



EPA REGION 2  
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION

March 29, 2024

**Via Email With Delivery and Read Receipt Requested**

Ms. Lorraine Afanador  
EHS Supervisor  
Patheon Puerto Rico Inc  
Carr. 670 Km 5.2,  
Manati, Puerto Rico, 00674  
[lorraine.afanador@thermofisher.com](mailto:lorraine.afanador@thermofisher.com)

**RE: RCRA § 3007 – REQUEST FOR INFORMATION**  
**Facility Name: Patheon Puerto Rico Inc**  
**EPA ID: PRR000000836**  
**CEPD-RCRA-24-3007-0000-008**

Dear Ms. Afanador:

The United States Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under Section 3008 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976 and the Hazardous and Solid Waste Amendments (HWSA) of 1984, 42 U.S.C. §§ 6901 and 6928.

This request for information is made pursuant to the provisions of Section 3007 of RCRA, 42 U.S.C. § 6927, which requires that you provide the information requested in Enclosure I to this letter using the instructions and definitions included in Enclosure II. This information is required to evaluate the full regulatory and compliance status of the facility. The information requested in Enclosure I must be submitted no later than thirty (30) calendar days from receipt of this letter. Requests for additional time to provide the information requested in Enclosure I must be justified and made in writing within ten (10) calendar days of receipt of this letter. The response must be signed by a responsible official or agent of your facility, using the form in Enclosure III to this letter.

Failure to respond to this letter truthfully and accurately within the time provided may subject you to sanctions authorized by federal law, including but not limited to a potential enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. Please also note that all information you provide may be used in an administrative, civil judicial, or criminal action. This information request is not subject to the requirements of the Paperwork Reduction Act as amended,

44 U.S.C. § 3501 et seq.

You may, if you desire, assert a business confidentiality claim covering all or part of the information herein requested. This claim may be asserted by placing on (or attaching to) the information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as “trade secret”, “proprietary”, or “company confidential”. The claim should set forth the information requested in 40 C.F.R. § 2.204(e)(4). Information covered by such a claim will be disclosed by EPA only to the extent permitted by, and by means of procedures set forth in 40 C.F.R. Part 2. EPA will review the information to determine the extent of confidentiality of the information, and may, at its discretion challenge the confidentiality claim pursuant to the procedures set forth at 40 C.F.R. Part 2. If no such claim accompanies the information when it is received by EPA, it may be available to the public by EPA without further notice you.

The responses to the information request in Enclosure I must be provided either by email or by mail to the following address:

Rosana Caballer-Cruz, Enforcement Officer  
RCRA & Revitalization Section  
U.S. Environmental Protection Agency - Region 2  
Caribbean Environmental Protection Division  
City View Plaza II, Suite 7000  
#48 PR-165 km 1.2  
Guaynabo, PR 00968-8069  
[caballer.rosana@epa.gov](mailto:caballer.rosana@epa.gov)

If you have any questions regarding this matter, please contact Rosana Caballer-Cruz, of my staff, at 787-977-5880 or via e-mail at [caballer.rosana@epa.gov](mailto:caballer.rosana@epa.gov).

Sincerely,

**HECTOR  
VELEZ-CRUZ** Digitally signed by  
HECTOR VELEZ-CRUZ  
Date: 2024.03.29  
18:56:20 -04'00'

Héctor L. Vélez Cruz, Esq,  
Acting Director

Enclosures:

- I. Request for Information
- II. Instructions and Definitions
- III. Certification of Answers

cc: Lorna Rodríguez, Chief  
Hazardous Waste Enforcement Program  
Puerto Rico Department of Natural & Environmental Resources  
8838 Street, Km 6.3, Sector El Cinco  
Rio Piedras, PR 00936  
[lornarodriguez@drna.pr.gov](mailto:lornarodriguez@drna.pr.gov)

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**ENCLOSURE I**  
**RCRA § 3007 REQUEST FOR INFORMATION**

Facility Name: Patheon Puerto Rico Inc  
EPA ID No.: PRR000000836

On or about February 1, 2024, a duly authorized representative of EPA conducted a RCRA Hazardous Waste Compliance Evaluation Inspection of the Patheon Puerto Rico Inc (Patheon) at Carr. 670 Km 5.2, Manati, Puerto Rico, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927.

Based on the information obtained during the inspection, EPA determined that the following information is required to determine the compliance status of the Facility.

1. General Information

- a. Provide the full legal name of Patheon Puerto Rico Inc. If the company has used any other names, please provide them.
- b. Provide the management structure of the company (President/Owner, Partners, General Manager, etc.). If the company is a subsidiary, indicate the parent company.
- c. Provide the type of company (corporation, partnership, etc.), employer identification number, Department of State certificate number, DUNS number, and business licenses, if any.
- d. Besides the EPA inspection performed on February 1, 2024, please provide information about any other inspection conducted by any other state or federal agency, since 2022-2024.
- e. Do you have any knowledge of any state or federal agency (EPA, Department of Justice, Puerto Rico Department of Natural and Environmental Resources, etc.) actions (complaints, suits, investigations, etc.) against Patheon Puerto Rico Inc? If yes, explain and elaborate your answers.
- f. Please certify if Patheon Puerto Rico Inc has filed for bankruptcy at any time under their current or any previous name.

