



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

77 WEST JACKSON BOULEVARD

CHICAGO, IL 60604-3590

March 9, 2022

VIA E-MAIL
DELIVERY RECEIPT REQUESTED

Tim Breunig, President & CEO
Coating Place Inc.
200 Paoli Street
Verona, Wisconsin 53593

Email: tbreunig@encap.com

Dear Tim Breunig:

Enclosed is a file-stamped Consent Agreement and Final Order (CAFO) which resolves Coating Place Inc., docket no. CAA-05-2022-0007. As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on March 9, 2022.

Pursuant to paragraph 108 of the CAFO, Coating Place Inc. must pay the civil penalty within 30 days of the filing date. Your electronic funds transfer must display the case name and case docket number.

Please direct any questions regarding this case to Thomas Martin, Associate Regional Counsel, 312-886-4273.

Sincerely,

SARAH
MARSHALL

Digitally signed by
SARAH MARSHALL
Date: 2022.03.08
08:27:34 -06'00'

Sarah Marshall, Supervisor
Air Enforcement and Compliance Assurance Section (MI/WI)

Enclosure

cc: Ann Coyle, Regional Judicial Officer/via electronic mail
Coyle.ann@epa.gov

Regional Hearing Clerk/via electronic mail
R5hearingclerk@epa.gov

Thomas Martin/via electronic mail
Martin.thomas@epa.gov

Maria Hill/via electronic mail
Maria.hill@wisconsin.gov

Consent Agreement and Final Order
In the matter of: Coating Place, Inc.
Docket Number: **CAA-05-2022-0007**

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, docket number **CAA-05-2022-0007**, which was filed on **March 9, 2022**, in the following manner to the following addressees:

Copy by E-mail to Respondent:	Tim Breunig tbreunig@encap.com
Copy by E-mail to Attorney for Complainant:	Thomas Martin martin.thomas@epa.gov
Copy by E-mail to Attorney for Respondent:	Todd Palmer tepalmer@michaelbest.com
Copy by E-mail to Regional Judicial Officer:	Ann Coyle coyle.ann@epa.gov

Isidra Martinez
Acting Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 5

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)	Docket No. CAA-05-2022-0007
)	
Coating Place Inc.)	Proceeding to Assess a Civil Penalty
Verona, Wisconsin)	Under Section 113(d) of the Clean Air Act,
)	42 U.S.C. § 7413(d)
Respondent.)	
<hr style="border: 1px solid black;"/>)	

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (the CAA), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), as codified at 40 C.F.R. Part 22.

2. Complainant is the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency (EPA), Region 5.

3. Respondent is Coating Place Incorporated (CPI), a corporation doing business in Wisconsin.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

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 interest and in the public interest.

6. Respondent consents to the assessment of the civil penalty specified in this CAFO and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO. Respondent neither admits nor denies the alleged violations of law as stated in this CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO and its right to appeal this CAFO.

Statutory and Regulatory Background

Wisconsin SIP and Permit Conditions

9. Section 110 of CAA, 42 U.S.C. § 7410, requires each state to adopt and submit to EPA a plan that provides for the implementation, maintenance, and enforcement of primary and secondary National Ambient Air Quality Standards in the state. Upon approval by EPA, the plan becomes part of the federally enforceable SIP for the state.

10. Pursuant to 40 C.F.R. § 52.23, failure to comply with any approved regulatory provision of a SIP, or with any permit condition or permit denial issued pursuant to approved or promulgated regulations for the review of new or modified stationary or indirect sources, or with any permit limitation or condition contained within an operating permit issued under an EPA-approved program that is incorporated in the SIP, shall render the person so failing to comply in violation of a requirement of an applicable implementation plan and subject to enforcement action under Section 113 of the CAA.

11. Title V of the CAA, 42 U.S.C. §§ 7661-7661f, and its implementing regulations at 40 C.F.R. Part 70, establish an operating permit program for certain sources, including major sources, and other sources made subject under Section 502(a) of the CAA, 42 U.S.C. § 7661a(a).

12. For the purposes of Title V, Section 501(2)(B) of the CAA, 42 U.S.C. § 7661(2)(B), and 40 C.F.R. § 70.2 define “major source” as, among other things, any stationary source that directly emits or has the potential to emit 100 tons per year (tpy) or more of any air pollutant.

13. Pursuant to Section 502(b) of the CAA, 42 U.S.C. § 7661a(b), EPA promulgated regulations establishing the minimum elements of a Title V permit program to be administered by any air pollution control agency. 57 Fed. Reg. 32295 (July 21, 1992). These regulations are codified at 40 C.F.R. Part 70.

