

**REGIONAL WATER QUALITY CONTROL BOARD
SAN DIEGO REGION**

**EXECUTIVE OFFICER SUMMARY REPORT
December 11, 2019**

ITEM 14

SUBJECT

NPDES Permit Reissuance: Waste Discharge Requirements Genentech, Inc. Discharge to the Pacific Ocean through the Oceanside Ocean Outfall (Tentative Order No. R9-2019-0168, NPDES No. CA0109193). (*Joann Lim and Keith Yaeger*)

STAFF RECOMMENDATION

Adoption of Tentative Order No. R9-2019-0168 (Tentative Order) is recommended.

KEY ISSUE

The Tentative Order (**Supporting Document No. 1**) includes a requirement to investigate alternatives for tracking the location and movement of the Oceanside Ocean Outfall (OOO) wastewater plume and its potential encroachment on shoreline water contact recreational areas. The question of where the OOO plume is going also has a regional component for determining when and where multiple plumes from different outfalls coningle. The San Diego Water Board has previously included similar requirements to investigate wastewater plume tracking in the National Pollutant Discharge Elimination System (NPDES) permits for the San Elijo Ocean Outfall and Encina Ocean Outfall, with the goal of using the findings from these studies to develop a unified regional monitoring program for all three ocean outfalls. The San Diego Water Board also included similar plume tracking investigative requirements in the NPDES permits for the Point Loma Ocean Outfall and the South Bay Ocean Outfall in support of coordinated regional monitoring at those outfalls.

PRACTICAL VISION

Consistent with the mission of the Strategy for Healthy Waters chapter of the Practical Vision, the Tentative Order integrates all applicable technology-based requirements, water quality-based effluent limitations, and receiving water quality standards to optimize protection of water quality and beneficial uses in the Pacific Ocean. Additionally, the Tentative Order has provisions allowing for participation in regional monitoring and assessment programs in keeping with San Diego Water Board Resolution No. R9-2012-0069, *Resolution in Support of a Regional Monitoring Framework*.

DISCUSSION

Genentech, Inc. (Discharger) is the owner and operator of the Oceanside Genentech, Inc. facility (Facility). The Facility is a mammalian cell culture facility that manufactures, purifies, formulates, and bulk fills mammalian cell culture derived proteins. The Facility's product and development programs address a variety of medical needs in the areas of oncology, neurology, dermatology, and rheumatology. A description of the Facility can be found in **Supporting Document No. 1**, Attachment F, section II.A. The location of the Facility is shown in **Supporting Document No. 2**.

The Facility discharges up to 0.155 MGD of waste brine to the OOO which also receives discharges from 1) the City of Oceanside's (City's) San Luis Rey Water Reclamation

Facility, La Salina Wastewater Treatment Plant, and Mission Basin Groundwater Purification Facility; 2) Fallbrook Public Utility District's Fallbrook Water Reclamation Plant; and 3) Marine Corps Base, Camp Pendleton's Southern Regional Tertiary Treatment Plant and Advanced Water Treatment Plant at Haybarn Canyon. These discharges are regulated by separate individual NPDES permits for each of these agencies. The reissuance of these three separate NPDES permits are also being considered by the San Diego Water Board at today's meeting under Agenda Item Nos. 11, 12, and 13. The maximum permitted flow from all dischargers to the OOO is 41.5 million gallons per day (MGD).

The Facility discharges combined waste streams to the OOO from the filter backwash and rinse, softener regeneration, drainage from clean steam generators, and blowdown from the vapor compression stills. Wastewater produced by the biologics manufacturing processes at the Facility (including cell culture production and harvesting, recovery and purification, and formulation) is discharged to the City's sanitary sewer system and thus is not regulated by this Order.

The discharges from the Facility to the OOO are currently regulated by Order No. R9-2014-0004, NPDES No. CA0109193. The Tentative Order will, if adopted, supersede Order No. R9-2014-0004 and reissue the NPDES Permit for a five-year term. The Tentative Order was developed based on information in the Discharger's reissuance application, self-monitoring reports, and other available sources (e.g. inspection reports, meetings, and emails with the Discharger).

