4/26/90

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
HERCULES, INC.	)	Docket No. TSCA-III-416
	)	
Respondent	)	

Notice of Treatment of Confidential Business Information

Portions of the attached ACCELERATED DECISION required consideration of information which Respondent submitted to the United States Environmental Protection Agency (EPA) as Confidential Business Information (CBI). Information based on CBI has not been included in the Decision. Thus, for purposes of the Decision, the chemical involved has been referrred to as Chemical A. The complaint, answer and other documents which contain the CBI material are filed with the Headquarters Hearing Clerk and the Regional Hearing Clerk. The information which the parties have treated as CBI will itself be treated as confidential unless the Respondent waives confidentiality thereto, or EPA releases the information in accordance with 40 C.F.R. Part 2.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
HERCULES, INC.,	)	Docket No. TSCA-III-416
	)	
Respondent	)	

TSCA: PREMANUFACTURE NOTIFICATION: NOTICE OF COMMENCEMENT OF MANUFACTURE: 15 U.S.C. § 2607(b):

The notification requirements for the commencement of manufacture (NOC) of a new chemical substance contained in 40 C.F.R. § 720.102, as clarified, revised and amended on April 22, 1986, do not apply retroactively to a manufacturer who, in 1985, sold, for commercial processing, a surplus quantity of a new chemical substance which had been manufactured for "exempt" test marketing (TME) purposes, and who filed an NOC within thirty (30) days after the sale but did not begin actual "non-exempt" commercial production until more than four (4) months after filing the NOC.

APPEARANCES:

For Complainant:
Douglas G. White, Esquire
Assistant Regional Counsel
U.S. EPA, Region III
841 Chestnut Building
Philadelphia, PA 19107

For Respondent:
Etta Ryan Clark, Esquire
Counsel, Law Department
Hercules, Inc.
Hercules Plaza
Wilmington, Delaware 19894

BEFORE: Henry B. Frazier, III
Chief Administrative Law Judge

ACCELERATED DECISION

I. Background

A. Violation Alleged

This proceeding arose under the Toxic Substances Control Act, 15 U.S.C. §§ 2601 et seq. (TSCA or the Act). An administrative complaint was issued on June 28, 1989, by the United States Environmental Protection Agency (EPA or Complainant or Agency), under § 16(a) of the Act, 15 U.S.C. § 2615(a). [1] Section 16(a) of the Act provides for the imposition of civil penalties for violations of § 15 of the Act, 15 U.S.C. § 2614. [2] The violations of § 15 alleged in the complaint were violations of rules promulgated under § 5, 15 U.S.C. § 2604. More specifically, the complaint alleged that Hercules, Inc. (Respondent or Hercules) had violated the rule in 40 C.F.R. § 720.102 requiring any person who commences the manufacture of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a premanufacture notification (PMN) under § 5(a) of the Act to submit

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[1] 15 U.S.C. § 2615(a) provides, in pertinent part: "(1) Any person who violates a provision of section 2614 of this title shall be liable to the United States for a civil penalty in an amount not to exceed $25,000 for each violation."

[2] 15 U.S.C. § 2614 provides, in pertinent part: "It shall be unlawful for any person to ----

(1) fail or refuse to comply with . . . (C) any rule promulgated . . .under section . . .2604. . .of this title. . . ;

* * * * * * *

(3) fail or refuse to . . . (B) submit reports, notices, or other information, . . . as required by this chapter or a rule thereunder . . . ."

a notice of commencement (NOC) of manufacture or import to EPA on, or no later than thirty (30) calendar days after, the first day of such manufacture. Hercules allegedly submitted a PMN for a new chemical substance (Chemical A) and, following the 90-day review period, submitted an NOC. However, the complaint alleged Hercules did not actually manufacture Chemical A for a commercial purpose "during any period permitted under § 5(a)(1) of the Act by the time of the May 12, 1987 EPA inspection." As a result, the complaint concluded that Hercules' alleged conduct was in violation of 15 U.S.C. § 2614(1)(C) and 15 U.S.C. § 2614(3)(B) in that Hercules submitted a "false" NOC.

