

**Response to Comments on
Draft NPDES Permit
Amgen Manufacturing Limited LLC PR0026695**

Summary

The draft permit for Amgen Manufacturing Limited LLC (PR0026695) was public noticed on June 2, 2026, on EPA’s website. The public notice period closed on July 2, 2026.

According to 40 Code of Federal Regulations (CFR) §124.17, at the time that any final permit decision is issued under §124.15, EPA shall issue a response to comments. This response shall (1) specify which provisions, if any, of the draft permit have been changed in the final permit decision, and the reasons for the change; and (2) briefly describe and respond to all significant comments on the draft permit raised during the public comment period, or during any hearing.

Comments were received from Ms. Sheila Soto Robles, EHSS Manager, Amgen on June 10, 2026. All comments are addressed below.

Comment No.	Permit Reference	Comment / Consideration (from Amgen)	Requested Clarification / Proposed Language (from Amgen)	Response from EPA
1	EPA Fact Sheet, Page 2 – Permittee and Facility Description; EPA Fact Sheet, Page 5 – Part II.A; Draft Permit Part II	The Fact Sheet states that the direct discharge NPDES permit is being maintained as a contingency for extreme circumstances that may render PRASA unavailable to receive wastewater and further states that the facility has not discharged through Outfall 001 to date. The Fact Sheet also states that certain additional monitoring parameters included for data collection purposes are only applicable in the event of a discharge from Outfall 001. However, these concepts are not clearly reflected in the draft permit.	Amgen respectfully requests clarification in the final permit that Outfall 001 is maintained as a contingency discharge point, and that discharge-related monitoring and compliance requirements become applicable only when an actual discharge occurs through Outfall 001. This clarification would include monitoring requirements associated with the additional monitoring-only parameters identified in the draft permit. Alternatively, EPA may consider incorporating language into the final permit consistent with the description provided in the Fact Sheet.	EPA has modified the final Permit to match the Fact Sheet’s specificity regarding monitoring only in the event of an emergency discharge, see Part 1.A of the Permit.

2	Draft Permit Part IV.B.1 and IV.B.2 – Whole Effluent Toxicity (WET) and Toxicity Reduction Evaluation (TRE); EPA Fact Sheet, Page 10	The draft permit includes Whole Effluent Toxicity (WET), Toxicity Reduction Evaluation (TRE), accelerated monitoring, notification requirements, and associated reporting requirements. Because Outfall 001 is maintained as a contingency discharge point and has not historically discharged, the applicability of these requirements during periods when no discharge occurs is not clear.	Amgen respectfully requests clarification in the final permit regarding whether WET testing, TRE requirements, accelerated monitoring, notification requirements, and associated reporting obligations apply only during periods when Outfall 001 is actively discharging and not during emergency discharges.	This request is denied. Attachment B of the Permit outlines situations for bypasses and upsets. WET testing and monitoring do not need separate or additional conditions in the case of these defined emergencies. No changes have been made to the permit.
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Additionally, in the process of addressing comments, EPA noticed and corrected some minor typographic errors in the permit including:

- Cadmium was incorrectly listed in Part II.D, the antibacksliding section, of the Fact Sheet, as having less stringent limits than the previous permit. Cadmium limits became more stringent and so it has been removed from the section.
- Revised determinations for ESA and EFH consultations in Part IV of the Fact Sheet.
- In the effluent limit table in Part II.A of the Permit for the parameter Effluent Flow, a numeric value of “3.0” was mistakenly listed in the maximum daily column. It has been removed from the table.