

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX

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In the matter of:

Genentech, Inc.,

EPA Identification Nos. CAD080129000 CAR000182634 CAR000182709 U.S. EPA Docket No.

RCRA-09-2023-0057

PROCEEDING TO COMMENCE AND CONCLUDE AN ACTION TO ASSESS A CIVIL PENALTY UNDER RCRA SECTION 3008 PURSUANT TO 40 C.F.R. SECTIONS 22.13 AND 22.18

Respondent.

CONSENT AGREEMENT

A. <u>PRELIMINARY STATEMENT</u>

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- This is a civil administrative enforcement action instituted pursuant to Section 3008 of the Resource Conservation and Recovery Act ("RCRA"), as amended, 42 U.S.C. § 6928, and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, Title 40 of the Code of Federal Regulations ("C.F.R.") Part 22, ("Consolidated Rules").
- 2. Complainant is the United States Environmental Protection Agency, Region IX ("EPA").
- 3. Respondent is Genentech, Inc. (a wholly owned subsidiary of Roche Holdings, Inc.), headquartered at 1 DNA Way, South San Francisco, CA 94080. Respondent is the owner and operator of the facility located at the same address, 1 DNA Way, South San Francisco, CA 94080, (the "Facility"). The Respondent is referred to herein as "Respondent" or "Genentech."
- 4. This Consent Agreement and Final Order ("CA/FO"), pursuant to 40 C.F.R. §§

22.13(b) and 22.18, simultaneously commences and concludes this proceeding, wherein EPA alleges that Respondent violated state regulations adopted pursuant to the approved California hazardous waste management program.

5. The Parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their respective interests and in the public interest.

B. <u>STATUTORY AND REGULATORY FRAMEWORK</u>

- 6. Subtitle C of RCRA requires the EPA Administrator to promulgate regulations establishing a hazardous waste management program. Section 3006 of RCRA, 42 U.S.C. § 6926, provides, *inter alia*, that authorized state hazardous waste management programs are carried out under Subtitle C of RCRA. Therefore, a violation of any requirement of law under an authorized state hazardous waste program is a violation of a requirement of Subtitle C of RCRA.
- 7. The State of California ("State" or "California") received authorization to administer the hazardous waste management program in lieu of the federal program pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, and 40 C.F.R. Part 271 on or about August 1, 1992. This authorization was updated on September 26, 2001, (see 66 FR 49118, September 26, 2001), on October 7, 2011, (see 76 FR 62303, October 7, 2011) and again on January 14, 2020 (see 85 FR 2038, as corrected (see 86 FR 29207, June 1, 2021)).
- 8. The authorized hazardous waste program is established pursuant to the Hazardous Waste Control Law, Chapter 6.5 of Division 20 of the California Health and Safety Code (or the "H&SC"), and the regulations promulgated thereunder at Title 22, Division 4.5 of the California Code of Regulations (or the "C.C.R."), 22 C.C.R. §§ 66001 *et seq.* The State has been authorized for all the relevant portions of the hazardous waste management regulations referenced in this CA/FO.¹

C. EPA'S GENERAL ALLEGATIONS

9. Respondent is a biopharmaceutical manufacturing company and owns and operates the Facility where it maintains biopharmaceutical manufacturing and test facilities ("pilot plants") and undertakes research and development, production, site and transportation services, and sales. The Facility consists of six (6) campuses (South, Mid, Lower, West, Upper, and Gateway) and maintains the following eleven (11) EPA RCRA ID numbers between the campuses: CAD080129000; CAL000348371; CAR000172338; CAR000182634;

¹ All citations to the "C.C.R." refer to Division 4.5 of Title 22 of the California Code of Regulations. EPA is enforcing California hazardous waste management program requirements as approved and authorized by the United States. As a convenience, corresponding Federal citations are provided in brackets.

CAR000179275; CAL000326251; CAL000308092; CAR000182709; CAL000297147; CAR000199539; CAR000075408. The Facility also generates at least 1,000 kilograms of hazardous waste in any calendar month.