B. Proposed Penalty

For the alleged violation, EPA proposed a civil penalty of $25,000.

C. Respondent's Answer

By way of answer, Hercules admitted that it had submitted a PMN to EPA for the manufacture of Chemical A and that it subsequently submitted an NOC to EPA. However, Hercules denied that a false NOC was submitted. Instead, Respondent averred that the initial manufacture of Chemical A had occurred pursuant to approval of a Test Market Exemption (TME). After the expiration of the TME and the 90-day review period following submission of the PMN, Respondent alleged that it received a commercial order for Chemical A which was filled from remaining excess TME inventory. Respondent maintained that it "interpreted the filling of this order with the remaining TME inventory as being the commencement of commercial

manufacture, thereby activating the Respondent's duty to file... [an NOC]." Respondent also claimed that further commercial manufacturing occurred in (CBI deleted) and (CBI deleted), after the filing of the NOC.

D. Processing of the Case

Respondent submitted a motion for accelerated decision dismissing the complaint on December 11, 1989. On January 19, 1990, Complainant submitted a motion for accelerated decision finding liability and in opposition to Respondent's motion for accelerated decision. On February 15, 1990, Respondent filed a reply in opposition to Complainant's motion. Both parties have filed memoranda in support of their respective motions and in opposition to each other's motion.

Under 40 C.F.R. § 22.20(a), the "Presiding Officer, upon motion of any party or sua sponte, may at any time render an accelerated decision in favor of the complainant or the respondent as to all or any part of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law, as to all or any part of the proceeding."

Respondent "avers . . . that the parties agree that no genuine issue of material fact exists." [3] Likewise, Complainant says "that

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[3] Respondent's "Motion for Accelerated Decision Dismissing the Complaint," (December 11, 1989) at 2.

no issue of material fact exists." [4] The parties have stipulated as to certain facts which are not in dispute.

II. Stipulation of Facts

The facts which the parties have stipulated may be assumed to be true for the purpose of this case are: [5]

> (1) On (CBI Deleted), a Test Market Exemption ("TME") was approved for a chemical, which for the purposes of the underlying TSCA Complaint shall be referenced to as "Chemical A". The TME expired on (CBI Deleted).
>
> (2) On (CBI Deleted), Hercules submitted a Premanufacturing Notice ("PMN") to EPA and on (CBI Deleted), the PMN review expired without incident for Chemical A. Subsequently Hercules was free to manufacture Chemical A for commercial purposes.
>
> (3) On (CBI Deleted), 5 gallons of Chemical A (produced in 1 gallon batches during the TME period, specifically, during (CBI Deleted)) were sold to a Hercules customer for unrestricted commercial use. Chemical A is used by the semiconductor industry, and Chemical A is presumed to have been processed for further distribution to commercial users and/or consumers.
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> (4) By letter dated (CBI Deleted), Hercules submitted notice to the EPA by reporting "commencement of manufacture" regarding Chemical A.
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> (5) Hercules' Notification of Commencement of Manufacture was received by EPA and Chemical A was included in the list of chemical substances maintained by EPA pursuant to Section 8 of TSCA, 15 U.S.C. § 2607(b)(1), (the "Inventory").

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[4] Complainant's "Motion for an Accelerated Decision," (January 19, 1990).

[5] Respondent's "Memorandum in Support of Respondent's Motion for Accelerated Decision Dismissing the Complaint," (December 11, 1989) at 4-6; Complainant's "Memorandum in Support of Complainant's Motion for Accelerated Decision Finding Liability and in Opposition of Respondent's Motion for Accelerated Decision," (January 19, 1990) at 1-3.

(6) The first post-PMN commercial batch of Chemical A was produced in (CBI Deleted). Thereafter, quantities of Chemical A were produced by Hercules and distributed into commerce.

(7) On May 12, 1987, the EPA conducted an inspection of Hercules corporate facility to determine compliance with TSCA Sections 5 and 8.

(8) On October 21, 1987, Hercules received the written report from EPA memorializing the inspection conducted in May, 1987.

