

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2**

In the Matter of:

TAPI Puerto Rico, Inc.
Highway 3, km 76.3
C Street, Humacao Industrial Park
Humacao, PR 00791

Respondent

Proceeding under Section 113
of the Clean Air Act, 42 U.S.C. § 7413

Docket No. CAA-02-2011-1204

**Administrative Complaint under
Section 113 of the Clean Air Act,
42 U.S.C. § 7413**

U.S. ENVIRONMENTAL
PROTECTION AGENCY
2011 SEP 13 A 11:00
ADMINISTRATIVE HEARING
CLERK

ADMINISTRATIVE COMPLAINT

I. JURISDICTION

1. This Complaint ("Complaint") initiates an administrative action for the assessment of a civil penalty pursuant to Section 113(d) of the Clean Air Act ("the Act"), 42 U.S.C. § 7413(d). The Complainant in this action is the Director of the Caribbean Environmental Protection Division of the United States Environmental Protection Agency ("EPA"), Region 2, who has been delegated the authority to institute this action.

2. EPA and the U.S. Department of Justice have determined, pursuant to Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), that EPA may pursue this matter through administrative enforcement action.

II. APPLICABLE STATUTES AND REGULATIONS

3. Section 113(d) of the Act, 42 U.S.C. § 7413(d), provides for the assessment of penalties for violations of Section 112(r) of the Act, 42 U.S.C. § 7412(r).

4. Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), requires the Administrator to promulgate release prevention, detection, and correction requirements regarding regulated substances in order to prevent accidental releases of regulated substances. EPA promulgated regulations in 40 C.F.R. Part 68 to implement Section 112(r)(7) of the Act, which set forth the requirements of risk management programs that must be established and implemented at affected stationary sources. The regulations at 40 C.F.R. Part 68, Subparts A through G, require owners and operators of stationary sources to, among other things, develop and implement: (1) a management system to oversee the implementation of the risk management program elements; and (2) a risk management program that includes, but is not limited to, a hazard assessment, a prevention program, and an emergency response program. Pursuant to 40 C.F.R. Part 68, Subparts A and G, the risk management program for a stationary source that is subject to these requirements is to be described in a risk management plan ("RMP") that must be submitted to EPA.

5. Sections 112(r)(3) and (5) of the Act, 42 U.S.C. §§ 7412(r)(3) and (5), require the Administrator to promulgate a list of regulated substances, with threshold quantities. EPA promulgated a regulation known as the List Rule, at 40 C.F.R. Part 68, Subpart F, to implement Section 112(r)(3) of the Act, 42 U.S.C. § 7412(r)(3), which lists the regulated substances and their threshold quantities.

6. Pursuant to Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), and 40 C.F.R. §§ 68.10(a), 68.12, and 68.150, an owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process shall comply with the requirements of 40 C.F.R. Part 68 (including, but not limited to, submission of an RMP to EPA), no later than June 21, 1999, or three years after the date on which such regulated substance is first listed under 40 C.F.R. § 68.130, or the date on which the regulated substance is first present in a process above the threshold quantity, whichever is latest.

7. The regulations at 40 C.F.R. Part 68 separate the covered processes into three categories, designated as Program 1, Program 2, and Program 3. A covered process is subject to Program 3 requirements, as per 40 C.F.R. § 68.10(d), if the process: a) does not meet one or more of the Program 1 eligibility requirements set forth in 40 C.F.R. § 68.10(b); and b) is listed in one of the specific North American Industry Classification System codes found at 40 C.F.R. § 68.10(d)(1) or is subject to the United States Occupational Safety and Health Administration ("OSHA") process safety management standard set forth in 29 C.F.R. § 1910.119.

8. 40 C.F.R. § 68.12(d) requires that the owner or operator of a stationary source with a Program 3 process undertake certain tasks, including, but not limited to, development and implementation of a management system (pursuant to 40 C.F.R. § 68.15), the implementation of prevention program requirements, which include mechanical integrity (pursuant to 40 C.F.R. §§ 68.65-68.87), the development and implementation of an emergency response program (pursuant to 40 C.F.R. §§ 68.90-

68.95), and the submission of additional information on prevention program elements regarding Program 3 processes (pursuant to 40 C.F.R. § 68.175).