- 10. On or about August 24, 2021 through August 26, 2021, EPA conducted a National Compliance Initiative inspection at the Facility (the "Inspection"). The purpose of the Inspection was to determine the Facility's compliance with applicable federal environmental statutes and regulations, in particular RCRA, as amended, and the regulations in 40 C.F.R. Parts 260 through 279, as well as the authorized statutory and regulatory requirements adopted by the State as part of its authorized hazardous waste program in the California Health and Safety Code, Division 20 and the California Code of Regulations, Title 22, Division 4.5. In addition, the Inspection had a particular focus on compliance with RCRA's hazardous waste air emission requirements.
- Respondent is a "person" as defined in the H&SC, Section 25118 [see also Section 1004(15) of RCRA, 42 U.S.C. § 6903(15)], and 22 C.C.R. § 66260.10 [see also 40 C.F.R. § 260.10].
- 12. Respondent is the "owner" of a facility as defined in 22 C.C.R. § 66260.10 [see also 40 C.F.R. § 260.10].
- 13. Respondent is the "operator" of a facility as defined in 22 C.C.R. § 66260.10 [see also 40 C.F.R. § 260.10].
- 14. Respondent is a "generator" of "hazardous waste" as defined in 22 C.C.R. §§ 66260.10 and 66261.3 [see also 40 C.F.R. §§ 260.10 and 261.3]. Hazardous waste streams generated at the Facility include, but are not limited to, ignitable wastes (Waste Code D001), wastes from manufacturing and industrial processes (F-listed waste), corrosive wastes (D002), reactive wastes (D003), and discarded commercial chemical products and toxic wastes (U-listed wastes). Additionally, Respondent generates universal waste at the Facility.
- 15. Based upon the findings EPA made during the Inspection, and additional information obtained subsequent to the Inspection, EPA determined that Respondent violated the H&SC §§ 25100 *et seq.*, and the regulations adopted pursuant thereto, as approved and authorized by the United States.
- 16. Section 3006 of RCRA, 42 U.S.C. § 6926, provides, *inter alia*, that authorized state hazardous waste programs are carried out under Subtitle C of RCRA. A violation of California's authorized hazardous waste program, found at H&SC §§ 25100 *et seq.*, constitutes a violation of Subtitle C of RCRA. Therefore, a person who violates California's authorized hazardous waste program is subject to the powers vested in the EPA Administrator by Section 3008 of RCRA, 42 U.S.C. § 6928.

- 17. Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the EPA Administrator to issue orders assessing a civil penalty and/or requiring compliance immediately or within a specified time for violation of any requirement of Subtitle C of RCRA, Section 3001 of RCRA *et seq.*, 42 U.S.C. § 6921 *et seq.* The Administrator has delegated enforcement authority under Section 3008 of RCRA, 42 U.S.C. § 6928, to the EPA Regional Administrators, with delegation 8-9A. The Regional Administrator, EPA Region IX, has redelegated that authority to the EPA signatory below, with delegation R9-8-9A.
- 18. Genentech has cooperated with EPA in good faith throughout EPA's investigation.
- D. <u>ALLEGED VIOLATIONS</u>

COUNT I

Failure to Comply with Manifest Regulations

- 19. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
- 20. 22 C.C.R. § 66262.23(a)(1) [*see also* 40 C.F.R. § 262.20(a)(1)] requires a generator of any hazardous or extremely hazardous waste that is transported offsite to prepare a hazardous waste manifest (including EPA form 8700-22A, as needed) according to the manifest instructions. In accordance with the instructions, the generator must enter the state and federal waste codes on the manifest that best describe the waste being shipped off-site.
- 21. While it operated the Facility, Respondent failed to include EPA waste code U220 on the following two (2) manifests both dated March 19, 2021 for lab-packed shipments: 015396900 FLE, and 015396899 FLE. These manifests included shipments of hazardous waste containing toluene waste streams. Respondent instead included EPA waste code D002 (for ignitability) and California waste code 551 (for lab packs) on each of those manifests.
- 22. Therefore, EPA alleges that Respondent failed to enter a necessary federal waste code on hazardous waste manifests 015396900 FLE (March 19, 2021) and 015396899 FLE (March 19, 2021), in violation of 22 C.C.R. § 66262.23(a)(1) [see also 40 C.F.R. § 262.20(a)(1)].

COUNT II

Storage of Hazardous Waste Without a Permit

23. Paragraphs 1 through 22 above, are incorporated herein by this reference as if they were set forth here in their entirety.

