December 11, 2019
Item No. 14
Supporting Document No. 4

California Regional Water Quality Control Board
San Diego Region

Response to Comments Report

Tentative Order R9-2019-0168

NPDES No. CA0109193

Waste Discharge Requirements for Genentech, Inc.
Discharge to the Pacific Ocean through the Oceanside Ocean Outfall

December 11, 2019

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INTRODUCTION

This report contains California Regional Water Quality Control Board, San Diego Region (San Diego Water Board) responses to written comments received on Tentative Order No. R9 2019-0168, NPDES No. CA0109193, *Waste Discharge Requirements for Genentech, Inc. Discharge to the Pacific Ocean through the Oceanside Ocean Outfall* (Tentative Order). The San Diego Water Board provided public notice of the release of the Tentative Order on September 27, 2019 and provided a period of 30 days for public review and comment on the Tentative Order. The public comment period ended on October 28, 2019.

Comments and Responses
The summarized written comments and San Diego Water Board responses are set forth below. The responses include a description of any actions taken to revise the Tentative Order in response to the comment. Proposed revisions to the Tentative Order are in red-underline for added text and ~~red strikeout~~ for deleted text.

COMMENTS AND RESPONSES

The San Diego Water Board responses are labeled and follow each comment.

1. Genentech, Inc.

1.1 Comment – Receiving Water Monitoring Requirements

The receiving water monitoring program is a dramatic departure from Genentech's existing permit obligations. Genentech recognizes that the State Water Resources Control Board's 2019 Water Quality Control Plan, Ocean Waters of California (Ocean Plan) includes core-monitoring requirements that are typically monitored in the immediate vicinity of the discharge from a permitted point source. However, as explained in more detail below, requiring a facility that is a de minimis component of the overall point source discharge to be held responsible for an extensive receiving water monitoring program not required under the Clean Water Act, the NPDES regulations, or the Ocean Plan. Doing so would disproportionately burden Genentech with responsibility and liability for things it cannot control.

Introducing another party to coordinate receiving water monitoring requirements would increase the complexity of the program and likelihood for errors. It would not strengthen or add to the quality of the program, which has existed in one form or another under past permits and has been jointly designed, implemented, and maintained by the City of Oceanside, Marine Corps Base, Camp Pendleton, and Fallbrook Public Utility District without participation by Genentech. The USEPA and SDRWQCB have classified each of those parties' discharges through the Oceanside Ocean Outfall ("OOO") as "Major," and have classified Genentech's discharge through the OOO as "Minor."

Genentech request the following edits:
1) Delete “and receiving water monitoring” from Attachment E, page E-2, first paragraph.
2) Delete the Receiving Water Monitoring Locations from Table E-1.
3) Add the following sentence to the beginning of Attachment E, Section IV: “The City of Oceanside, the Marine Corps Base, Camp Pendleton (MCBCP), and the Fallbrook Public Utility District conduct receiving water monitoring for the combined discharge from the OOO.”
4) Modify the second paragraph of Attachment E, Section IV, Receiving Water Monitoring Requirements, as follows:
Receiving water in the vicinity of the OOO shall be conducted ~~as specified below~~ by the City of Oceanside, the MCMCP, and Fallbrook Public Utility District, as set forth in their respective permits [SDRWQCB to insert #s] as specified below. In the event of any conflict between receiving water monitoring requirements as set forth in permit numbers [SDRWQCB to insert

#s] and this Order ,the terms in permit numbers [SDRWQCB to insert #s] shall govern and be applicable to their respective permit holder. If requested by the City of Oceanside, MCBCP, of Fallbrook Public Utility District, the Discharger shall promptly enter into an agreement with those parties whereby Discharger reimburses those parties for a portion of receiving water monitoring requirement costs on an annual basis. The allocation of costs shall based on each parties' allocated capacity relative to total capacity of the OOO. The Discharger shall review the receiving water monitoring reports submitted by the City of Oceanside, the MCBCP, and the Fallbrook Public Utility District as they become available on the State Water Board website at http://ciwqs.waterboards.ca.gov/ciwqs/readOnly/PublicReportEsmrAtGlanceServlet?inCommand=reset. The Discharger shall also promptly cooperate with all reasonable requests for information related to receiving water monitoring requirements by the City of Oceanside, MCBCP, of Fallbrook Public Utility District.