14. In 1995, EPA delegated to the Wisconsin Department of Natural Resources (WDNR) the authority to issue federally-enforceable operating permits under Title V of the CAA, 42 U.S.C. §§ 7661 et seq., as part of the Wisconsin SIP (See 60 Fed. Reg. 3543, Jan. 18, 1995 and 40 C.F.R. Part 70). The Wisconsin Title V permitting process is codified in Wisconsin Administrative Code (WAC) NR 406 Construction Permits and NR 407 Operation Permits.

15. Under Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), and EPA’s implementing regulations at 40 C.F.R. § 70.7(b), it is unlawful for any person to violate any requirement or conditions of a permit issued under Title V.

Coating Place’s Title V Permit

16. WDNR issued Renewal of Part 70 Operating Permit No. 113020380-P30 (Title V Permit) to CPI, effective May 1, 2015.

17. Permit Condition H.2.b.(1) for Process P44, Stack S35 – Unit K2 (46-inch Dedicated Wurster Coater, installed September 2010) states that “[t]his coating unit may not be equipped with a by-pass stack.”

18. Permit Condition H.2.c.(2) for Process P44, Stack S35 – Unit K2, states that “[t]he permittee shall maintain on site plans and specifications or equivalent documentation which demonstrate emissions from the coating unit cannot be diverted from the control device.”

19. Permit Condition A.3.a.(1) for Operation of the Thermal Oxidizer states that “[w]henver the thermal oxidizer is operating, the permittee shall maintain the minimum temperature of the thermal oxidizer combustion chamber at the most stringent of the following:

(a) no less than 1400 degrees Fahrenheit (°F); or

(b) at the minimum temperature determined from the most recent compliance emission test demonstrating compliance with the most stringent applicable [volatile organic compounds] VOC or [hazardous air pollutants] HAP reduction requirement.”

20. Permit Condition A.3.b.(2) for Operation of the Thermal Oxidizer states that “[t]he permittee shall conduct a compliance test to determine the operating parameter levels for the control device. These parameters to include the minimum temperature of the gasses exiting the combustion chamber and resulting destruction efficiency necessary to meet the required control efficiencies and HAP reductions [...]”

21. Permit Condition A.3.c.(2)(b) for Operation of the Thermal Oxidizer states that “copies of the compliance emission tests results to include date, temperature of oxidization chamber, and control efficiency.”

NESHAP

22. Pursuant to Section 112(b) of the CAA, 42 U.S.C. § 7412(b), Congress established a list of Hazardous Air Pollutants (HAPs). EPA must periodically review this list and publish the results thereof and, where appropriate, revise such list by rule, adding pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health or environmental effects.

23. Section 112(c)(1), 42 U.S.C. § 7412(c)(1), requires EPA to publish, and revise from time to time under 112(b)(3), a list of all categories and subcategories of major sources and area sources, of the HAPs listed pursuant to Section 112(b). Section 112(c)(2), 42 U.S.C. § 7412(c)(2), requires EPA to establish emission standards under Section 112(d) for the listed categories and subcategories. These standards are known as “national emission standards for hazardous air pollutants” (NESHAP). EPA codifies these requirements at 40 C.F.R. Part 63.

24. Section 112(d) of the CAA requires EPA to establish NESHAP for both major and area sources of HAP that are listed for regulation under CAA Section 112(c)(2). A “major source” includes a “stationary source” that emits or has the potential to emit 10 tpy or more of any single HAP or 25 tpy or more of any combination of HAP. An “area source” is a “stationary source” that is not a major source. See 42 U.S.C. § 7412(a).

25. For purposes of NESHAPs, a “stationary source” is any building, structure, facility, or installation that emits or may emit any air pollutant. See 42 U.S.C. § 7412(a).

26. The NESHAP General Provisions (Subpart A), 40 C.F.R. §§ 63.1-63.16, apply to affected sources regulated by a relevant NESHAP, provided that the NESHAP explicitly identifies whether each General Provision is included in the NESHAP.

27. Subpart A at 40 C.F.R. § 63.4, prohibits the owner or operator of an affected source from operating such source in violation of any NESHAP applicable to such source.

NESHAP for Pharmaceuticals Production (Pharma MACT or Subpart GGG)

28. On September 21, 1998, EPA promulgated Subpart GGG, 63 Fed. Reg. 50326 (September 21, 1998).

29. Subpart GGG, at 40 C.F.R. § 63.1250(a), defines an affected source as manufacturing operations that: a) manufacture a pharmaceutical product as defined in 63.1251;

b) are located at a plant site that is a major source as defined in Section 112(a) of the CAA; and
c) process, use or produce HAP.

30. Subpart GGG, at 40 C.F.R. § 63.1250(a)(2), states that “[d]etermination of the applicability of this subpart shall be reported as part of an operating permit application or as otherwise specified by the permitting authority.”