9. Pursuant to Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7), and 40 C.F.R. § 68.190(b), an owner or operator of a stationary source shall revise and update the RMP submitted pursuant to 40 C.F.R. § 68.150 at least once every five years from the date of its initial submission or most recent update required by 40 C.F.R. § 68.190(b)(2)-(7), whichever is later.

III. DEFINITIONS

10. 40 C.F.R. § 68.3 defines “hot work” as work involving electric or gas welding, cutting, brazing, or similar flame or spark-producing operations.

11. 40 C.F.R. § 68.3 defines “mechanical integrity” as the process of ensuring that process equipment is fabricated from the proper materials of construction and is properly installed, maintained, and replaced to prevent failures and accidental releases.

12. 40 C.F.R. § 68.3 defines “stationary source” in relevant part, as any buildings, structures, equipment, installations, or substance-emitting stationary activities which belong to the same industrial group, which are located on one or more contiguous properties, which are under the control of the same person (or persons under common control), and from which an accidental release may occur.

13. 40 C.F.R. § 68.3 defines “threshold quantity” as the quantity specified for regulated substances pursuant to Section 112(r)(5) of the Act as amended, listed in 40 C.F.R. § 68.130, and determined to be present at a stationary source as specified in 40 C.F.R. § 68.115.

14. 40 C.F.R. § 68.3 defines “regulated substance” as any substance listed pursuant to Section 112(r)(3) of the Act in 40 C.F.R. § 68.130.

15. 40 C.F.R. § 68.3 defines “process” in relevant part, 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.

16. 40 C.F.R. § 68.3 defines “covered process” as a process that has a regulated substance present in more than a threshold quantity pursuant to 40 C.F.R. § 68.115.

IV. FINDINGS OF VIOLATIONS

17. Respondent is, and at all times referred to herein was, a “person” as defined by Section 302(e) of the Act, 42 U.S.C. § 7602(e).

18. Respondent owned and operated a bulk pharmaceutical manufacturing plant located at Highway 3, km 76.3, C Street, Humacao Industrial Park Humacao, Puerto Rico, (hereinafter referred to as the "Facility").

19. Respondent temporarily ceased its operations at the Facility on March 31st, 2010.

20. The Facility was a "stationary source" pursuant to Section 112(r)(2)(C) of the Act and 40 C.F.R. § 68.3.

21. Fluorine is a "regulated substance" pursuant to Section 112(r)(2) and (3) of the Act and 40 C.F.R. § 68.3. The threshold quantity for fluorine as listed in 40 C.F.R. § 68.130, Table 1, is 1,000 pounds.

22. The Facility is currently registered under the RMP program as "TAPI Puerto Rico, Inc."

23. The Facility's current owner is Teva Group, Inc. Teva Group, Inc. purchased the Facility in April, 2008, from Archimica Puerto Rico, Inc.

24. The Facility is located in a commercial/industrial section of the Municipality of Humacao.

25. Respondent filed to the EPA Reporting Center its initial RMP for the Facility on August 24, 1999, at that time, the Facility was owned by Archimica, Inc.

26. On June 22, 2004, the RMP was resubmitted by Clariant Puerto Rico LSM. A corrected version of the RMP was submitted on November 17, 2008, changing the name from Clariant LSM Puerto Rico, Inc. to TAPI Puerto Rico, Inc.

27. EPA conducted an inspection of the Facility on September 10, 2008, (the "Inspection"), to assess compliance with Section 112(r) of the Clean Air Act.

28. During the Inspection, Respondent's representative informed EPA that the Facility was dedicated exclusively to the production of 5-Fluorouracil, a drug used to treat cancer.

29. 5-Fluorouracil is a mixture containing the regulated substance fluorine in a concentration above one percent by weight of the mixture and with a partial pressure of more than 10 millimeters of mercury.

30. Fluorine gas is received at the Facility in a tube trailer. Each trailer contains eight fluorine tube cylinders. Each tube cylinder contains 20% fluorine and 80% nitrogen. There are approximately 225-lbs. of fluorine in each tube cylinder.

31. The Facility reported that it had a maximum of two fluorine tube trailers on-site at any time. This was consistent with the reported registration quantity of 3,600-lbs.