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- 24. 22 C.C.R. §§ 66262.34(c) and 66270.1 [see also 40 C.F.R. § 270.1] provide, among other things, that a generator who accumulates hazardous waste onsite for over 90 days is an operator of a storage facility, subject to the requirements (including, but not limited to, the air emission and tank systems standards) for owners and operators of hazardous waste transfer, treatment, storage, and disposal facilities, and must be eligible for interim status or obtain a permit for such transfer, treatment, storage, or disposal.
- 25. Additionally, 22 C.C.R. § 66273.35(a) [see also 40 C.F.R. §§ 273.15(a), 273.35(a)] states that a universal waste handler shall accumulate universal waste for no longer than one year from the date the universal waste was generated, or was received from another universal waste handler.
- 26. Respondent is a generator of hazardous waste including, but not limited to, ignitable wastes (Waste Code D001), wastes from manufacturing and industrial processes (F-listed waste), corrosive wastes (D002), reactive wastes (D003), and discarded commercial chemical products and toxic wastes (U-listed wastes). Additionally, Respondent generates universal waste at the Facility.
- 27. At the time of the Inspection, Respondent did not apply for or have a permit or grant of interim status to store hazardous waste under 22 C.C.R. § 66270.1 [see also 40 C.F.R. § 270.1].²
- 28. Based on information gathered during the Inspection, and additional information obtained subsequent to the Inspection, EPA determined that from June 2019–June 2020, Respondent had stored eleven (11) hazardous waste containers over the 90-day storage limit. Additionally, Respondent had stored five (5) containers of universal waste over the one-year storage limit. EPA also identified two (2) containers with unknown types of waste and accumulation start dates.
- 29. Therefore, EPA alleges that Respondent stored waste without a required permit and over the accumulation time limits in the eighteen (18) instances described in Paragraph 28, in violation of 22 C.C.R. §§ 66262.34(c), 66270.1, and 66273.35(a) [see also 40 C.F.R. §§ 270.1, 273.15(a), and 273.35(a)].

²Additionally, Respondent had not been granted an extension of the 90-day storage limit and an exemption for accumulation of limited amounts of hazardous waste did not apply under 22 C.C.R. § 66262.34.

COUNT III³

Failure to Follow Calibration and Detection Instrument Requirements Under the Air Emission Standards for Equipment Leaks

- 30. Paragraphs 1 through 29 above, are incorporated herein by this reference as if they were set forth here in their entirety.
- 31. Under 22 C.C.R. §§ 66264.1063(a) and (b) [see also 40 C.F.R. § 264.1063(a) and (b)], leak detection monitoring for air emissions (as required in 22 C.C.R. §§ 66264.1052–66264.1062), requires, in part, that "the instrument ... be calibrated before use on each day of its use by the procedures specified in Reference Method 21 in 40 CFR, part 60" and that calibration gases be: "(A) zero air (less than 10 ppm of hydrocarbon in air); and (B) a mixture of methane or n-hexane and air at a concentration of approximately, but less than, 10,000 ppm methane or n-hexane."
- 32. At the time of the Inspection, Respondent was using an Industrial Scientific MX6 5-gas photo-ionization detector ("PID") as the instrument for leak detection and repair ("LDAR") monitoring for air emissions. Facility personnel stated during the Inspection that calibration of the PID occurred the night or a few days prior to the day of its use. Additionally, 100 ppm isobutylene gas and a four-gas mixture of hydrogen sulfide, carbon monoxide, pentane, and nitrogen were used to calibrate the PID. EPA found that these gases used to calibrate the PID do not meet the regulatory requirements for zero air and a concentration of approximately equal to (but less than) 10,000 ppm methane or n-hexane.
- 33. Following the Inspection, Respondent stated that it is now using a Thermo TVA1000A/B meter, which is capable of measuring VOC concentrations from 0 to 50,000 ppm, and that it has implemented operating procedures, which include calibrating the instrument on each day of its use and using calibration gases that include a mixture of air and methane according to the requirements of the C.C.R.'s air emission standards for leak detection monitoring and Reference Method 21.

