maximum limits for five-day Biochemical Oxygen Demand (BOD<sub>5</sub>), Total Suspended Solids (TSS), and Chemical Oxygen Demand (COD). These limitations are required by new source performance standards, as required by the effluent limitation guideline, which establishes minimum technical standards applicable on a nationwide basis.

#### Special Conditions

The Special Conditions in the draft permit are part of EQB's Intent to Issue a WQC dated June 30, 2010.

#### Whole Effluent Toxicity

Special Condition 15 was modified from the requirement imposed in the water quality certificate issued by the Puerto Rico EQB. EPA has imposed the quarterly testing requirement to collect data necessary to determine whether this discharge has the reasonable potential to cause or contribute to an exceedance of Puerto Rico's water quality standards for toxicity. This Special Condition is pursuant to water quality based permitting requirements at 40 CFR 122.44(d)(1), which requires EPA and delegated states to evaluate each National Pollutant Discharge Elimination System (NPDES) permit for the potential to exceed state numeric or narrative water quality standards, including those for toxics, and to establish effluent limitations for those facilities with the "reasonable potential" to exceed those standards. This Special Condition is also consistent with the "Region 2 Whole Effluent Toxicity Implementation Strategy". Federal regulations require both chemical specific limits, based on the state numeric water quality

standards or other criteria developed by EPA, and whole effluent toxicity effluent limits if reasonable potential to exceed water quality standards is determined.

EPA has also included a requirement to identify and reduce any toxicity that is found in the discharge. An acute toxicity result where the lethal concentration of 50% (LC50) result is found to be less than 100% effluent will trigger accelerated monitoring. If additional toxicity is found, the permittee must activate a toxicity evaluation and reduction process to identify and abate the source of toxicity.

Special Condition 15 also asserts the right of EPA and EQB to require additional monitoring based on the results of the quarterly samples, and the right of EPA to reopen this permit to include additional toxicity requirements, such as identification of toxic sources and treatability, and/or effluent limitations if warranted.

#### ESA Consultation

Consultation under section 7 (a) (2) of the Endangered Species Act is ongoing and will be completed prior to issuance of the final permit.

#### General Conditions

These conditions apply to all permits as required by 40 CFR Section 122.7.

#### Permit Expiration Date

The validity of the permit is being limited to five years.