32. Based on the findings of the September 10, 2008 inspection, EPA found Respondents in violation of the CAA, and issued an Administrative Compliance Order, Docket Number CWA-02-2009-1016, against Respondents.

33. EPA conducted a second inspection (the "Follow up Inspection") of the Facility on February 24, 2010.

34. From the findings of the follow up inspection, EPA concluded that TAPI took the necessary steps to comply with the regulatory requirements under Part 68.

COUNT 1

35. During the Inspection, Respondent did not have a written description of its RMP management system and other persons responsible for implementing individual requirements of the RMP with defined lines of authority, as required by 40 C.F.R. § 68.15(a) and (c).

36. During the Inspection, Respondent did not produce process safety information pertaining to the equipment in the process required by 40 C.F.R. § 68.65(d), including: electrical classification, ventilation system design, design codes and standards, and description of safety systems.

37. During the Inspection, Respondent did not produce any documentation stating that the equipment complies with recognized and generally accepted good engineering practices as required by 40 C.F.R. 68.65(d)(2).

38. During the Inspection, Respondent did not produce documentation that it had resolved the Process Hazard Analysis ("PHA") recommendations in a timely manner, as required by 40 C.F.R. § 68.67(e).

39. During the Inspection, Respondent did not have a record of annual certification of Standard Operating Procedures ("SOPs"), as required by 40 C.F.R. § 68.69(c).

40. During the Inspection, Respondent did not have a complete mechanical integrity program, as required by 40 C.F.R. § 68.73. The Facility Manager reported that the Pressure Safety Valves (PSVs) maintenance inspection was not performed in 2006, 2007 and 2008.

41. During the Inspection, Respondent did not have documentation to identify the date of each inspection and test that has been performed on process equipment, the name of the person who performed the inspection or test, the serial number or other identifier of the equipment on which the inspection or test was performed, a description of the inspection or test performed, and the results of the inspection or test, as required by 40 C.F.R. § 68.73(d)(4).

42. During the Inspection, EPA reviewed the Change Control Procedure (SOP-API-012; July, 17, 2007) and concluded that it does not explicitly address the safety and health review of changes, as required by 40 C.F.R. § 68.75(b)(2).

43. During the Inspection, Respondent did not have updated process safety information after changes covered by 40 C.F.R. § 68.75, as required by 40 C.F.R. § 68.75(d).

44. During the Inspection, Respondent did not have a Pre-startup Review completed for all changes involving the need to update PSI, as required by 40 C.F.R. § 68.77.

45. During the Inspection, Respondent did not have records of completed RMP compliance audits, as required by 40 C.F.R. § 68.79.

46. During the Inspection, Respondent did not have a written employee participation plan available for review, as required by 40 C.F.R. § 68.83(a). Respondent's failure to comply with the requirements of 40 C.F.R. Part 68 as described above in Paragraphs 34-45 constitutes a violation of Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7). Respondent is therefore subject to the assessment of penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d).

47. Respondent's failure to comply with the requirements of 40 C.F.R. Part 68, as described above, constitutes a violation of Section 112(r)(7) of the Act, 42 U.S.C. § 7412(r)(7). Respondent is therefore subject to the assessment of penalties under Section 113(d) of the Act, 42 U.S.C. § 7413(d).

V. NOTICE OF PROPOSED ORDER ASSESSING A CIVIL PENALTY

Pursuant to Section 113(d) of the Act, 42 U.S.C. § 7413(d), and 40 C.F.R. Part 19, Adjustment of Civil Monetary Penalties for Inflation, EPA is authorized to assess civil penalties not to exceed \$27,500 per day for each violation of Section 112 of the Act, 42 U.S.C. § 7412, that occurred on or after January 30, 1997 through March 15, 2004, and \$32,500 per day for each violation of Section 112 of the Act that occurred after March 15, 2004 through January 12, 2009, and up to \$37,500 for violations that occurred after January 12, 2009. Civil penalties under Section 113 of the Act may be assessed by Administrative Order. On the basis of the violations of the Act described above, Complainant alleges that Respondent is subject to penalties for violating Section 112(r) of the Act, 42 U.S.C. § 7412(r).