2. Specific Information

a. Waste Generation

- i. At the time of the inspection, in the Light Mechanical Shop Area, scrap metals were observed throughout the location, in open containers with overflow content, in non-operational equipment, among other locations. Please describe

and provide information related to, but not limited to the determination, handling, storing, and disposal activities conducted to the latter in order to remove it from the Light Mechanical Shop Area.

- ii. At the time of the inspection, in the Light Mechanical Shop Area, spent batteries were observed throughout the location, while eight (8) spent batteries above a wood panel were observed. Please describe and provide information related to, but not limited to the determination, handling, storing, and disposal activities conducted to the latter in order to remove it from the Light Mechanical Shop Area.

b. Waste Determination

- i. As part of the inspection activity, the facility representatives acknowledged that they conducted their used oil determination by knowledge. Please describe and provide information related to, but not limited to how Patheon Puerto Rico Inc determined that the used oil generated, stored, and disposed of is non-hazardous waste.
- ii. As part of the inspection activity, the facility representatives acknowledged that they conducted their spent paint determination by knowledge. Please describe and provide information related to, but not limited to how Patheon Puerto Rico Inc determined that the spent paint generated, stored, and disposed of is non-hazardous waste.

c. Hazardous Waste Tanks

- i. On a February 9, 2022 inspection by EPA, two (2) 90-day hazardous waste accumulations tanks, identified as TK-3201-1, and TK-3201-2, respectively, were out of service. By that time, additional information related to the future use of the latter was requested. As a result, an electronic communication, dated February 18, 2022, was received. The mentioned letter provided information related to the future use and/or potential actions of the facility related to those hazardous waste tanks. By the time of the 2024 inspection activity, those hazardous waste tanks no longer existed and ongoing construction activities were observed at the location of the former hazardous waste tanks area. Hence, questions and information were raised and asked in order to obtain additional information and actions taken from the facility related to the hazardous waste tanks. Therefore, please describe and/or provide information attesting that the facility met the closure conditions for containers, tanks, drip pads, and containment buildings, as established on 40 CFR 262.17(a)(8)(i)(A) or in 40 CFR 262.17(a)(8)(i)(B).

## **ENCLOSURE II**

### **INSTRUCTIONS AND DEFINITIONS**

In responding to this Request for Information, apply the following instructions and definitions:

1. The signatory should be an officer or agent who is authorized to respond on behalf of the company or facility. The signatory must complete and return the attached Certification of Answers to Responses (ENCLOSURE III).
2. A complete response must be made to each individual question in this Request for Information. Identify each answer with the number of the question to which it is addressed.
3. In preparing your response to each question, consult with all present and former employees and agents of the company or facility who you have reason to believe may be familiar with the matter to which the question pertains.
4. In answering each question, identify all contributing sources of information.
5. If you are unable to answer a question in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any question, state that person's name and last known address and phone number and the reasons for your belief.
6. If you cannot provide a precise answer to any question, please approximate and state the reason for your inability to be specific.
7. For each document produced in response to this Request for Information, indicate on the document or in some other reasonable manner, the number of the question to which it applies.
8. If anything is deleted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion.
9. If a document is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.
10. The company and/or facility for the purposes of this Request for Information is Patheon Puerto Rico Inc at Carr. 670 Km 5.2, Manati, Puerto Rico.

11. A *hazardous waste generator* is defined, for the purposes of this Request for Information, as any person (which includes this facility), by site, whose act or process produces hazardous waste or whose act first causes a hazardous waste to become subject to regulation.
12. *Hazardous waste* is defined, for the purposes of this Request for Information, as it is defined in Section 1004(5) of RCRA, as amended, 42 USC 6903(5).
13. *Manage* is defined, for the purposes of this Request for Information, as to market, generate, treat, store, dispose, or otherwise handle.
14. *Hazardous Constituents* is defined, for the purposes of this Request for Information, as those substances listed in 40 CFR 261 Appendix VIII.
15. The term *Solid Waste Management Unit (SWMU)* is defined, for the purposes of this Request for Information, as any landfill, surface impoundment, land application area, waste pile, incinerator, tank, injection well, transfer station, waste recycling operation, tank, or container storage area that currently or formerly was used to manage a solid waste.
16. *Used oil* shall be defined for the purposes of this Request for Information as any oil that has been refined from crude oil, or any synthetic oil, that has been used and as a result of such use is contaminated by physical or chemical impurities.

**ENCLOSURE III**  
**Certification of Answers**

**CERTIFICATION OF ANSWERS TO REQUEST FOR INFORMATION**

I certify, under penalty of law, that I have personally examined and am familiar with the information submitted in response to EPA's Request for Information, and all documents submitted herewith; that the submitted information is true, accurate, and complete; and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

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Name (Print or Type)

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Title (Print or Type)

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Signature

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Date (Print or Type)

Patheon Puerto Rico  
Inc

PRR000000836