



EPA REGION 2
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION

February 5, 2024

VIA ELECTRONIC MAIL

Ms. Wanda Marrero
EHS1 Manager at San Lorenzo Facility
Ethicon LLC
Carr. #183 Km. 8.3 Hato Industrial
San Lorenzo, Puerto Rico, 00754
wmarrer2@its.inj.com
lrodr274@its.inj.com
creyes35@its.inj.com

RE: **RCRA § 3008 – NOTICE OF VIOLATION**
Facility Name: Ethicon LLC
EPA ID: PRD982542219
CEPD-RCRA-24-0000-3008-007

Dear Ms. Marrero:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 et seq. Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Notice of Violation (NOV), the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984. The Commonwealth of Puerto Rico is not authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926.

On or about November 29, 2023, a duly authorized representative of the EPA conducted a Compliance Evaluation Inspection (CEI) of Ethicon LLC, located in San Lorenzo, Puerto Rico, (the "Facility") pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA representative found the Facility in violation of §§ 262.42(a)(2) and 262.261(f) of the RCRA Regulations.

CITY VIEW PLAZA II BUILDING, 7TH FLOOR
ROUTE 165 GUAYNABO, PR 00968

This Notice of Violation (Enclosure I) is issued pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by RCRA and HSWA, 42 U.S.C. §§ 6901 and 6928. Issuance of this NOV and compliance with its terms does not preclude EPA from taking formal enforcement action against you and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

If you have not already done so, you must take immediate action to correct the violations described in Enclosure I. Please submit, within thirty (30) days of the receipt of this letter, a response which includes (1) a description of the actions you have taken to correct the violations noted in Enclosure I, (2) documentation that the violations have been corrected, and (3) a description of the procedures that will be put into place to prevent such violations from occurring in the future. For consistency, please provide your answers in a format which is keyed to the sections as outlined in Enclosure I to this letter.

Your response to this NOV can be sent through email to the following email address caballer.rosana@epa.gov and can also be mailed to the following address:

Rosana Caballer-Cruz, Enforcement Officer
Response and Remediation Branch
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

Failure to respond in full to the above requirements may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. If you have any questions regarding this matter, please contact Ms. Rosana Caballer-Cruz, from my staff, at 787-977-5880 or via e-mail at caballer.rosana@epa.gov.

Sincerely,

**HECTOR
VELEZ-CRUZ**

Digitally signed by
HECTOR VELEZ-CRUZ
Date: 2024.02.05
12:57:51 -04'00'

Héctor L. Vélez Cruz, Esq,
Acting Director

Enclosures:

- I. Enclosure I - Notice of Violation

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

CEPD-RCRA-24-0000-3008-007



EPA REGION 2

CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION

ENCLOSURE I – RCRA § 3008 NOTICE OF VIOLATION

Ethicon LLC

EPA ID: PRD982542219

CEPD-RCRA-24-0000-3008-007

On or about November 29, 2023, a duly authorized representative of EPA conducted a Resource Conservation and Recovery Act (RCRA) Hazardous Waste Compliance Evaluation Inspection (CEI) of the ETHICON LLC (the Facility) located at Carr. #183 Km. 8.3 Hato Industrial, San Lorenzo, Puerto Rico, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. As a result of the CEI, EPA has identified the following violations of the RCRA regulations.

i. 40 C.F.R. § 262.42(a)(2)

At the time of the inspection, the Facility failed § 40 C.F.R, § 262.42(a)(2) which required *“A large quantity generator must submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if he has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter...”*

The facility failed to comply with this requirement. Although a notification letter was generated, and the intention of the facility to communicate the issue was proven, it was confirmed with the facility representatives that such notification was sent to the State Agency, not to the EPA Regional Administrator, as requested by the Regulation.

ii. 40 C.F.R. § 262.261 (f)

At the time of the inspection, the Facility failed § 262.261(f) which required *“The plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate*

evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires)."

The facility failed to comply with this requirement. During the discussion of the contingency plan, it was confirmed that the signal(s) to be used to begin an evacuation, evacuation routes, and alternate evacuation routes were not included nor available on the document provided for evaluation.