

EXECUTIVE OFFICER SUMMARY REPORT
February 12, 2014

- ITEM: 5
- 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. R9-2014-0004, NPDES Permit No. CA0109193)
(Michelle Mata)
- PURPOSE: To reissue waste discharge requirements and a National Pollutant Discharge Elimination System (NPDES) Permit with the adoption of the revised Tentative Order, No. R9-2014-0004.
- RECOMMENDATION: Adoption of Tentative Order No. R9-2014-0004 is recommended.
- KEY ISSUES: The permitted discharge volume, type of discharge, and the effluent limitations have essentially remained the same in the Tentative Order from current Order No. R9-2008-0082. The changes outlined below are minor and consistent with other similar types of discharges in the San Diego Region.
- DISCUSSION: Genentech, Inc. is the owner and operator of a pharmaceutical manufacturing facility (Facility) in Oceanside, CA. (**See Supporting Document No. 1 for facility location map.**) Discharges from the Facility are currently regulated under Order No. R9-2008-0082, which was adopted on December 10, 2009 and expired on January 1, 2014. Following the Discharger's submittal of a complete reissuance application prior to the expiration date, Order No. R9-2008-0082 was administratively extended and will remain fully effective and enforceable until such time as it is superseded by adoption of the Tentative Order or other Order.
- The Tentative Order (**Supporting Document No. 2**) reissues requirements for the discharge of up to 0.155 million gallons per day (MGD) of combined discharges from water softening and purification processes and other maintenance-related activities. The combined waste discharges regulated under the Tentative Order are routed to the Pacific Ocean through the Oceanside Ocean Outfall (OO).

No wastes produced by or in conjunction with the biologics manufacturing processes (including cell culture production, harvesting, recovery, purification, and formulation) at the Facility will be regulated under the Tentative Order. All wastewater produced by the biologics manufacturing processes will be discharged to the City of Oceanside's (City) sanitary sewer system.

The Tentative Order was developed based on information in the Discharger's reissuance application, self-monitoring reports, and other available sources, such as Facility inspection reports. The Tentative Order implements the requirements in the federal Clean Water Act, the Code of Federal Regulations, and the California Water Code applicable to the NPDES Permits Program. The Tentative Order also updates the waste discharge requirements to be consistent with other ocean discharges in the San Diego Region, the Ocean Plan, and the Basin Plan. If adopted, the Tentative Order would supersede Order No. R9-2008-0082 and update waste discharge requirements for the waste discharges from the Facility to the Oceanside OO. If adopted, the Tentative Order will remain in effect for a five-year fixed term.

To date, the San Diego Water Board has received no comments on the Tentative Order.

The Tentative Order was developed with the San Diego Water Board's Practical Vision entitled *Healthy Waters, Healthy People* in mind. NPDES permits, such as the Tentative Order, are the chief regulatory approach for controlling point source pollutant discharges to surface waters for the protection of human health and the environment. Consistent with the mission of the *Strategy for Healthy Waters* chapter of the Practical Vision, the Tentative Order integrates all applicable technology-based and water quality-based standards to optimize protection of water quality and beneficial uses in ocean waters. Staff made only the highest priority updates to the permit, including aligning the Tentative Order with the statewide NPDES template, in an effort to streamline the permit reissuance process and ensure a sustainable NPDES program. Also, consistent with the *Monitoring and Assessment chapter*, staff incorporated specific questions into most of the monitoring program elements (Attachment E of the Tentative Order) in order to ensure that

data is gathered for identified purposes. Doing so will help to ensure that important basic information is produced including information about the Discharger's compliance with the terms and conditions of the Tentative Order, the condition of the receiving water (Pacific Ocean) and the overall effectiveness of the Tentative Order. Additionally, the monitoring program has provisions for the Discharger to participate in regional monitoring to address questions about cumulative impacts in the ocean waters of the Southern California Bight with an effort relative to their contribution of pollutants.

SIGNIFICANT
CHANGES:

The following terms and conditions of Tentative Order No. R9-2014-0004 differ from current Order No. R9-2008-0082:

1. Monitoring for Ocean Plan Table 1 (formerly Table B) parameters has been increased from once in five years to annually to be consistent with the 2012 Ocean Plan update.
2. The effluent limitation for total suspended solids (TSS) has been modified to be consistent with the Ocean Plan. The proposed effluent limitation, 60 mg/L, is less stringent than in the previous permit. Anti-backsliding regulations found at 40 CFR 122.44(l) prohibit reissuing or modifying an NPDES permit to include effluent limitations less stringent than in the previous permit, unless one of the exceptions described in 40 CFR 122.44(l) are met. In this instance, the less stringent TSS effluent limitation is appropriate under the exception described in 40 CFR 122.44(l)(2) because the current TSS effluent limitations were based on a technical mistake or mistaken interpretation of law.
3. The Ocean Plan requires Regional Water Boards to characterize discharges to ocean waters using specified statistical procedures to determine which Ocean Plan Table 1 water quality objectives require effluent limitations to be specified in an NPDES permit. The purpose of the assessment is to determine if a pollutant in the discharge has the reasonable potential to cause or contribute to an exceedance above Ocean Plan Table 1 water quality objectives and requires effluent limitations. The results of this assessment for the Genentech discharge indicate that the discharge does not have reasonable potential to cause or contribute to an exceedance of water quality objectives for chronic toxicity. Due to the lack of reasonable potential, the

Tentative Order removes the water quality-based effluent limitation for chronic toxicity, replacing it with a performance goal. The Tentative Order also requires continued monitoring for chronic toxicity.

COMPLIANCE
RECORD:

During the term of Order No. R9-2008-0082, there were no violations of the Order according to the Discharger's self-monitoring reports. The Discharger has demonstrated compliance with current Order No. R9-2008-0082.

LEGAL CONCERNS:

None

SUPPORTING
DOCUMENTS:

1. Site Map
2. Tentative Order No. R9-2014-0004
3. Public Notice for Tentative Order No. R9-2014-0004

PUBLIC NOTICE:

A public notice of the Tentative Order was posted on the San Diego Water Board website on December 17, 2013. (**Supporting Document No. 3**) The Tentative Order was emailed to the Discharger and all known interested persons on December 17, 2013. The Tentative Order was also posted on the San Diego Water Board's website on December 17, 2013.