5) Delete the last three paragraph of Attachment E, Section IV, Receiving Water Monitoring Requirements

6) Delete Attachment E, Sections IV.A, IV.B, IV.C, IV.D, IV.E, and IV.F and the related report requirements in Table E-8.

7) Delete the requirements contained in Attachment E, Section VI, Special Studies Requirements, and the related report requirements in Table E-8.

8) Delete the language in Attachment F, Section VII.B, Receiving Water Monitoring and Section VII.D, Special Studies Requirements.

Response

Genentech's current order, Order No. R9-2014-0004, Attachment E, section VIII, contains the receiving water monitoring requirements including surf zone water quality monitoring, nearshore water quality monitoring, offshore water quality monitoring, benthic monitoring, and additional biological monitoring. These receiving water monitoring requirements are the same as what is required in the current orders for the other three dischargers to the OOO (Order No. R9-2011-0016 for the City of Oceanside, Order No. R9-2013-0112 for Marine Corps Base Camp Pendleton, and Order No. R9-2012-0004 for Fallbrook Public Utility District). Thus, some of the receiving water monitoring requirements are simply being carried over from the current order and Genentech has been responsible for conducting the receiving water program since 2014.

Some of the receiving water monitoring requirements are updated or new, such as 1) the addition of required parameters and modification of sample types to better understand the characteristics of the wastewater plume, evaluate compliance with receiving water limitations, and incorporate the requirements of Ocean Plan; 2) modification of bacterial monitoring requirements to reflect the 2018 Ocean Plan amendment and to determine the source of the bacterial exceedances in the receiving waters; and 3) the

addition of the plume tracking monitoring program to determine if the plume is moving towards the shore or surface where it may encroach upon water recreation areas. The same updated or new requirements for receiving water monitoring were added to all four of the Tentative Orders discharging to the OOO. Similar to the current Order, the Tentative Order provides that the receiving water and sediment monitoring program for the OOO may be conducted either individually or jointly with other dischargers to the OOO. The Tentative Order does not specify the allocation of costs for receiving water monitoring. Therefore, the four dischargers to the OOO have the discretion as the commenter requested to allocate the costs for receiving water monitoring based upon their discharge capacity.

The San Diego Water Board agrees that discharge from Genentech does not have a reasonable potential to contribute to bacteria exceedance in the receiving water and is not a significant contributor to impacts on sediment and fish and invertebrate communities. Therefore, monitoring of bacteria, sediment, fish and invertebrate communities, and bioaccumulation should not be incorporated into Genentech's receiving water monitoring requirements. However, Genentech's discharge does have the potential to alter dissolved oxygen, light transmittance, temperature, salinity, and plume dynamics. Therefore, the nearshore and offshore water quality, and plume tracking have been retained in the Tentative Order.

The San Diego Water Board has removed the surf zone monitoring requirements (Attachment E section IV.A), benthic monitoring requirements (Attachment E section IV.C), fish and macroinvertebrate monitoring requirements (Attachment E section IV.D), and the nearshore and offshore human marker HF-183 monitoring requirements (Attachment E section IV.B.2), and has modified the nearshore and offshore monitoring requirements as follows:

Attachment E section B, questions 6, 7, 9

The nearshore for the purposes of monitoring and assessment is considered to extend from the shoreline to a distance of 1,000 feet from the shoreline or the 30-foot depth contour, whichever is further from the shoreline. Offshore for the purposes of monitoring and assessment is considered to extend beyond the nearshore zone. Nearshore and offshore monitoring is necessary to answer the following questions:

(1) Is natural light significantly reduced at any point outside the ZID as a result of the discharge?

