

State of California  
Regional Water Quality Control Board  
San Diego Region

**REVISED**  
EXECUTIVE OFFICER SUMMARY REPORT  
December 10, 2008

ITEM: 7

SUBJECT: NPDES Permit Reissuance: Waste Discharge Requirements for Genentech, Inc. discharge to the Pacific Ocean via the Oceanside Ocean Outfall, San Diego County (Tentative Order No. R9-2008-0082, NPDES Permit No. CA0109193) (Michelle Mata)

PURPOSE: To adopt Waste Discharge Requirements and NPDES Permit for the discharge of up to 0.155 million gallons per day (MGD) of combined discharges from water softening and purification processes and other non-biologics maintenance activities.

PUBLIC NOTICE: A public notice of the tentative Order was published in the San Diego Union Tribune on August 4, 2008. Copies of the tentative order were mailed on August 8, 2008 to Genentech, Inc. and to all known interested parties and agencies. Copies were made available for public review at the Regional Board office on August 8, 2008. The tentative order was also posted on the Regional Board's web site on August 8, 2008. A public notice of the changed location for the public hearing was published in the San Diego Union Tribune on August 27, 2008.

The comment period was extended to November 26, 2008 by letter dated November 5, 2008.

DISCUSSION: Genentech, Inc. is currently regulated under Order No. R9-2003-0140. Order No. R9-2003-0140 established requirements for the discharge of up to 0.155 MGD of combined discharges from water softening and purification processes and other non-biologics maintenance activities. The combined waste discharges regulated under this NPDES permit are routed to the Pacific Ocean through the Oceanside Ocean Outfall (OOO).

No wastes produced by or in conjunction with the biologics manufacturing processes (including cell culture production and harvesting, recovery and purification, and formulation) at the Facility will be regulated under this Order. All wastewater produced by the biologics manufacturing processes will be

discharged to the City of Oceanside's (City) sanitary sewer system.

Requirements from Order No. R9-2003-0140 have remained essentially unchanged since there have been no modifications to the Facility operations or discharge.

The Regional Board received comments from Genentech, Inc on August 27, 2008. A written Responses to Comments document and an Errata Sheet were prepared and provided to interested parties by email and through regular mail in a letter dated September 5, 2008. The Errata sheet has been incorporated into the draft Order using underline/strikeout-format.

In a letter dated November 5, 2008 the Regional Board extended the comments period for the tentative draft Order to November 26, 2008. ~~To date, no additional comments have been received during the extended comment period.~~ **The Regional Board has received comments from Genentech, Inc. A written Responses to Comments document and an Errata Sheet have been prepared and provided to interested parties by email and through regular mail in a letter dated December 4, 2008. The Responses to Comments documents and Errata Sheet are included in this supplemental mailing.**

SIGNIFICANT  
CHANGES:

The following areas in Tentative Order No. R9-2008-0082 differ from the current Order No. R9-2003-0140:

1. The tentative Order has a new look based on the statewide template for NPDES permits. While each region is unique, there are many aspects of NPDES permits that can be standardized. Since 2004, staffs of the State and Regional Boards, along with USEPA's contractor, have embarked in standardizing NPDES permits in the state.
2. Based on the Ocean Plan Reasonable Potential Analysis (RPA) Amendment that was adopted by the State Board on April 21, 2005 and historical effluent data, the initial dilution ratio has been recalculated, resulting in a slight increase from 80:1 to 87:1. The Fact Sheet of the tentative order contains information regarding how the new dilution factor was calculated. The new dilution factor matches the dilution factor in the other NPDES permits for discharges through the

Oceanside Ocean Outfall.

3. A RPA was conducted using data supplied by Genentech, Inc. Effluent limitations were included for constituents with reasonable potential to exceed water quality objectives. Constituents that do not have reasonable potential or had inconclusive RPA results are assigned performance goals in the tentative order. These constituents are also assigned monitoring requirements, but the results will be used for informational purposes only, not compliance determination.
4. **The effluent temperature limitation has been removed and replaced with Receiving Water Limitations as outlined in the Water Quality Control Plan for Control of Temperature in the Coastal and Interstate Waters and Enclosed Bays and Estuaries of California (Thermal Plan).**

**Effluent temperature limitations were previously included as a result of the discharge being incorrectly categorized as a Thermal Waste. The tentative Order revised limitations to incorporate applicable requirements for New Elevated Temperature Waste to Coastal Waters.**

COMPLIANCE: Genentech, Inc. discharges to the Pacific Ocean via the OOO and has demonstrated compliance with current Order No. R9-2003-0140.

LEGAL ISSUES: None

SUPPORTING DOCS: 

1. Site Map
2. Postponement Letter Dated November 5, 2008
3. Tentative Order No. R9-2008-0082
4. **Comment Letter from Genentech, Inc dated November 25, 2008.**
5. **Regional Board Transmittal Letter for Responses to Comments and Errata Sheet dated December 4, 2008**
6. **Responses to Comments**
7. **Errata Sheet**

RECOMMENDATION: Adoption of Tentative Order No. R9-2008-0082 **with Errata** is recommended.