The Tentative Order was noticed for a public hearing and released for public review and comment for a 30-day period on September 27, 2019. The public comment period closed on October 28, 2019. The San Diego Water Board received one comment letter on the Tentative Order during the comment period (**Supporting Document No. 3**) which was from the Discharger. The comment letter has been provided to San Diego Water Board Members for consideration and is available for review by interested persons upon request. The Response to Comments Report (**Supporting Document No. 4**) contains the San Diego Water Board responses to all of the comments received and, if applicable, describes actions taken to revise the Tentative Order in response to the comments received. A copy of the Response to Comments Report was provided to the Discharger.

The following is a summary of the most significant comments and the responses to those comments:

1 *The Discharger objected to the receiving water limitations and monitoring requirements.*

The Discharger's comment on this issue is summarized and responded to in Comment Nos. 1.1 and 1.4 of the Response to Comments Report. Receiving water limitations and some monitoring requirements have been carried over from the current order (Order No. R9-2014-0004) to the Tentative Order. Receiving water monitoring requirements have been removed for some parameters where the Discharger is not a significant contributor of pollutants. Monitoring for bacteria, sediment, fish and invertebrate communities, and bioaccumulation are no longer part of the Tentative Order. The receiving water limitations in the permit implement applicable water quality control plans (e.g., *Water Quality Control Plan, Ocean*

Waters of California and Water Quality Control Plan for the San Diego Basin). The receiving water monitoring requirements are required in all the OOO NPDES permits, including the Discharger's NPDES permit.

- 2 The Discharger requested that the San Diego Water Board change the location of the compliance monitoring for chronic toxicity from Monitoring Location EFF-001 (Genentech's discharge location) to a location that represents the commingled effluent from all discharges contributing to the OOO.*

The Discharger's comment on this issue is summarized and responded to in Comment No. 1.5 of the Response to Comments Report. The compliance monitoring location for chronic toxicity has been carried over from the current order to the Tentative Order. Chronic toxicity monitoring at Monitoring Location EFF-001 is appropriate to determine if Genentech is discharging any toxic materials in toxic amounts absent the influence of other wastewater streams.

The Revised Tentative Order (Supporting Document No. 1) displays the changes made after the September 27, 2019 public release in red-underline for added text and ~~red-strikeout~~ for deleted text. Some changes have been made in response to the Discharger's comments, while other changes were made to be consistent with the other three Tentative Orders for the OOO being considered by the San Diego Water Board at today's meeting under Agenda Item Nos. 11, 12, and 13.

SIGNIFICANT CHANGES

The following are the significant differences between the Tentative Order and the current Order:

1. The Tentative Order requires the Discharger to evaluate the chronic toxicity in the discharge using USEPA's 2010 Test of Significant Toxicity (TST) hypothesis testing approach at the discharge "in-stream" waste concentration (IWC) of 1.15%, as described in **Supporting Document No. 1**, Attachment E, section III.C.
2. The Tentative Order adds a requirement to conduct a Plume Tracking Monitoring Program consistent with the other Tentative Orders regulating the other discharges to the OOO.
3. The Tentative Order removes the receiving water monitoring requirements for bacteria, sediment, and fish and macroinvertebrate communities.

COMPLIANCE RECORD

From April 2014 to August 2019, the San Diego Water Board noted 11 deficient reporting violations for missing daily flow rates and monitoring results. Details on these violations are contained in the compliance summary information provided in the Fact Sheet of the Tentative Order in Attachment F, section II.D. On June 11, 2019, the San Diego Water Board sent the Discharger a staff enforcement letter to address these violations.

PUBLIC NOTICE

The Tentative Order was noticed and released for public review and comment on September 27, 2019, with comments due October 28, 2019. The Notice of Public Hearing and Comment Period was posted on the San Diego Water Board website for the duration

of the comment period and sent to all interested parties. The Notice announced a public hearing to be held on December 11, 2019; availability of the Tentative Order for review; and provided instructions for submittal of written comments. A copy of the Notice is provided in **Supporting Document No. 5**. Notice of the public hearing on the Tentative Order was also provided in the Meeting Notice and Agenda for the December 11, 2019 San Diego Water Board meeting, which is posted on the Board website.

SUPPORTING DOCUMENTS

1. Revised Tentative Order
2. Location Map
3. Comment Letter from Genentech, Inc.
4. Response to Comments Document
5. Notice of Public Hearing and Comment Period