(2) Does the discharge cause a discoloration of the ocean surface?

(3) Does the discharge of oxygen demanding waste cause the dissolved oxygen concentration to be depressed at any time more than 10 percent from that which occurs naturally outside the ZID?

(4) Does the discharge of waste cause the pH to change at any time more than 0.2 standard units from that which occurs naturally outside the ZID?

(5) Does the discharge of waste cause the salinity to become elevated in the receiving water?

~~(6) Do nutrients cause objectionable growth or degrade indigenous biota?~~

~~(7) Is the wastewater plume encroaching upon receiving water areas used for swimming, surfing, diving, and shellfish harvesting?~~

(8) What is the fate of the discharge plume?

~~(9) Is fecal indicator bacteria present outside the zone of initial dilution? If so, is the bacteria human source?~~

Attachment E, section B.1, Table E-3 and Notes 2, 3, 4 of Table E-3

Parameter	Units	Sample Type	Minimum Sampling Frequency
~~Fecal Coliform~~	~~CFU /100 ml~~	~~Grab[2,3]~~	~~1/Quarter~~
~~*Enterococci*~~	~~CFU/100 ml~~	~~Grab[2,3]~~	~~1/Quarter~~
~~Human Marker HF-183~~	~~Number of copies (molecules)/100 mL~~	~~Grab[2,4]~~	~~1/Quarter~~
~~Nitrogen, Total~~	~~mg/L~~	~~Grab[2]~~	~~1/Quarter~~
~~Phosphorus, Total (as P)~~	~~mg/L~~	~~Grab[2]~~	~~1/Quarter~~

~~[1] At the surface for nearshore monitoring locations N1 through N7 and surface and mid-depth for offshore monitoring locations A1 through A5, B1, and B2.~~

~~[2] Samples for fecal coliform and enterococci shall be collected on the same day fecal coliform and enterococci are sampled at monitoring location M-004.~~

~~[3] Samples shall be collected at the offshore monitoring locations A1-A5, B1 and B2 and analyzed inIn accordance with section IV.B.2 of this MRP.~~

Attachment F section VII.B

The receiving water ~~and sediment~~ monitoring requirements set forth below are designed to measure the effects of the OOO discharge on the receiving water. These monitoring requirements will remain in effect on an interim basis, pending development of a new and updated monitoring and assessment program.

This Order removes the requirements from Order No. R9-2014-0004 to monitor for total and fecal coliform, and *Enterococci* at the surf zone, nearshore and offshore monitoring locations, and the requirement to monitor sediment and conduct demersal fish and macroinvertebrate diver surveys at the offshore monitoring location as the Discharger is not a significant contributor to bacteria levels and impacts to sediment and demersal fish and invertebrate communities.

Attachment F section VII.B.2

Nearshore and offshore water quality monitoring is required to determine if the effluent is causing or contributing to exceedances of the water quality standards outside of the ZID, to determine the fate of the effluent plume, ~~evaluate the contribution of the discharge to ocean acidification,~~ and to gather data for future permit reissuances. The following changes were made to the n~~N~~earshore and offshore monitoring requirements ~~have been carried over from Order No. R9-2011-0016 with the following exceptions~~:

~~a.~~ For nearshore monitoring requirements, this Order adds monitoring requirements for temperature, depth, dissolved oxygen, light transmittance, pH, and salinity to better understand the characteristics of the wastewater plume, evaluate compliance with receiving water limitations, and incorporate the requirements of Ocean Plan. ~~This Order also adds monitoring requirements for nitrogen and phosphorus to evaluate the contribution of nutrients to the receiving water, which has implications for ocean acidification, hypoxia, and harmful algal blooms.~~