34. Therefore, EPA alleges that Respondent did not meet the relevant calibration and

³ Respondent is subject to the standards for owners and operators of hazardous waste transfer, treatment, storage, and disposal facilities under Chapter 14, Division 4.5 of Title 22 of the C.C.R. (22 C.C.R. §§ 66264.1–66264.1110) ("Chapter 14") because it stored hazardous waste, as alleged under Count II. Under the C.C.R., a generator who stores hazardous waste for over 90 days is an operator of a storage facility, subject to Chapters 14 and 15 and the permit requirements of Chapter 20. *See* 22 C.C.R. §§ 66262.34(c) and 66270.1 [*see also* 40 C.F.R. § 270.1]. Chapter 14 applies to and establishes standards for owners and operators of storage facilities, while Chapter 15, Division 4.5 of Title 22 of the C.C.R. (22 C.C.R. §§ 66265.1–66265.1110) more specifically applies to and establishes standards for owners and operators after they have completed a permit application. *See* 22 C.C.R. §§ 66241.1(a)–(b), 66265.1(a)–(b), and 66270.1 [*see also* 40 C.F.R. §§ 264.1(a)–(b), 265.1(a)–(b), and 270.1]. As alleged under Count II, Paragraph 27, at the time of the Inspection, Respondent did not apply for or have a permit or grant of interim status. Therefore, EPA has cited to Chapter 14 and the corresponding Federal citations for Counts III–VI in this CA/FO.

detection instrument requirements, in violation of 22 C.C.R. §§ 66264.1063(a) and (b) [*see also* 40 C.F.R. § 264.1063(a) and (b)].

COUNT IV

Failure to Follow Equipment Marking and Monitoring Plan Requirements Under the Air Emission Standards for Equipment Leaks

- 35. Paragraphs 1 through 34 above, are incorporated herein by this reference as if they were set forth here in their entirety.
- 36. 22 C.C.R. § 66264.1050(d) [*see also* 40 C.F.R. § 264.1050(d)] states that each piece of equipment "shall be marked in such a manner that it can be distinguished readily from other pieces of equipment."
- 37. 22 C.C.R. § 66264.1064(b)(1) [see also 40 C.F.R. § 264.1064(b)(1)] requires, among other things, that "for each piece of equipment to which this article applies... [the] equipment identification number and hazardous waste management unit identification" be recorded in the facility's operating record.
- 38. During the Inspection, EPA observed that equipment at the Facility and subject to the C.C.R.'s air emission standards for equipment leaks, were not marked in such a manner as to readily distinguish it from other equipment. In particular, EPA found that seven valves and one ball valve located in the Facility's purification and pilot plants were unlabeled and missing identification tags.
- 39. At the time of the inspection, Respondent had not recorded the above-described equipment (see Paragraph 38) or corresponding identification numbers in the Facility's LDAR monitoring plan.
- 40. Therefore, EPA alleges that Respondent failed to properly mark equipment and record it in the facility operating record, in violation of 22 C.C.R. §§ 66264.1050(d) and 66264.1064(b)(1) [see also 40 C.F.R. §§ 264.1050(d) and 264.1064(b)(1)].

COUNT V

Failure to Follow Hazardous Waste Tank Inspection Requirements Under the Air Emission Standards for Tanks, Surface Impoundments, and Containers

- 41. Paragraphs 1 through 40 above, are incorporated herein by this reference as if they were set forth here in their entirety.
- 42. 22 C.C.R. § 66264.1084(c)(4)(A) and (B) [see also 40 C.F.R. § 264.1084(c)(4)(i) and (ii)] require inspections of air emission control equipment to be performed "in accordance with the following requirements. (A) The fixed roof and its closure devices shall be visually inspected by the owner or operator to check for defects

that could result in air pollutant emissions. Defects include, but are not limited to, visible cracks, holes, or gaps in the roof sections ... (B) The owner or operator shall perform an initial inspection of the fixed roof and its closure devices ... Thereafter, the owner or operator shall perform the inspections at least once every year except under the special conditions provided for in subsection (l) of this section."

- 43. Respondent completed annual inspections in 2019 and 2020 for four (4) hazardous waste tanks located at the Facility. Respondent's annual inspection reports directed the inspector to observe the tank roof and closure devices for visible cracks, holes, gaps, broken or damaged seals or gaskets, broken or missing hatches, access covers and caps. However, during the Inspection, Facility personnel stated that the roof was not normally accessed for annual inspections to view vents and closure devices of hazardous waste tanks.
- 44. Therefore, EPA alleges that Respondent failed to perform required inspections of hazardous waste tanks, in violation of 22 C.C.R. § 66264.1084(c)(4)(A) and (B) [see also 40 C.F.R. § 264.1084(c)(4)(i) and (ii)].