31. Subpart GGG, requires an owner or operator of an existing affected source subject to the provisions of Subpart GGG to comply with 40 C.F.R. § 63.1250 through § 63.1261, no later than October 21, 2002.

32. Subpart GGG, at 40 C.F.R. § 63.1250(c), provides that the owner or operator of an affected source subject to the provisions of Subpart GGG must also comply with the requirements of Subpart A according to the applicability of Subpart A to such source, as identified in Table 1 of Subpart GGG.

33. Subpart GGG, at 40 C.F.R. § 63.1252, requires an owner or operator of any affected source subject to the provisions of Subpart GGG to control HAP emissions to the level specified in 40 C.F.R. § 63.1252 on and after the compliance dates specified in 40 C.F.R. § 63.1250(f). Initial compliance with the emission limits is demonstrated in accordance with the provisions of 40 C.F.R. § 63.1257, and continuous compliance is demonstrated in accordance with the provisions of 40 C.F.R. § 63.1258.

Process Vents

34. Subpart GGG, at 40 C.F.R. § 63.1254, provides standards for process vents.

35. Subpart GGG, at 40 C.F.R. § 63. 1251, defines “process vent” as a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not

limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 parts per million volume HAP are not considered process vents.

36. Subpart GGG, at 40 C.F.R. § 63.1254(a), states that for existing affected sources, “[f]or each process, the owner or operator of an existing affected source must comply with the requirements in paragraphs (a)(1) and (3) of this section or paragraphs (a)(2) and (3) of this section.”

37. Subpart GGG, at 40 C.F.R. § 63.1254(a)(2), provides a process-based annual mass limit, which may exclude emissions from vents that are subject to the requirements of paragraph 40 C.F.R. § 63.1254(a)(3).

Equipment Leaks

38. Subpart GGG, at 40 C.F.R. § 63.1255, provides standards for equipment leaks.

39. Subpart GGG, at 40 C.F.R. § 63.1251, defines “equipment” as each pump, compressor, agitator, pressure relief device, sampling connection system, open-ended valve or line, valve, connector, and instrumentation system in HAP service; and any control devices or closed-vent systems required by Subpart GGG.

40. Subpart GGG, at 40 C.F.R. § 63.1251, defines “in HAP service” as a piece of equipment that either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAP's as determined according to the provisions of 40 C.F.R. § 63.180(d).

41. Subpart GGG, at 40 C.F.R. § 63.1255(a), states that provisions of this section apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and

closed-vent systems required by this section that are intended to operate in HAP service 300 hours or more during the calendar year within a source subject to the provisions of this subpart.

42. Subpart GGG, at 40 C.F.R. § 63.1255(a)(7), states that “[e]quipment to which this section applies shall be identified such that it can be distinguished readily from equipment that is not subject to this section. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, or by designation of process boundaries by some form of weatherproof identification. If changes are made to the affected source subject to the leak detection requirements, equipment identification for each type of component shall be updated, if needed, within 90 calendar days or by the next Periodic Report following the end of the monitoring period for that component, whichever is later.”

43. Subpart GGG, at 40 C.F.R. § 63.1255(a)(9), states that “equipment that is in organic HAP service, but is in such service less than 300 hours per calendar year, is excluded from the requirements of this section.”

44. Subpart GGG, at 40 C.F.R. § 63.1255(b)(1), states that the owner or operator of a source subject to this section shall comply with the provisions of Subpart H of 40 C.F.R. Part 63, as specified in paragraphs (b)(2) through (4) of this section.

45. Subpart GGG, at 40 C.F.R. § 63.1255(b)(4), states that the owner or operator of a source subject to this section shall comply with Subpart H, at 40 C.F.R. §§ 63.171, 63.172, 63.174, 63.178, and 63.180 (see Paragraphs 63 through 65, below).

Wastewater

46. Subpart GGG, at 40 C.F.R. § 63.1256, provides standards for wastewater.

47. Subpart GGG, at 40 C.F.R. § 63.1256(a), requires that the owner or operator of an affected source subject to the provisions of Subpart GGG to comply with the requirements of this section for wastewater and maintenance wastewater containing partially soluble or soluble HAP.

48. Subpart GGG, at 40 C.F.R. § 63.1256(a)(1), requires that the owner or operator of an affected source subject to the provisions of Subpart GGG to identify wastewater that requires control. For each point of determination (POD), the owner or operator shall comply with the requirements in either paragraph (a)(1)(i) or (ii) of this section to determine whether a wastewater stream is an affected wastewater stream that requires control for soluble and/or partially soluble HAP compounds or to designate the wastewater stream as an affected wastewater stream, respectively.