a. For offshore monitoring requirements, this Order changes the pH monitoring from a grab sample at the surface to profile monitoring; the temperature, dissolved oxygen, and light transmittance monitoring from surface, mid-depth, and bottom to profile monitoring; and the conductivity surface, mid-depth, and bottom monitoring to salinity profile monitoring. These changes are also made to better understand the characteristics of the wastewater plume. ~~This Order also adds monitoring requirements for nitrogen and phosphorus to evaluate the contribution of nutrients to the receiving water, which has implications for ocean acidification, hypoxia, and harmful algal blooms.~~

b. This Order removes the requirement to monitor for total and fecal coliform, and *Enterococci* at the nearshore and offshore monitoring locations as the San Diego Water Board does not believe the discharge is a source of bacteria.

c. This Order modifies the frequencies of offshore monitoring from once per month during the first year to once per quarter for the entire permit term.

~~d. For nearshore and offshore monitoring requirements, monitoring for enterococcus bacteria has been changed to monitoring for enterococci and monitoring requirements for total coliform has been removed. These changes reflect the new bacterial provisions contained in the 2018 amendment to the Ocean Plan.~~

~~e. This Order requires the Discharger to collect samples for the Human Marker HF-183 concurrently with samples collected for fecal coliform at the nearshore and offshore monitoring locations. The Human Marker HF-183, derived from the 16S rRNA gene of Bacteroides, has been widely used to identify sewage pollution in coastal waters. For this Order, monitoring for the Human Marker HF-183 is used to confirm the presence of human fecal material when the single sample maximum receiving water limitation for fecal coliform is exceeded. Analysis of the Human Marker HF-183 is only required if the sample for fecal coliform exceeds the single sample maximum receiving water limitation. Results for the Human Marker HF-183 is used for informational purposes only, there is no receiving water limitation for the Human Marker HF-183. This requirement was included due tobecause of the large number of65 exceedances of bacteria receiving water limitations near the Oceanside Ocean Outfall at the offshore monitoring locations located near the OOO (i.e., monitoring locations A1-A5).~~

~~f. Monitoring frequency at nearshore and offshore stations has been reduced from monthly to quarterly to help offset the costs of additional monitoring requirements and the development of a Plume Tracking Monitoring Program.~~

g. Monitoring locations N6 and N7 were not specified in Order No. R9-201~~4~~1-00~~04~~16 and will be determined by the San Diego Water Board based on the results of the Plume Tracking Monitoring Program.

Refer to sections IV.A~~B~~ of the MRP (Attachment E).

Action Taken

The San Diego Water Board has removed the surf zone monitoring requirements (Attachment E section IV.A and Attachment F section VII.B.1), benthic monitoring requirements (Attachment E section IV.C and Attachment F section IV.B.3), fish and macroinvertebrate monitoring requirements (Attachment E section IV.D and Attachment F section IV.B.4), and the nearshore and offshore human marker HF-183 monitoring requirements (Attachment E section IV.B.2), and has modified Attachment E section B, questions 6, 7, 9; Attachment E, section B.1, Table E-3 and Notes 2, 3, 4 of Table E-3; Attachment F section VII.B; and Attachment F section VII.B.2.

1.2 Comment – Incorporating Other Comments

Genentech adopts and incorporates the technical comments on the OOO Receiving Water Monitoring Program and its components, as well as the Plume Tracking Study submitted by the City of Oceanside, Marine Corps Base Camp Pendleton, and Fallbrook Public Utility District with respect to Tentative Order Nos. R9-2019-0166, R9-2019-0167, and R9-2019-0169,

respectively, to the extent they are not inconsistent with Genentech's comments.

Response

Please see the Response-to-Comment documents contained in Agenda Item Nos. 11 and 12 for the San Diego Water Board's responses to the comments on the Plume Tracking Study submitted by City of Oceanside and Fallbrook Public Utility District. Marine Corps Base Camp Pendleton did not submit comments.

Action Taken

None.

