REGION 5
CHICAGO, IL 60604

VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

Charvi Payghode, EHS Manager
Regis Technologies, Inc.
charvi.payghode@registech.com

Re: Finding of Violation
Regis Technologies, Inc.
Morton Grove, Illinois

Dear Charvi Payghode:

The U.S. Environmental Protection Agency is issuing the enclosed Finding of Violation (FOV) to Regis Technologies, Inc. (you) under Section 113(a) of the Clean Air Act, 42 U.S.C. § 7413(a). We find that you are violating 40 C.F.R. Part 68, the Chemical Accident Prevention Provisions, at your Morton Grove, Illinois facility.

Section 113 of the Clean Air Act gives us several enforcement options. These options include issuing an administrative compliance order, issuing an administrative penalty order and bringing a judicial civil or criminal action.

We are offering you an opportunity to confer with us about the violations alleged in the FOV. The conference will give you an opportunity to present information on the specific findings of violation, any efforts you have taken to comply and the steps you will take to prevent future violations. In addition, in order to make the conference more productive, we encourage you to submit to us information responsive to the FOV prior to the conference date.

Please plan for your facility's technical and management personnel to attend the conference to discuss compliance measures and commitments. You may have an attorney represent you at this conference. The EPA contacts in this matter are Natalia Vazquez. You may call her at (312) 353-8314, or email her at vazquez.natalia@epa.gov, to request a conference. You should make the request within 10 calendar days following receipt of this letter. We should hold any conference within 30 calendar days following receipt of this letter.

Sincerely,

SARAH MARSHALL
Digitally signed by SARAH MARSHALL
Date: 2024.07.01 11:34:27 -05'00'

Sarah Marshall
Supervisor

cc: Kent Mohr, Manager
Compliance Section Bureau of Air
Illinois Environmental Protection Agency
Kent.mohr@illinois.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
Regis Technologies, Inc.	)	**FINDING OF VIOLATION**
Morton Grove, Illinois	)	
	)	**EPA-5-24-IL-11**
Proceedings Pursuant to	)	
the Clean Air Act,	)	
42 U.S.C. §§ 7401 *et seq*.	)	

FINDING OF VIOLATION

The U.S. Environmental Protection Agency finds that Regis Technologies, Inc. (Regis) is violating Section 112 of the Clean Air Act, 42 U.S.C. § 7412. Specifically, Regis is violating the Chemical Accident Prevention Provisions (CAPP), codified at 40 C.F.R. Part 68.

Statutory Authority

1. Section 112(r)(1) of the Clean Air Act, 42 U.S.C. § 7412(r)(1), provides that it shall be the objective of the regulations and programs authorized under this subsection to prevent the accidental release and to minimize the consequences of any such release of any substance listed pursuant to Section 112(r)(3), or any other extremely hazardous substance.

2. Section 112(r)(3) of the Clean Air Act, 42 U.S.C. § 7412(r)(3), provides that the Administrator shall promulgate, not later than 24 months after November 15, 1990, an initial list of 100 substances which, in the case of an accidental release, are known to cause or may reasonably be anticipated to cause death, injury, or serious adverse effects to human health or the environment.

3. Section 112(r)(7)(A) of the Clean Air Act, 42 U.S.C. § 7412(r)(7)(A), provides that in order to prevent accidental releases of regulated substances, the Administrator is authorized to promulgate release prevention, detection, and correction requirements which may include monitoring, record-keeping, reporting, training, vapor recovery, secondary containment, and other design, equipment, work practice, and operational requirements.

4. Section 112(r)(7)(B)(i) of the Clean Air Act, 42 U.S.C. § 7412(r)(7)(B)(i), provides that within 3 years after November 15, 1990, the Administrator shall promulgate reasonable regulations and appropriate guidance to provide, to the greatest extent practicable, for the prevention and detection of accidental releases of regulated substances and for response to such releases by the owners or operators of the sources of such releases.

5. Section 112(r)(7)(B)(ii) of the Clean Air Act, 42 U.S.C. § 7412(r)(7)(B)(ii), provides that the regulations under this subparagraph shall require the owner or operator of stationary sources at which a regulated substance is present in more than a threshold quantity to prepare and implement a Risk Management Plan (RMP) to detect and prevent or minimize accidental releases of such substances from

the stationary source, and to provide a prompt emergency response to any such releases in order to protect human health and the environment.