The proposed civil penalty in this matter has been determined in accordance with the "Combined Enforcement Policy for CAA Section 112(r) Risk Management Program," dated August 15, 2001 ("Section 112(r) Penalty Policy") and the September 21, 2004 memorandum from Thomas V. Skinner, Acting Assistant Administrator, to the Regional Administrators. A copy of the Section 112(r) Penalty Policy accompanies this Complaint. A Penalty Calculation Worksheet which shows how the proposed penalty was calculated is included as Attachment 1.

In determining the amount of any penalty to be assessed, Section 113(e) of the Act, 42 U.S.C. § 7413(e), requires EPA to take into consideration the size of Respondent's business, the economic impact of the proposed penalty on Respondent's business, Respondent's full compliance history and good faith efforts to comply, the duration of the violations as established by any credible evidence, payment by Respondent of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violations.

In accordance with Section 113(d) of the Act, 40 C.F.R. Part 19, and the Section 112(r) Penalty Policy, and based on the facts alleged in this Complaint, Complainant proposes to assess a civil penalty of \$136,364 against Respondent.

Payment of a civil penalty shall not affect Respondent's ongoing obligation to comply with the Act and other applicable federal, state or local laws.

The proposed penalty reflects a presumption of Respondent's ability to pay the penalty and to continue in business based on the size of its business and the economic impact of the proposed penalty on its business. Respondent may submit appropriate documentation to rebut this presumption.

VI. PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

The rules of procedure governing this civil administrative litigation are entitled, "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits" (hereinafter, the "Consolidated Rules"), and are codified at 40 C.F.R. Part 22. A copy of the Consolidated Rules accompanies this Complaint.

Notice of Opportunity to Request a Hearing and Answering the Complaint

To request a hearing, Respondent must file an Answer to the Complaint, pursuant to 40 C.F.R. §§ 22.15(a)-(c). Pursuant to 40 C.F.R. § 22.15(a), such Answer must be filed within 30 days after service of the Complaint.

An Answer is also to be filed, pursuant to 40 C.F.R. § 22.15(a), if Respondent contests any material fact upon which the Complaint is based, contends that the proposed penalty is inappropriate, or contends that Respondent is entitled to judgment as a matter of law. If filing an Answer, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written Answer to the Complaint. The address of the Regional Hearing Clerk of EPA, Region 2, is:

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

Respondent shall also serve one copy of the Answer to the Complaint upon Complainant and any other party to the action, 40 C.F.R. § 22.15(a). Complainant's copy of Respondent's Answer, as well as a copy of all other documents that Respondent files in this action, shall be sent to:

Carolina Jordán-García
Office of Regional Counsel
U.S. Environmental Protection Agency - Region 2
1492 Ponce de León Ave.
Centro Europa Building, Suite 417
Santurce, Puerto Rico 00907- 4127
Email: jordan-garcia.carolina@epa.gov
Tel.: (787) 977-5834
Fax: (787) 729-7748

Pursuant to 40 C.F.R. § 22.15(b), Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations contained in the Complaint with regard to which Respondent has any knowledge. Where Respondent lacks knowledge of a particular factual allegation and so states in its Answer, the allegation is deemed denied, pursuant to 40 C.F.R. § 22.15(b). The Answer shall also set forth: (1) the circumstances or arguments that are alleged to constitute the grounds of defense; (2) the facts which Respondent disputes; (3) the basis for opposing any proposed relief; and (4) whether Respondent requests a hearing.

If Respondent fails in its Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation, pursuant to 40 C.F.R. § 22.15(d).

Respondent's failure to affirmatively raise in the Answer facts that constitute or that might constitute the grounds of its defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a hearing.

Any hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. § 22.21(d). A hearing of this matter will be conducted in accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of 40 C.F.R. Part 22.

Failure to Answer

If Respondent fails to file a timely answer to the Complaint, EPA may file a Motion for Default pursuant to 40 C.F.R. §§ 22.17(a) and (b), which may result in the issuance of a default order assessing the proposed penalty pursuant to 40 C.F.R. § 22.17(c). If a default order is issued, any penalty assessed in the default order shall become due and payable by Respondent without further proceedings 30 days after the default order becomes final. If necessary, EPA may then seek to enforce such final order of default against Respondent, and to collect the assessed penalty amount, in federal court.