49. Subpart GGG, at 40 C.F.R. § 63.1256(a)(4), describes maintenance wastewater requirements. Each owner or operator of a source subject to this subpart shall comply with the requirements of paragraphs (a)(4)(i) through (iv) of this section for maintenance wastewater containing partially soluble or soluble HAP listed in Tables 2 and 3 of this subpart. Maintenance wastewater is exempt from all other provisions of this subpart.

(i) The owner or operator shall prepare a description of maintenance procedures for management of wastewater generated from the emptying and purging of equipment in the process during temporary shutdowns for inspections, maintenance, and repair (i.e., a maintenance turnaround) and during periods which are not shutdowns (i.e., routine maintenance). The descriptions shall be included in a document that is maintained at the plant site and shall:

(A) Specify the process equipment or maintenance tasks that are anticipated to create wastewater during maintenance activities; and

(B) Specify the procedures that will be followed to properly manage the wastewater and minimize organic HAP emissions to the atmosphere; and

(C) Specify the procedures to be followed when clearing materials from process equipment.

50. Subpart GGG, at 40 C.F.R. § 63.1256(a)(5)(i) states that the owner or operator of an affected source subject to the provisions of Subpart GGG transferring the wastewater or residual shall comply with the provisions specified in paragraphs (b) through (f) of 40 C.F.R. § 63.1256(a)(5)(i), Subpart GGG, for each waste management unit that receives or manages affected wastewater or a residual removed from affected wastewater prior to shipment or transport.

51. Subpart GGG, at 40 C.F.R. § 63.1256(a)(5)(ii), states that the owner or operator of an affected source subject to the provisions of Subpart GGG may not transfer the affected wastewater or residual unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any affected wastewater or residual removed from affected wastewater received from a source subject to the requirements of this subpart in accordance with the requirements of this section.

52. Subpart GGG, at 40 C.F.R. § 63.1251, defines “POD” as the point where a wastewater stream exits the process, storage tank, or last recovery device. If soluble and/or partially soluble HAP compounds are not recovered from water before discharge, the discharge point from the process equipment or storage tank is a POD. If water streams are routed to a recovery device, the discharge from the recovery device is a POD.

53. Subpart GGG, at 40 C.F.R. § 63.1251, defines “process” as all equipment which collectively function to produce a pharmaceutical product or isolated intermediate (which is also a pharmaceutical product). Cleaning operations conducted are considered part of the process.

54. Subpart GGG, at 40 C.F.R. § 63.1251, defines “wastewater” as any portion of an individual wastewater stream or any aggregation of wastewater streams.

55. Subpart GGG, at 40 C.F.R. § 63.1251, defines “wastewater streams” as water that is discarded from a pharmaceutical manufacturing process unit (PMPU) through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr.

56. Subpart GGG, at 40 C.F.R. § 63.1251, defines “maintenance wastewater” as a wastewater generated by the draining of process fluid from components in the PMPU into an individual drain system in preparation for or during maintenance activities. Wastewater from cleaning operations is not considered maintenance wastewater.

Emission Testing

57. Subpart GGG, at 40 C.F.R. § 63.1257(b)(8), states that for an affected source, “[t]esting of emissions on equipment where the flow of gaseous emissions is intermittent (batch operations) shall be conducted as specified in paragraphs (b)(8)(i) through (iii) of this section.”

58. Subpart GGG, at 40 C.F.R. § 63.1257(b)(8)(i), states that for an affected source, “testing shall be conducted at absolute worst-case conditions or hypothetical worst-case conditions [...]. The absolute worst-case or hypothetical worst-case conditions shall be characterized by the criteria presented in paragraphs (b)(8)(i)(A) and (B) of this section.”

59. Subpart GGG, at 40 C.F.R. § 63.1257(b)(8)(ii), states that the owner or operator of an affected source subject to the provisions of Subpart GGG may choose to perform tests only during those periods of the worst-case conditions that the owner or operator selects to control as part of achieving the required emission reduction. The owner or operator must develop an emission profile for the vent to the control device that describes the characteristics of the vent stream at the inlet to the control device under worst case conditions. The emission profile shall be developed based on any one of the procedures described in (b)(8)(ii)(A) through (C) of this section, as required by paragraph (b)(8)(i).

(A) Emission profile by process. The emission profile must consider all emission episodes that could contribute to the vent stack for a period of time that is sufficient to include all processes venting to the stack and shall consider production scheduling. The profile shall describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour. Emissions per episode shall be calculated using the procedures specified in paragraph (d)(2) of this section. Emissions per episode shall be divided by the duration of the episode only if the duration of the episode is longer than 1 hour.