1.3 Comment – State-only Requirements

Please update Section II.C of the Tentative Order to reflect any remaining sections that reference Ocean Plan requirements after making any other changes based on these comments.

Response

Neither federal nor state law requires NPDES permits to identify state law only requirements. The broad statement in Section II.C of the Tentative Order is appropriate. The purpose of Section II.C of the Tentative Order is to identify the general legal authorities for the Tentative Order. Based on Genentech's comments, the San Diego Regional Board further reviewed the listed provisions in Section II.C of the Tentative Order. Several provisions listed in Section II.C of the Tentative Order are imposed to implement federal law, do not implement state law only, and thus their references were removed.

Action Taken

Section II.C of the Tentative Order was revised to remove provisions that implement federal law. In particular, the San Diego Water Board has modified section II.C as follows:

> **Provisions and Requirements Implementing State Law.** The provisions/requirements in subsections IV.B, IV.C, and V.B~~, VI.A.2.a, and VI.C.4.a-c~~ are included to implement State law only. These provisions/requirements are not required or authorized under the federal CWA; consequently, violations of these provisions/requirements are not subject to the enforcement remedies that are available for NPDES violations.

1.4 Comment – Receiving Water Limitations

Based on the overall comments regarding applicability of receiving water monitoring requirements, Genentech recommends deleting the receiving water limitations contained in Section V.A of the Tentative Order for clarity

and adding the following language: “Not Applicable except as specified in Section IV (Attachment E), below.

Response

The Clean Water Act generally requires NPDES permits to include technology-based effluent limitations and any more stringent limitations necessary to meet water quality standards. (33 U.S.C. § 1311(b)(1)(B), (C).) Further, under the Porter-Cologne Water Quality Control Act, waste discharge requirements must implement applicable water quality control plans, including water quality objectives. (California Water Code section 13263). Based on these principles, Genentech’s current order, Order No. R9-2014-0004, contains the receiving water limitations needed to implement water quality objectives contained in the *Water Quality Control Plan for the San Diego Basin* (Basin Plan) and the Ocean Plan. Thus, the receiving water limitations of the Tentative Order are simply carried over from the current order. Regardless of whether the permit has receiving water monitoring requirements or not, the receiving water limitations still apply to Genentech’s permit to discharge to the Pacific Ocean.

Action Taken

None.

1.5 Comment – Chronic Toxicity Monitoring Requirements

Genentech believes the chronic toxicity should be monitored at a location where representative samples of commingled effluent from all discharges contributing to the OOO, not at Monitoring Location EFF-001 (Genentech’s discharge location). Genentech is willing to partially fund the chronic toxicity monitoring but believes the primary POTW dischargers should handle this monitoring.

Response

Genentech’s current order, Order No. R9-2014-0004, contains annual monitoring for chronic toxicity at Monitoring Location EFF-001 (A location where a representative sample of the brine discharge can be obtained, upstream of the City of Oceanside’s 14” brine line prior to comingling with any other discharge). Thus, the Tentative Order simply carries over the same requirements. Chronic toxicity monitoring at location EFF-001 is appropriate to determine if Genentech is discharging any toxic materials in toxic amounts absent the influence of other wastewater streams.

Action Taken

None.

1.6 Comment – Description for EFF-001 in Attachment A

Genentech requests that we add the description of Monitoring Location EFF-001 to Attachment A.

Response

The description for monitoring location is located in Table E-1. Maintaining the descriptions only in this table is standard in NPDES permits across the State.

Action Taken

None.

1.7 Comment – Nutrient Effluent Monitoring

Delete effluent monitoring requirements for total nitrogen and total phosphorus because the Tentative Order does not contain any effluent limitations for these parameters. In lieu of these parameters, add ammonia as nitrogen because the tentative order does contain effluent limitations for these parameters.

Response

Since the brine waste from Genentech is not likely to contain significant amounts of nitrogen and phosphorus as compared to treated wastewater, the San Diego Water Board has removed the requirements to monitoring for total nitrogen and total phosphorus.