COUNT VI

Failure to Maintain Overfill Protection Controls Under the Tank Systems Standards

- 45. Paragraphs 1 through 44 above, are incorporated herein by this reference as if they were set forth here in their entirety.
- 46. 22 C.C.R. § 66264.194(b)(2) [see also 40 CFR § 264.194(b)(2)] requires
 "appropriate controls and practices to prevent spills and overflows from tank or containment systems ... [which] include at a minimum: (2) overfill prevention controls (e.g., level sensing devices, high level alarms, automatic feed cutoff, or bypass to a standby tank)."
- 47. Based on information gathered during the Inspection, including daily hazardous waste tank inspection reports from 2020–2021, and additional information obtained subsequent to the Inspection, EPA determined that one of the hazardous waste tanks located at the Facility had persistent issues with its level indicator not working. The level indicator is an overfill prevention control.
- 48. Following the Inspection, Respondent confirmed that the level indicator had been repaired and is operational and in good working condition.
- 49. Therefore, EPA alleges that Respondent failed to maintain overfill protection controls for hazardous waste tanks, in violation of 22 C.C.R. § 66264.194(b)(2) [*see also* 40 CFR § 264.194(b)(2)].

E. <u>CIVIL PENALTY</u>

- 50. The Complainant proposes that Respondent be assessed, and Respondent agrees to pay ONE HUNDRED FIFTY-EIGHT THOUSAND TWO HUNDRED AND EIGHT DOLLARS AND SEVENTY-FIVE CENTS (\$158,208.75) in full settlement of the federal civil penalty claims alleged in this CA/FO.
- 51. The civil penalty is based upon EPA's consideration of a number of factors, including the penalty criteria set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), including the following: the seriousness of the violation and any good faith efforts to comply with applicable requirements. Respondent responded promptly to return to full compliance and regularly communicated with the EPA on its cooperative progress. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA's "June 2003 RCRA Civil Penalty Policy," and adjusted for inflation in accordance with the Civil Monetary Inflation Adjustment Rule, 40 C.F.R. Part 19.

F. ADMISSIONS AND WAIVERS OF RIGHTS

52. In accordance with 40 C.F.R. § 22.18(b)(2) and for the purpose of this proceeding, the Respondent: (i) admits that EPA has jurisdiction over the subject matter of this CA/FO and over Respondent; (ii) neither admits nor denies the specific factual allegations contained in this CA/FO; (iii) consents to any and all conditions specified in this CA/FO and to the assessment of the civil administrative penalty under Section E of this CA/FO; (iv) waives any right to contest the allegations contained in Sections C or D of the CA/FO; and (v) waives the right to appeal the proposed final order attached to this Consent Agreement and made part of this CA/FO.

G. PARTIES BOUND

- 53. This CA/FO shall apply to and be binding upon Respondent and its agents, successors and assigns, until the civil penalty required under Section E has been paid in accordance with Section H. At that time, this CA/FO shall terminate and constitute full settlement of civil penalty liability for the violations alleged herein.
- 54. No change in ownership relating to the Facility will in any way alter Respondent's obligations and responsibilities under this CA/FO.
- 55. The undersigned representative of the Respondent hereby certifies that he or she is fully authorized to enter into this CA/FO, to execute it and to legally bind the Respondent to it.

H. PAYMENT OF CIVIL PENALTY

56. Respondent shall submit payment of ONE HUNDRED FIFTY-EIGHT

THOUSAND TWO HUNDRED AND EIGHT DOLLARS AND SEVENTY-FIVE CENTS (\$158,208.75) within thirty (30) calendar days of the Effective Date of this CA/FO, in accordance with one of the options set forth below. The Effective Date of this CA/FO is the date the Final Order, signed by the Regional Judicial Officer, is filed with the Regional Hearing Clerk. All payments shall indicate the name of the Facility, the Respondent's name and address, and the EPA docket number of this action.