(B) Emission profile by equipment. The emission profile must consist of emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions. The profile shall describe equipment configurations used to generate the emission events, volatility of materials processed in the equipment, and the rationale used to identify and characterize the emission events. The emissions may be based on using a compound more volatile than compounds actually used in the process(es), and the emissions may be generated from all equipment in the process(es) or only selected equipment.

(C) Emission profile by capture and control device limitation. The emission profile shall consider the capture and control system limitations and the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment (e.g., fans, LEL alarms and safety bypasses).

60. Subpart GGG, at 40 C.F.R. § 63.1258(b)(vii), states that for an affected source, “[f]or each thermal incinerator, the owner or operator shall establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter which must be measured and recorded at least once every 15 minutes during the period in which the combustion device is functioning in achieving the HAP removal required by this subpart.”

61. Subpart GGG, at 40 C.F.R. § 63.1259(b)(9), states for an affected source, that the owner or operator must keep a “[d]escription of worst-case operating conditions as required in § 63.1257(b)(8)” up-to date and accessible.

Notification of Compliance Status Report

62. Subpart GGG, at 40 C.F.R. § 63.1260(f), requires an owner or operator of an affected source subject to the provisions of Subpart GGG to submit a Notification of Compliance Status (NOCS) report which shall include, among other things, the following:

- (1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.
- (2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.
- (3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.
- (4) Listing of all operating scenarios.
- (5) Descriptions of worst-case operating and/or testing conditions for control devices.

NESHAP for Equipment Leaks (Subpart H)

63. Subpart H, at 40 C.F.R. § 63.178(b), states for an affected source, that “[t]he following requirements shall be met if an owner or operator elects to use pressure testing of batch product-process equipment to demonstrate compliance with this subpart. An owner or operator who complies with the provisions of this paragraph is exempt from the monitoring provisions of §§ 63.163, 63.168 and 63.169, and §§ 63.173 through 63.176 of this subpart.

- (1) Each time equipment is reconfigured for production of a different product or intermediate, the batch product-process equipment train shall be pressure-tested for leaks before organic HAP is first fed to the equipment and the equipment is placed in organic HAP service.
 - (i) When the batch product-process train is reconfigured to produce a different product, pressure testing is required only for the new or disturbed equipment.

(ii) Each batch product process that operates in organic HAP service during a calendar year shall be pressure tested at least once during that calendar year.

(iii) Pressure testing is not required for routine seal breaks, such as changing hoses or filters, which are not part of the reconfiguration to produce a different product or intermediate.

(2) The batch product process equipment shall be tested either using the procedures specified in § 63.180(f) of this subpart for pressure or vacuum loss or with a liquid using the procedures specified in § 63.180(g) of this subpart.

(3)(i) For pressure or vacuum tests, a leak is detected if the rate of change in pressure is greater than 6.9 kilopascals (1 psig) in 1 hour or if there is visible, audible, or olfactory evidence of fluid loss.

(ii) For pressure tests using a liquid, a leak is detected if there are indications of liquids dripping or if there is other evidence of fluid loss.

(4)(i) If a leak is detected, it shall be repaired and the batch product-process equipment shall be retested before start-up of the process.

(ii) If a batch product-process fails the retest or the second of two consecutive pressure tests, it shall be repaired as soon as practicable, but not later than 30 calendar days after the second pressure test, provided the conditions specified in paragraph (d) of this section are met.”

64. Subpart H, at 40 C.F.R. § 63.180(g), states for an affected source, that “[t]he following procedures shall be used to pressure-test batch product-process equipment using a liquid to demonstrate compliance with the requirements of § 63.178(b)(3)(ii) of this subpart.

(1) The batch product-process equipment train, or section of the train, shall be filled with the test liquid (e.g., water, alcohol) until normal operating pressure is obtained. Once the equipment is filled, the liquid source shall be shut off.

(2) The test shall be conducted for a period of at least 60 minutes, unless it can be determined in a shorter period of time that the test is a failure.

(3) Each seal in the equipment being tested shall be inspected for indications of liquid dripping or other indications of fluid loss. If there are any indications of liquids dripping or of fluid loss, a leak is detected.

(4) An alternative procedure may be used for leak testing the equipment, if the owner or operator demonstrates the alternative procedure is capable of detecting losses of fluid.”

65. Subpart H, at 40 C.F.R. § 63.181(e)(5), states for an affected source, that “[t]he owner or operator of a batch product process who elects to pressure test the batch product process equipment train to demonstrate compliance with this subpart [...] shall maintain [...] [r]ecords of any visible, audible, or olfactory evidence of fluid loss.”

Section 113(d)(1)

66. The Administrator of EPA (the Administrator) may assess a civil penalty of up to \$51,796 per day of violation up to a total of \$414,364 for violations that occurred after November 2, 2015 under Section 113(d)(1) of the CAA, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19.