6. Pursuant to Section 112(r)(3) of the Clean Air Act, 42 U.S.C. § 7412(r)(3), the Administrator initially promulgated a list of regulated substances, with threshold quantities for applicability, at 59 Fed. Reg. 4478 (January 31, 1994), which is codified, as amended, at 40 C.F.R. § 68.130.

7. Pursuant to Section 112(r)(7) of the Clean Air Act, 42 U.S.C. § 7412(r)(7), the Administrator promulgated "Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7)," 61 Fed. Reg. 31668 (June 20, 1996), which is codified, as amended, at 40 C.F.R. Part 68: Chemical Accident Prevention Provisions (CAPP). This included the RMP requirements at 40 C.F.R. Part 68, Subpart G.

8. The CAPP seek to prevent accidental releases of regulated substances and minimize the consequences of those releases that do occur, by requiring owners and operators of certain stationary sources to, among other things: (1) develop and implement a management system to oversee the implementation of the risk management program elements; (2) develop and implement a risk management program that includes, but is not limited to, a hazard assessment, a prevention program, and an emergency response program; and (3) submit to EPA an RMP describing the risk management program for the source. See 40 C.F.R. Part 68, Subparts A to H.

9. Section 112(r)(7)(E) of the Clean Air Act, 42 U.S.C. § 7412(r)(7)(E), provides that after the effective date of any regulation or requirement promulgated pursuant to Section 112(r) of the Act, it shall be unlawful for any person to operate any stationary source in violation of such regulation or requirement.

Chemical Accident Prevention Provisions

Applicability

10. 40 C.F.R. § 68.10(a) provides, in part, that the owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process, as determined under 40 C.F.R. § 68.115, shall comply with the requirements of the CAPP, 40 C.F.R. Part 68, Subparts A to H, no later than the date on which a regulated substance is first present above a threshold quantity in a process.

11. 40 C.F.R. § 68.3 defines the term "regulated substance" as any substance listed pursuant to Section 112(r)(3) of the Clean Air Act as amended, in 40 C.F.R. § 68.130.

12. 40 C.F.R. § 68.3 defines the term "process" as any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances, or combination of these activities. For the purposes of this definition, any group of vessels that are interconnected, or separate vessels that are located such that a regulated substance could be involved in a potential release, shall be considered a single process.

13. 40 C.F.R. § 68.3 defines the term "covered process" as a process that has a regulated substance present in more than a threshold quantity as determined under 40 C.F.R. § 68.115.

14. 40 C.F.R. § 68.3 defines the term "environmental receptor" as natural areas such as national or state parks, forests, or monuments; officially designated wildlife sanctuaries, preserves, refuges, or areas; and Federal wilderness areas, that could be exposed at any time to toxic concentrations, radiant heat, or overpressure greater than or equal to the endpoints provided in 68.22(a), as a result of an accidental release and that can be identified on local U. S. Geological Survey maps.

15. 40 C.F.R. § 68.3 defines the term "public receptor" as offsite residences, institutions (e.g., schools, hospitals), industrial, commercial, and office buildings, parks, or recreational areas inhabited or occupied by the public at any time without restriction by the stationary source where members of the public could be exposed to toxic concentrations, radiant heat, or overpressure, as a result of an accidental release.

16. 40 C.F.R. § 68.3 defines the term "LEPC" as a local emergency planning committee as established under 42 U.S.C. § 11001(c).

17. 40 C.F.R. § 68.3 defines the term "RMP" as the risk management plan required under Subpart G of the CAPP in 40 C.F.R. Part 68.

18. 40 C.F.R. § 68.10(g) provides that a covered process is eligible for Program 1 requirements as provided in 40 C.F.R. § 68.12(b) if it meets all of the following requirements:

a. the process has not had an accidental release of a regulated substance where exposure to the substance, its reaction products, overpressure generated by an explosion involving the substance or radiant heat generated by a fire involved the substance led to any of the following offsite consequence: death, injury, or response or restoration activities for an exposure of an environmental receptor;

b. the distance to a toxic or flammable endpoint for a worst-case release assessment conducted under 40 C.F.R. Part 68, Subpart B, and 40 C.F.R. § 68.25 is less than the distance to any public receptor, as defined in 40 C.F.R. § 68.3; and

c. Emergency response procedures have been coordinated between the stationary source and local emergency planning and response organizations.