Regular Mail:

Payment shall be made by certified or cashier's check payable to "Treasurer, United States of America," and sent as follows:

U.S. Environmental Protection Agency Fines and Penalties Cincinnati Finance Center PO Box 979077 St. Louis, MO 63197-9000

Alternate Payment Methods:

Payment may also be made by one of the alternate payment methods described at <u>https://www.epa.gov/financial/makepayment</u>.

If clarification regarding a particular method of payment remittance is needed, contact the EPA Cincinnati Finance Center at 513-487-2091.

57. At the time payment is made, Respondent shall send a PDF copy of the notification that the payment has been made by one of the methods identified in Paragraph 56, including proof of the date payment was made, to the following email addresses:

Regional Hearing Clerk U.S. Environmental Protection Agency - Region 9 <u>R9HearingClerk@epa.gov</u>

and to:

Christopher Rollins Enforcement and Compliance Assurance Division U.S. Environmental Protection Agency - Region 9 Rollins.Christopher@epa.gov

58. In accordance with the Debt Collection Act of 1982 and U.S. Treasury directive -10-

(TFRM 6-8000), payment must be received by the due date set forth in this CA/FO to avoid additional charges. If payment is not received by the due date, interest will accrue from the Effective Date of this CA/FO at the current rate published by the United States Treasury as described at 40 C.F.R. § 13.11. In addition, a 6% per annum penalty assessed monthly will further apply on any principal amount not paid within ninety (90) calendar days of its due date. Respondent further will be liable for stipulated penalties as set forth below for any payment not received by its due date.

59. The penalties specified in this CA/FO shall represent civil penalties assessed by EPA and shall not be deducted by Respondent or any other person or entity for federal, state, or local taxation purposes.

I. DELAY IN PERFORMANCE/STIPULATED PENALTIES

- 60. In the event Respondent fails to submit payment of the civil penalty to EPA by the time required in this CA/FO, Respondent shall pay stipulated penalties up to: FIVE HUNDRED DOLLARS (\$500) per day for the first to fifteenth day of delay; ONE THOUSAND DOLLARS (\$1,000) per day for the sixteenth to thirtieth day of delay; and ONE THOUSAND FIVE HUNDRED DOLLARS (\$1,500) per day for each day of delay thereafter.
- 61. All stipulated penalties owed to EPA under this Section shall be due within thirty (30) days of receipt by the Respondent of a notification of noncompliance. Such notification shall describe the noncompliance and shall indicate the amount of the penalties due. Interest at the current rate published by the United States Treasury, as described at 40 C.F.R. §13.11, shall begin to accrue on the unpaid balance at the end of the thirty-day period.
- 62. All stipulated penalties shall be made payable by certified or cashier's check to "Treasurer of the United States" and shall be remitted as described in Paragraph 56, with notice as described in Paragraph 57.
- 63. The payment of stipulated penalties shall not alter in any way Respondent's obligation to submit the civil penalty required in accordance with Sections E and H, hereunder.
- 64. Notwithstanding any other provision of this Section, EPA may, in its unreviewable discretion, waive any portion of stipulated penalties that have accrued pursuant to this CA/FO.

J. CERTIFICATION OF COMPLIANCE

65. In executing this CA/FO, Respondent certifies under penalty of law to EPA that Respondent has taken all steps necessary to return to full compliance with Section

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3008 of RCRA, 42 U.S.C. § 6928, and those implementing regulations that formed the basis of the violations above.

66. This certification of compliance is based upon true, accurate, and complete information, which the signatory can verify personally or regarding which the signatory has inquired of the person or persons directly responsible for gathering the information.

K. <u>RESERVATION OF RIGHTS</u>

- 67. Except as addressed in this CA/FO, EPA hereby reserves all of its statutory and regulatory powers, authorities, rights and remedies, both legal and equitable, including the right to require that Respondent perform tasks in addition to those required by this CA/FO. EPA further reserves all of its statutory and regulatory powers, authorities, rights and remedies, both legal and equitable, which may pertain to Respondent's failure to comply with any of the requirements of this CA/FO, including without limitation, the assessment of penalties under Section 3008 of RCRA, 42 U.S.C. § 6928. This CA/FO shall not be construed as a covenant not to sue, release, waiver or limitation of any rights, remedies, powers or authorities, civil or criminal, which EPA has under RCRA, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), or any other statutory, regulatory or common law enforcement authority of the United States. Nothing herein shall be construed to limit the power of the EPA to undertake any action against Respondent or any person in response to conditions that may present an imminent and substantial endangerment to the public health, welfare, or the environment.
- 68. Compliance by Respondent with the terms of this CA/FO shall not relieve Respondent of the obligation to comply with RCRA or any other applicable local, State or federal laws and regulations.
- 69. The entry of this CA/FO and Respondent's consent to comply shall not limit or otherwise preclude EPA from taking additional enforcement actions should EPA determine that such actions are warranted. Respondent's full compliance with this Consent Agreement shall only resolve Respondent's liability for federal civil penalties.
- 70. This CA/FO is not intended to be nor shall it be construed as a permit. This CA/FO does not relieve Respondent of any obligation to obtain and comply with any required local, State or federal permits.