(9) A complaint was filed by EPA on June 28, 1989, against Hercules, alleging violations of TSCA Section 5.

In addition, on April 3, 1990, the parties submitted copies of five (5) documents which counsels for both parties have stipulated as being authentic and accurate. These documents are:

1. Hercules' Notice of Commencement of Manufacture for Chemical A.
2. Hercules' Run Summary and Cumulative Product Inventory for Chemical A.
3. Hercules' Interoffice Memo of Chemical A Samples Shipping List.
4. Hercules' summary of Chemical A production and shipping.
5. Hercules' Sales Invoice for sale of Chemical A to (CBI deleted).

III. Discussion and Conclusions

A. Introduction

The basic issue in this case is whether, as alleged by Complainant, Respondent "submitted a false NOC" for Chemical A in violation of 40 C.F.R. § 720.102 because "Respondent did not actually manufacture . . . [Chemical A] for a commercial purpose

during any period permitted under § 5(a)(1) of the Act [15 U.S.C. § 2604(a)(1)] by the time of the May 12, 1987 EPA inspection," thereby violating 15 U.S.C. § 2614(1)(C) and (3)(B).

Hercules initially manufactured Chemical A under one of the statutory exemptions to the PMN requirement, specifically the TME. [6] Prior to the expiration of the TME, Hercules submitted a PMN for Chemical A and properly observed the 90-day review period. The PMN review expired without incident for Chemical A. Thereafter, Hercules was free to manufacture Chemical A for commercial purposes. Later that same year, after the TME had expired, Hercules received a commercial order for 5 gallons of Chemical A which it filled by shipping some surplus product which had been manufactured under the TME. This batch of Chemical A was sold for unrestricted commercial use. Chemical A is used by the semiconductor industry, and Chemical A is presumed to have been processed for further

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[6] Section 5(h)(1) of TSCA, 15 U.S.C. § 2604(h)(1) provides:

> The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) of this section to permit such person to manufacture or process a chemical substance for test marketing purposes----
>
> (A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and
>
> (B) under such restrictions as the Administrator considers appropriate.

distribution to commercial users and/or consumers. Hercules filed with EPA an NOC within 30-days of this commercial distribution of the surplus TME product. Chemical A was included in the list of chemical substances maintained by EPA pursuant to § 8 of TSCA, 15 U.S.C. § 2607(b)(1), (the Inventory). Just over four (4) months after filing the NOC, Hercules commenced the first post-PMN commercial manufacture of Chemical A. Thereafter, quantities of Chemical A were produced by Hercules and distributed into commerce.

Thus, the issue in this case comes down to whether Hercules properly filed an NOC when it made a commercial shipment of Chemical A which had been manufactured for an exempt purpose or whether Hercules should have waited to file the NOC until it manufactured the first post-PMN quantity of Chemical A a little more than four (4) months after that initial commercial shipment. As EPA views the issue, by filing an NOC and failing, "during any period permitted under § 5(a)(1) of the Act" to manufacture commercially an additional amount of Chemical A, Hercules is guilty of having submitted a "false" NOC. As Hercules views the issue, by filing the NOC, "Hercules was using its best efforts to comply with regulations that clearly did not, and still do not, address the situation" facing Hercules, namely, the commercial sale and distribution of a surplus TME quantity of a chemical after the expiration of the PMN period for that chemical. Further, Hercules contends that its actions promoted the purposes of TSCA and afforded EPA the opportunity to take whatever actions were

necessary to protect human health and the environment before commercial manufacture began.

B. Application of Statutory and Regulatory Provisions

Under § 5 of TSCA, 15 U.S.C. § 2604, any person who intends to manufacture a new chemical substance for commercial purposes in the United States must submit a notice to EPA at least ninety (90) days before that person commences manufacture. At the end of the notification period, the person may manufacture the substance unless EPA has taken regulatory action under § 5(e) or § 5(f) to ban or otherwise regulate the substance.