19. 40 C.F.R. § 68.10(h) provides that a covered process is subject to Program 2 requirements if it does not meet the eligibility requirements of either Program 1 as described in paragraph (g) or Program 3 as described in paragraph (i) of the CAPP.

20. 40 C.F.R. § 68.10(i) provides that a covered process is subject to Program 3 requirements if the process does not meet the requirements of Program 1 as described in 40 C.F.R. § 68.10(g) and if either of the following conditions is met: (1) the process is in NAICS code 32211, 32411, 32511, 325181, 325188, 325192, 325199, 325211, 325311, or 32532; or (2) the process is subject to the U.S. Occupational Safety and Health Administration (OSHA) process safety management standard, 29 C.F.R. § 1910.119.

21. 40 C.F.R. § 68.12(a) requires an owner or operator of a stationary source subject to this part to submit a single RMP, as provided in 40 C.F.R. § 68.150 through 68.185, and that the RMP shall include a registration that reflects all covered processes.

22. 40 C.F.R. § 68.12(b) requires an owner or operator stationary source subject to Program 1 requirements to meet the requirements of 40 C.F.R. 68.12(a) and:

a. Analyze the worst-case release scenario for the process(es), as provided in § 68.25; document that the nearest public receptor is beyond the distance to a toxic or flammable endpoint defined in § 68.22(a); and submit in the RMP the worst-case release scenario as provided in 40 C.F.R. § 68.165;

b. Complete the five-year accident history for the process as provided in §68.42 of the CAPP and submit it in the RMP as provided in 40 C.F.R. § 68.168;

c. Ensure that response actions have been coordinated with local emergency planning and response agencies; and

d. Certify in the RMP the following: "Based on the criteria in 40 C.F.R. 68.10, the distance to the specified endpoint for the worst-case accidental release scenario for the following process(es) is less than the distance to the nearest public receptor: [list process(es)]. Within the past five years, the process(es) has (have) had no accidental release that caused offsite impacts provided in the risk management program rule (40 C.F.R. 68.10(g)(1)). No additional measures are necessary to prevent offsite impacts from accidental releases. In the event of fire, explosion, or a release of a regulated substance from the process(es), entry within the distance to the specified endpoints may pose a danger to public emergency responders. Therefore, public emergency responders should not enter this area except as arranged with the emergency contact indicated in the RMP. The undersigned certifies that, to the best of my knowledge, information, and belief, formed after reasonable inquiry, the information submitted is true, accurate, and complete. [Signature, title, date signed]."

23. 40 C.F.R. § 68.12(c) requires an owner or operator of a stationary source subject to Program 2, in addition to meeting the requirements of paragraph 68.12(a), to:

a. Develop and implement a management system as provided in 40 C.F.R. § 68.15;

b. Conduct a hazard assessment as provided in 40 C.F.R. §§ 68.20 through 68.42;

c. Implement the Program 2 prevention steps provided in 40 C.F.R. §§ 68.48 through 68.60 or implement the Program 3 prevention steps provided in 40 C.F.R. §§ 68.65 through 68.87;

d. Coordinate response actions with local emergency planning and response agencies as provided in 40 C.F.R. § 68.93;

e. Develop and implement an emergency response program, and conduct exercises, as provided in 40 C.F.R. §§ 68.90 through 68.96; and

f. Submit as part of the RMP the data on prevention program elements for Program 2 processes as provided in 40 C.F.R. § 68.170.

24. 40 C.F.R. § 68.12(d) requires an owner or operator of a stationary source subject to the requirements of Program 3, in addition to meeting the requirements of 40 C.F.R. § 68.12(a), to:

a. Develop and implement a management system as provided in 40 C.F.R § 68.15;

b. Conduct a hazard assessment as provided in 40 C.F.R. §§ 68.20 through 68.42;

c. Implement the prevention requirements of 40 C.F.R. §§ 68.65 through 68.87;

d. Coordinate response actions with local emergency planning and response agencies as provided in 40 C.F.R. § 68.93;

e. Develop and implement an emergency response program, and conduct exercises, as provided in 40 C.F.R. §§ 68.90 through 68.96; and

f. Submit as part of the RMP the data on prevention program elements for Program 3 processes as provided in 40 C.F.R. § 68.175.