L. <u>OTHER CLAIMS</u>

71. Nothing in this CA/FO shall constitute or be construed as a release from any other claim, cause of action or demand in law or equity by or against any person, firm,

partnership, entity or corporation for any liability it may have arising out of or relating in any way to the generation, storage, treatment, handling, transportation, release, or disposal of any hazardous constituents, hazardous substances, hazardous wastes, pollutants, or contaminants found at, taken to, or taken from the Facility.

M. MISCELLANEOUS

- 72. This CA/FO may be amended or modified only by written agreement executed by EPA and Respondent.
- 73. The headings in this CA/FO are for convenience of reference only and shall not affect interpretation of this CA/FO.
- 74. Each party to this action shall bear its own costs and attorneys' fees.
- 75. EPA and Respondent consent to entry of this CA/FO without further notice.

N. <u>EFFECTIVE DATE</u>

76. In accordance with 40 C.F.R. §§ 22.18(b)(3) and 22.31(b), this CA/FO shall be effective on the date that the Final Order contained in this CA/FO, having been approved and issued by the Regional Judicial Officer, is filed with the Regional Hearing Clerk.

IT IS SO AGREED.

FOR RESPONDENT GENENTECH, INC .:

Allen Napetian, Vice President Site Services

19 MAY 2023

Date

FOR COMPLAINANT U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 9: AMY MILLER-BOWEN Digitally signed by AMY MILLER-BOWEN Date: 2023.07.27 09:32:30 -07'00'

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Amy C. Miller-Bowen, Director Enforcement and Compliance Assurance Division Date

FINAL ORDER

IT IS HEREBY ORDERED that this Consent Agreement and Final Order pursuant to 40 C.F.R. Sections 22.13 and 22.18 (U.S. EPA Docket No. RCRA-09-2023-0057) be entered and that Respondent shall pay a civil penalty of ONE HUNDRED FIFTY-EIGHT THOUSAND TWO HUNDRED AND EIGHT DOLLARS AND SEVENTY-FIVE CENTS (\$158,208.75) in accordance with the terms of this CA/FO.

A notice of payment and a copy of the check or other form of payment shall be sent to the EPA Region IX addresses specified in Section H of this Consent Agreement and Final Order at the time payment is made.

This Final Order shall be effective upon filing with the Regional Hearing Clerk.

Beatrice Wong Date Regional Judicial Officer United States Environmental Protection Agency Region 9

CERTIFICATE OF SERVICE

This is to certify that the original of the fully executed Consent Agreement and Final Order in the matter of Genentech, Inc. (Docket Number RCRA-09-2023-0057) was filed with the Regional Hearing Clerk and that a true and correct copy of the same was sent to the following parties via electronic mail, as indicated below:

RESPONDENTS:	Allen Napetian
	Vice President Site Services
	Genentech, Inc.
	1 DNA Way
	South San Francisco, CA 94080
	napetian.allen@gene.com

Sergio Borgiotti Assistant General Counsel Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 borgiotti.sergio@gene.com

COMPLAINANTS:

Emily Rosenblum Office of Regional Counsel U.S. EPA, Region IX 75 Hawthorne Street ORC-HWB-HWSI2 San Francisco, CA 94105 Rosenblum.Emily@epa.gov

Christopher Rollins Enforcement and Compliance Assurance Division U.S. EPA, Region IX 75 Hawthorne Street (ENF-2-2) San Francisco, CA 94105 <u>Rollins.Christopher@epa.gov</u>

Ponly J. Tu Date Regional Hearing Clerk U.S. EPA, Region IX