VII. INFORMAL SETTLEMENT CONFERENCE

Whether or not Respondent requests a formal hearing, EPA encourages settlement of this proceeding consistent with the provisions and objectives of CERCLA and EPCRA and the applicable regulations, 40 C.F.R. § 22.18(b). At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in this Complaint, and Respondent may also provide whatever additional information that it believes is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged; (2) any information relevant to Complainant's calculation of the proposed penalty; (3) the effect the proposed penalty would have on Respondent's ability to continue in business; and/or (4) any other special facts or circumstances Respondent wishes to raise. Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists.

Any request for an informal conference or any questions that Respondent may have regarding this Complaint should be directed to the EPA Assistant Regional Counsel identified in Section VI, above.

Respondent's request for a formal hearing does not prevent it from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a hearing pursuant to 40 C.F.R. § 22.15(c).

A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. § 22.15. No penalty reduction will be made simply because an informal settlement conference is held.

In the event settlement is reached, its terms shall be recorded in a written Consent Agreement signed by the parties and incorporated into a Final Order, pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3).

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in such Consent Agreement terminates this administrative litigation and the civil proceedings arising out of the allegations made in this Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

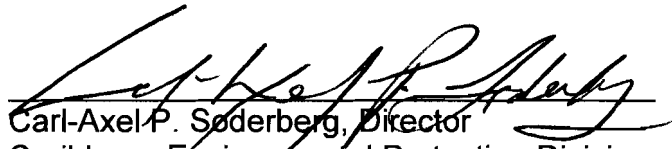
VIII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE

Instead of filing an Answer, Respondent may choose to pay the total amount of the proposed penalty within 30 days after receipt of the Complaint, provided that Respondent files with the Regional Hearing Clerk, Region 2 (at the address provided in Section VI.A., above), a copy of the check or other instrument of payment, as provided in 40 C.F.R. § 22.18(a). A copy of the check or other instrument of payment should be provided to the EPA Assistant Regional Counsel identified in Section VI, above. Payment of the penalty assessed should be made by sending a cashier's or certified check payable to the "Treasurer, United States of America," in the full amount of the penalty assessed in this Complaint to the following addressee:

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

The check must be identified with a notation of the name and docket number of this case, set forth in the caption on the first page of this Complaint. Pursuant to 40 C.F.R. § 22.18(a)(3), upon EPA's receipt of such payment, a Final Order shall be issued. Furthermore, as provided in 40 C.F.R. § 22.18(a)(3), the making of such payment by Respondent shall constitute a waiver of Respondent's rights to contest the allegations made in the Complaint and to appeal the Final Order. Such payment does not extinguish, waive, satisfy or otherwise affect Respondent's obligation and responsibility to comply with all applicable regulations and requirements, and to maintain such compliance.

Dated: 09/06/11


Carl-Axel P. Soderberg, Director
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency, Region 2
Centro Europa Building, Suite 417
1492 Ponce De León Avenue
San Juan, Puerto Rico 00907

TO: TAPI, PR Inc.
Highway 3, km 76.3
C Street, Humacao Industrial Park
Humacao, PR 00791
Attn: Santiago Hernández, Site Manager

Attachment

cc: Karen Maples, Region 2 Hearing Clerk

IN THE MATTER OF:

TAPI Puerto Rico, Inc.
Highway 3, Km 76.3
C Street, Humacao Industrial Park
Humacao, PR 00791

Respondent

Proceeding under Section 113 of the
Clean Air Act 42 U.S. C. §7413

Docket No. CAA-02-2011-1204

**Administrative Complaint under Section
113 of the Clean Air Act, 42 U.S.C. § 7413**

CERTIFICATE OF SERVICE

I certify that the foregoing Complaint was sent to the following persons, in the manner specified, on the date below:

Original and Copy via UPS Mail to:

Karen Maples
Regional Hearing Clerk
Region II
U.S. Environmental Protection Agency
290 Broadway, 16th Floor
New York, NY 10007-1866

Copy by Certified Mail Return Receipt:

Santiago Hernández
Site Manager
TAPI, PR Inc.
Highway 3, km 76.3
C Street, Humacao Industrial Park
Humacao, PR 00791

Dated: 9/8/2011