67. Section 113(d)(1) limits the Administrator’s authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and the Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an administrative penalty action.

68. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

Factual Allegations and Alleged Violations

Factual Allegations

69. CPI owns and operates a pharmaceutical manufacturing facility at 200 Paoli Street, Verona, Wisconsin to manufacture a pharmaceutical product (facility).

70. The facility is a major source of HAP as defined in Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

71. CPI uses HAPs, mainly methanol, in its pharmaceutical manufacturing operations.

72. CPI's Title V Permit states that Subpart GGG requirements apply to all existing units at the facility at the time of issuance of the Title V Permit (May 1, 2015).

73. The facility is an existing source constructed prior to April 2, 1997.

74. On June 2, 2016, EPA conducted a CAA inspection of the facility (2016 Inspection).

75. On December 6, 2017, EPA issued an information request to CPI pursuant to Section 114 of the CAA, 42 U.S.C. § 7414. On February 12, 2018, CPI provided a response to the Section 114 request ("Section 114 Response").

76. On March 5, 2019, EPA requested additional information via electronic mail (e-mail). CPI provided responses on April 30, 2019 and May 9, 2019 ("Supplemental 114 Responses").

77. On September 24, 2019, EPA issued to Coating Place a Notice and Finding of Violation (NOV/FOV) alleging violations of Subpart A, Subpart GGG, and by reference Subpart H.

By-pass Stack

78. In its Section 114 Response, CPI provided EPA with a "Set Up Records for K2 Suite", which indicate that the emissions from K2 Unit can either be set to "Thru" or "Bypass" during setup. CPI states that "[t]he "Thru" setting indicates that the process air will be routed through the [Regenerative Thermal Oxidation System] RTO."

Testing at Worse-Case Conditions

79. In its Section 114 Response and Supplemental 114 Response, CPI provided EPA with the results of the emissions tests conducted at the RTO on January 3, 2013, August 13, 2016, and September 29, 2018. The emissions tests did not indicate which coating units were venting to the RTO during the test.

80. In its Section 114 Response, when asked to provide a copy of the facility's description of worse-case operating conditions under which initial compliance was demonstrated for control devices used to control batch processes, CPI provided the August 13, 2016 emissions test report and referenced a testing protocol which was not included in the emissions test report.

81. In its Supplemental 114 Response, CPI provided spreadsheets suggesting that the K2 Unit was the only coating unit venting to the control device during the emissions test.

82. Following the 2016 Inspection, CPI provided a copy of its Subpart GGG NOCS report which states, among other things, that it would conduct its emissions testing under hypothetical worse-case conditions for testing, which would include running the K2 Unit at its maximum target spray rate of 300 pounds per hour of methanol during each run.

83. CPI's Supplemental 114 Response did not include production records indicating the production/process rate during each test to each unit compared to its design capacity. As a result, EPA was unable to confirm that the facility was operating at its maximum target spray rate during the emissions tests.

Minimum Temperature of the RTO

84. In its Section 114 Response and in its Supplemental 114 Response, CPI provided the results of the emissions tests conducted at the RTO on January 3, 2013, August 13, 2016, and September 29, 2018. The emissions tests did not include the temperature of the RTO's combustion chamber and did not identify the coating units venting to the control device.

85. In its Supplemental 114 Response, CPI provided temperature monitoring results corresponding to the emissions tests conducted at the RTO on January 3, 2013, August 13, 2016, and September 29, 2018. The minimum temperature determined during the tests were 1,605, 1,580, and 1,672 °F, respectively.

86. Because the minimum temperature determined from the compliance emission tests are more stringent than 1,400 °F, CPI must comply with the minimum temperature determined from the most recent compliance emission test per the Title V, Permit Condition A.3.a.(1).

87. In its Supplemental 114 Response, CPI provided continuous records of the temperature of the RTO from June 1, 2014 to February 28, 2019. The records indicate that the RTO is “at temperature and ready” when the temperature is below the minimum temperature determined during the most recent emissions test.

Improper Wastewater Management at K2 Unit

88. In its Section 114 Response, CPI provided a description of maintenance procedures for management of wastewater generated from emptying and purging of equipment, pursuant to 40 C.F.R. § 63.1256(a)(4). The procedures stated that “remaining solution must be discarded to solvent waste”. The procedures did not specify how quickly wastewater generated from emptying and purging of equipment be removed in order to minimize organic HAP emissions to the atmosphere.