25. 40 C.F.R. § 68.15(a) states that the owner or operator of a stationary source with processes subject to Program 2 or Program 3 shall develop a management system to oversee the implementation of the risk management program elements.

26. 40 C.F.R. § 68.15(b) states that the owner or operator shall assign a qualified person or position that has the overall responsibility for the development, implementation, and integration of the risk management program elements.

27. 40 C.F.R. § 68.15(c) states that when responsibility for implementing individual requirements of this part is assigned to persons other than the person identified under 40 C.F.R. § 68.15(b), the names or positions of these people shall be documented, and the lines of authority defined through an organization chart or similar document.

28. The list of substances in Table 1 in 40 C.F.R. § 68.130 includes chloroform with a threshold quantity of 20,000 pounds.

29. 40 C.F.R. § 68.150(a) states that the owner or operator shall submit a single RMP that includes the information required by 40 C.F.R. §§ 68.155 through 68.185 for all covered processes. The RMP shall be submitted in the method and format to the central point specified by EPA as of the date of submission.

30. 40 C.F.R.§ 68.150(b) states that the owner or operator shall submit the first RMP no later than the latest of the following dates:

a. June 21, 1999;

b. Three years after the date on which a regulated substance is first listed under §68.130; or

c. The date on which a regulated substance is first present above a threshold quantity in a process.

Statement of Facts

31. Regis owns and operates a pharmaceutical and biotechnology facility at 8210 North Austin Avenue, Morton Grove, Illinois (the Facility).

32. On March 23, 2023, federally credentialled EPA inspectors completed an unannounced on-site inspection at the Facility (2023 Inspection).

33. During the 2023 Inspection, EPA inspectors observed 35 55-gallon drums (24,925 total pounds) of chloroform at Regis's warehouse.

34. After the 2023 Inspection, Regis provided EPA with copies of its safety data sheets for four chemical substances including chloroform, a description of the Facility's emergency procedures, a list of the personal protective equipment used while handling chloroform, and the Facility inventory for the regulated substances (substances listed under 40 C.F.R. § 68.130) on site.

35. Based on information provided by Regis after the 2023 Inspection, between June 11, 2018, to April 10, 2023, there were 392 nonconsecutive days where the onsite inventory of chloroform was above the threshold quantity at the Facility. The earliest date chloroform was above the threshold quantity at the Facility is June 11, 2018. The maximum onsite inventory of chloroform was 44,229 pounds at the Facility on April 26, 2019.

36. EPA issued a Clean Air Act Section 114 Information Request to Regis on June 7, 2023 (2023 Information Request).

37. Regis provided a response to the 2023 Information Request on June 29, 2023 (2023 Response). Regis's 2023 Response record is named "EPA response-signed.pdf".

38. Regis's 2023 Response stated, in part, the following:

a. Regis is not subject to the OSHA Process Safety Management Standards in 29 C.F.R. § 1910.119; and

b. Regis is not subject to 40 C.F.R. Part 68 as it does not store chloroform above the threshold quantity. It, therefore, does not need to provide a worst-case release scenario.

39. Regis's statement in paragraph 38.b, above, was provided in response to EPA's request for a hazard assessment, specifically a worst-case scenario.

40. Regis has not submitted a Risk Management Plan to EPA.

Violations

41. Regis failed to comply with the requirements of the CAPP, 40 C.F.R. Part 68, Subparts A through H, on the date on which a regulated substance (chloroform) was first present above a threshold quantity in a process, in violation of 40 C.F.R. § 68.10(a).

42. Regis failed to submit a single RMP as provided in 40 C.F.R. § 68.150(a) that includes the information required by 40 C.F.R. §§ 68.155 through 68.185 on the date on which a regulated substance (chloroform) was first present above the threshold quantity in a process, in violation of 40 C.F.R. §§ 68.12(a) and 68.150(b).

43. Regis failed to analyze and report a hazard assessment, that is a worst-case release scenario analysis, in violation of 40 C.F.R. §§ 68.22(a) and 68.25(a).

MICHAEL HARRIS

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Michael D. Harris
Division Director
Enforcement and Compliance Assurance Division