Action Taken

The San Diego Water Board has modified Attachment E, section III.B, Table E.2 as follows:

Parameter	Units	Sample Type	Minimum Sampling Frequency	Required Analytical Test Method
Flow	million gallons per day (MGD)	Recorder/ Totalizer	Continuous	--
Temperature	°F	Grab	2/Year	[2]
Specific Electrical Conductivity (@ 25°C)	micromhos per centimeter (µmhos/cm)	Grab	1/Month	[2]
~~Nitrogen, Total~~	~~mg/L~~	~~24-hr Composite~~	~~1/Quarter~~	~~[2]~~
~~Phosphorus, Total (as P)~~	~~mg/L~~	~~24-hr Composite~~	~~1/Quarter~~	~~[2]~~

Parameter	Units	Sample Type	Minimum Sampling Frequency	Required Analytical Test Method
Oil and Grease	milligram per liter (mg/L)	Grab	2/Year[3,4]	[2]
Total Suspended Solids (TSS)	mg/L	24-hr Composite	2/Year[3,4]	[2]
Settleable Solids	milliliter per liter (ml/L)	Grab	2/Year[4]	[2]
Turbidity	nephelometric turbidity unit (NTU)	Grab	2/Year[4]	[2]
pH	standard units	Grab	2/Year[4]	[2]

The San Diego Water Board has modified Attachment F, section VII.A.2.d as follows:

~~This Order adds quarterly monitoring requirements for total nitrogen and total phosphorus to gather data on the contribution nutrients to the receiving water.~~

1.8 Comment – Chlorine Effluent Monitoring

Please note that total chlorine residual is included in Table 4, Effluent Limitations at Monitoring Location EFF-001, but not in Table E-2, Effluent Monitoring at Monitoring Location EFF-001.

Response

Total chlorine residual is included in both Table 4 and Table E-2 (with a minimum sampling frequency of once per quarter).

Action Taken

None.

1.9 Comment – Typographical Errors

Genentech noted four typos in the document. See its redlined version of the Tentative Order

Response

The San Diego Water Board made the corrections.

Action Taken

The San Diego Water Board made the following correction to Attachment A, definition for Chronic Toxicity:

> **Chronic Toxicity**
> Chronic toxicity is the measure of the sub-lethal effects of a discharge or ambient water sample (e.g. reduced growth or reproduction.). Certain chronic toxicity tests include an additional measurement of lethality.

The San Diego Water Board made the following correction to Attachment D, section V.E.1, last paragraph:

> As of December 21, 2020, all reports related to combined sewer overflows, sanitary sewer overflows, or bypass events ~~<Optional language (see instructions at I.G.5)~~: must be submitted to the San Diego Water Board and> must be submitted electronically to the initial recipient defined in Standard Provisions – Reporting V.J. The reports shall comply with 40 CFR part 3, 40 CFR section 122.22, and 40 CFR part 127. The San Diego Water Board may also require the Discharger to electronically submit reports not related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section. (40 CFR section 122.41(l)(6)(i).)

The San Diego Water Board made the following correction to Attachment F, section II, first paragraph:

> The Facility is a mammalian cell culture facility that manufactures, purifies, formulates, and bulk fills mammalian cell culture ~~deprived~~ derived proteins. The site's product and development programs address a variety of medical needs in the areas of oncology, neurology, dermatology, and rheumatology.

The San Diego Water Board made the following correction to Attachment F, title of Table F-10:

> Table F-10. Summary of Performance Goals at Monitoring Location EFF-001~~1~~[1]

1.10 Comment – Effluent Monitoring Requirements

Genentech requested that the San Diego Water Board change the term "Parameters" to "Performance Goals" in Attachment E, Table E-2

Response

Table E-2 requires effluent monitoring for the parameters listed in Table 3 of the Ocean Plan and is not dependent on the which parameters have effluent limitations or performance goals.

Action Taken

None.