89. During its 2016 Inspection, EPA observed a bucket located under the filter in the mix room that contained solvent. EPA used a forward-looking infrared camera to observe solvent volatilizing from the bucket. In subsequent discussions with CPI after the inspection, CPI told EPA that the maintenance solvent in the bucket was a result of a maintenance activity which had been interrupted by the inspection and was immediately placed into a satellite collection vessel after the EPA inspection. CPI also told EPA that the air from the mix room is routed to the RTO.

Pressure Leak Tests

90. In its Section 114 Response, when asked to provide a list of each piece of equipment at the facility that is subject to equipment leak requirements, CPI provided a list of all emission units subject to leak provisions and a plant map identifying the location of each emission unit instead of identifying equipment such that it can be distinguished readily from equipment that is not subject to leak provisions.

91. In its Section 114 Response, CPI provided set up records of pressure tests for the batch product process equipment trains. The records for M Suite (Process P33) did not state the duration of the tests while running processes that use HAP.

Wastewater

92. During EPA's 2016 Inspection, CPI stated that it does not generate any wastewater from its production processes, and thus has not identified wastewater streams that require control.

93. CPI's Subpart GGG NOCS report failed to include the results of any applicability determination on its wastewater operations, including its cleanout and maintenance operations.

94. In its Section 114 Response, CPI stated the wastewater generated from CPI's pharmaceutical manufacturing process units does not meet the definition of "wastewater stream" at 40 C.F.R. § 63.1251, Subpart GGG and that the facility has not identified any PODs that meet the definition of "POD" at 40 C.F.R. § 63.1251, Subpart GGG. Furthermore, CPI stated that wastewater generated from each manufacturing process during the cleanout procedures has no HAP present, and if present, wastewater containing HAP are "physically removed from the production suite and treated/handled as solvent waste, prior to initial rinse."

95. In its Supplemental 114 Response, CPI failed to provide to EPA underlying calculations and data the facility used to determine their wastewater generated during the

cleanout procedures has no HAP present and is therefore not wastewater streams that are subject to requirements in Subpart GGG at 40 C.F.R. § 63.1256.

Alleged Violations

By-pass Stack

96. CPI equipped the K2 Unit with a by-pass stack, as described in Paragraph 78, in violation of the Permit Condition H.2.b.(1) and Permit Condition H.2.c.(2) of CPI's Title V Permit.

Testing at Worse-Case Conditions

97. CPI failed to demonstrate that it had conducted the January 3, 2013, August 13, 2016, and September 29, 2018 emissions tests at worse-case conditions, as described in Paragraphs 79 through 83, in violation of the Subpart A at 40 C.F.R. § 63.4 and the Subpart GGG at 40 C.F.R. § 63.1257(b)(8).

98. CPI failed to maintain a description of worst-case operating conditions, as described in Paragraphs 79 through 83, in violation of the Subpart A at 40 C.F.R. § 63.4 and the Subpart GGG at 40 C.F.R. §§ 63.1257(b)(8) and 63.1259(b)(9).

Minimum Temperature of the RTO

99. CPI failed to properly conduct compliance testing on January 3, 2013, August 13, 2016, and September 29, 2018 to determine the minimum temperature of the gasses exiting the combustion chamber and to maintain copies of the compliance emission tests results which include the temperature of the oxidization chamber, as described in Paragraphs 84 through 87, in violation of the Permit Condition A.3.b.(2) and the Permit Condition A.3.c.(2)(b) of CPI's Title V Permit. The temperature information was later obtained.

100. CPI failed to establish the minimum temperature of the gases exiting the combustion chamber as the site-specific operating parameter during the compliance testing on

January 3, 2013, August 13, 2016, and September 29, 2018, as described in Paragraphs 84 through 87, in violation of the Subpart A at 40 C.F.R. § 63.4 and the Subpart GGG at 40 C.F.R. § 63.1258(b)(vii).

101. CPI failed to maintain the operating minimum temperature of the thermal oxidizer combustion chamber at the minimum temperature determined from the most recent compliance emission test conducted on January 3, 2013, August 13, 2016, and September 29, 2018, respectively, as described in Paragraph 87, in violation of the Permit Condition A.3.a.(1) of CPI's Title V Permit.

Improper Wastewater Management at K2 Unit

102. CPI failed to prepare a description of maintenance procedures for management of wastewater generated from emptying and purging equipment and specifying the procedures that will be followed to properly manage the wastewater and minimize organic HAP emissions to the atmosphere, as described in Paragraph 89, in violation of the Subpart A at 40 C.F.R. § 63.4 and the Subpart GGG at 40 C.F.R. § 63.1254(a)(4).

Pressure Leak Tests

103. CPI failed to identify equipment subject to equipment leak requirements, as described in Paragraph 90, in violation of the Subpart A at 40 C.F.R. § 63.4 and the Subpart GGG at 40 C.F.R. § 63.1255(a)(7).

104. CPI failed to demonstrate that it conducted pressure tests for a period of at least sixty minutes at the M Suite, as described in Paragraph 91, in violation of the Subpart A at 40 C.F.R. § 63.4, the Subpart GGG at 40 C.F.R. § 63.1255(b)(1), and the Subpart H at 40 C.F.R. § 63.180(g)(2).

Wastewater

105. CPI failed to identify all PODs for wastewater streams and determine whether the wastewater streams required control, as described in Paragraphs 92 through 95, in violation of the Subpart A at 40 C.F.R. § 63.4, and the Subpart GGG at 40 C.F.R. Subpart GGG, at 40 C.F.R. §§ 63.1260(f) and 63.1256(a)(1).

106. On December 5, 2019 and subsequently thereafter, representatives of CPI and EPA discussed the September 24, 2019 NOV/FOV and CPI's corrective actions relating to the violations set out in the NOV/FOV.

Civil Penalty

107. Based on analysis of the factors specified in Section 113(e) of the CAA, 42 U.S.C. § 7413(e), the facts of this case, cooperation, and prompt return to compliance, Complainant has determined that an appropriate civil penalty to settle this action is \$50,000.

108. Within 30 days after the effective date of this CAFO, Respondent must pay a \$50,000 civil penalty by ACH electronic funds transfer, payable to "Treasurer, United States of America," and sent to:

US Treasury REX/Cashlink ACH Receiver
ABA: 051036706
Account Number: 310006, Environmental Protection Agency
CTX Format Transaction Code 22-checking

In the comment area of the electronic funds transfer, state Respondent's name and the docket number of this CAFO.

109. Respondent must send a notice of payment that states Respondent's name and the docket number of this CAFO to EPA at the following addresses when it pays the penalty:

Air Enforcement and Compliance Assurance Branch
U.S. Environmental Protection Agency, Region 5
r5airenforcement@epa.gov

Tom Martin
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 5
martin.thomas@epa.gov

Regional Hearing Clerk (E-19J)
U.S. Environmental Protection Agency, Region 5
r5hearingclerk@epa.gov

110. This civil penalty is not deductible for federal tax purposes.

111. If Respondent does not pay timely the civil penalty, EPA may request the Attorney General of the United States to bring an action to collect any unpaid portion of the penalty with interest, nonpayment penalties and the United States enforcement expenses for the collection action under Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

112. Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any overdue amount from the date payment was due at a rate established by the Secretary of the Treasury pursuant to 26 U.S.C. § 6621(a)(2). Respondent must pay the United States enforcement expenses, including but not limited to attorney's fees and costs incurred by the United States for collection proceedings. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue. This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter. 42 U.S.C. § 7413(d)(5).

General Provisions

113. The parties consent to service of this CAFO by e-mail at the following valid e-mail addresses: martin.thomas@epa.gov (for Complainant), and tbreunig@encap.com (for Respondent). The CAFO does not affect the rights of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

114. Full payment of the penalty agreed to in this CAFO shall only resolve 's liability for federal civil penalties for the violations and facts alleged in this CAFO.

115. This CAFO does not affect Respondent's responsibility to comply with the CAA and other applicable federal, state and local laws. Except as provided in paragraph 114, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by EPA.

116. Respondent certifies that it is complying fully with Subpart GGG.

117. It is EPA's position that this CAFO constitutes an "enforcement response" as that term is used in EPA's Clean Air Act Stationary Civil Penalty Policy to determine Respondent's "full compliance history" under Section 113(e) of the CAA, 42 U.S.C. § 7413(e).

118. The terms of this CAFO bind Respondent, its successors and assigns.

119. Each person signing this consent agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

120. Each party agrees to bear its own costs and attorney's fees in this action.

121. This CAFO constitutes the entire agreement between the parties.

**Consent Agreement and Final Order
In the Matter of: Coating Place Inc.**

Coating Place Incorporated, Respondent

March 4, 2022
Date

Jim A Breunig
Timothy A. Breunig, President & CEO
Coating Place Incorporated

**Consent Agreement and Final Order
In the Matter of: Coating Place Inc.**

United States Environmental Protection Agency, Complainant

**MICHAEL
HARRIS**

Digitally signed by
MICHAEL HARRIS
Date: 2022.03.08
14:33:47 -06'00'

Michael D. Harris
Division Director
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 5

**Consent Agreement and Final Order
In the Matter of: Coating Place Inc.
Docket No. CAA-05-2022-0007**

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

Date

ANN COYLE Digitally signed by ANN
COYLE
Date: 2022.03.08
15:51:07 -06'00'

Ann L. Coyle
Regional Judicial Officer
U.S. Environmental Protection Agency
Region 5