There are certain exceptions to the § 5(a) PMN requirement. Section 5(h) provides an exemption for chemical substances manufactured for test marketing purposes upon a showing to the Administrator of EPA that it will not present any unreasonable risk of injury to health or the environment and under such restrictions as the Administrator considers appropriate. [7]

Under § 8(b) of TSCA, the Administrator of EPA is required to compile and maintain a current, published Inventory of each chemical substance which is manufactured or processed in the United States. In the case of a chemical substance for which a PMN is submitted under § 5, that chemical substance must be included in the Inventory as of the earliest date (as determined by the Administrator) on which it was manufactured or processed in the United States. After EPA adds the substance to the Inventory, any

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[7] Supra, n. 6.

person may produce the substance without giving notice to EPA under § 5(a)(1)(A) of TSCA.

On January 10, 1979, EPA published a proposed rule for reporting the commencement of manufacture which provided, in pertinent part:

> § 720.52 Notice of commencement of manufacture or import.
>
> (a) Applicability. Any person who commences to manufacture or import for a non-exempt commercial purpose a new chemical substance for which the person previously submitted a premanufacture notice under this Part shall submit the notice prescribed by this section.
>
> (b) When to report. The person must submit the notice to EPA no later than the day the person first manufactures or imports the substance for a non-exempt commercial purpose.[8]

In that same proposed regulation, "manufacture or import for a non-exempt commercial purpose" was defined to mean "to manufacture or import for any commercial purpose for which a person would be required to submit a premanufacture notice. Specifically, the term excludes any manufacture or importation . . . [f]or test marketing purposes, under restrictions imposed by EPA in conjunction with an exemption granted . . . ." [9] Therefore, under the rules as proposed in early 1979, an NOC was not required when a person commenced to manufacture a new chemical substance for

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[8] 44. F.R. 2278 (January 10, 1979).

[9] Id. at 2265.

test marketing purposes because such manufacture was for an exempt purpose.

On May 15, 1979, EPA published a Statement of Interim Policy on the premanufacture notification requirements under § 5 of TSCA [10] wherein it also set forth an interim policy for the implementation of § 8(b) of TSCA. The interim NOC policy provided, in pertinent part, that "[a]ny person who submits a notice under this interim policy, and who begins to manufacture or import the new substance for commercial purposes, must submit a notice of this fact to EPA on or about the date when manufacture or import commences so that the Agency can add the substance to the Inventory. At a minimum, this notice must include the identity of the substance; the premanufacture document number which the Agency previously assigned to the substance in the § 5(d)(2) Federal Register notice; and the date upon which manufacture or import commences. There is no requirement that the notice be submitted in any particular form. It should be addressed to the Document Control Officer, Office of Toxic Substances, at the address indicated above." [11] There are two pertinent differences between the interim policy for NOC's and the previously proposed regulation. First, the term "non-exempt" was not used in the interim policy statement; therefore, an NOC was required whenever a person began to manufacture a new chemical substance for commercial purposes.

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[10] 44 F.R. 28564 (May 15, 1979).

[11] Id. at 28567.

There was no specific exclusion of exempt commercial purposes, such as test marketing purposes, in the Interim Policy Statement. Second, the time for the submission of the NOC under the interim policy was "on or about the date" manufacture commenced rather than "no later than" that date.

On November 7, 1980, EPA published a Statement of Revised Interim Policy on the premanufacture notification requirements under § 5 of TSCA. [12] It said, in pertinent part, that "[p]rovisions of the May 15 notice which are not addressed in this statement will remain in effect as published on May 15, until the final rules are promulgated." [13] Since the interim NOC policy announced on May 15 was not addressed, it remained in effect. The November revision also acknowledged that "EPA cannot require compliance with the proposed rulemaking before the completion of rulemaking." [14]

On May 13, 1983, EPA published the "final" rule for the PMN requirements and procedures under § 5 of TSCA. [15] Its effective date was announced as July 12, 1983. [16] Section 720.52 of the

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12 45 F.R. 74378.

13 Id.

14 Id.

15 48 F.R. 21722 (May 13, 1983).

16 Id.

proposed regulations was renumbered 720.102 in the "final" rule and revised, in pertinent part, as follows:

> § 720.102 Notice of commencement of manufacture or import.
>
> (a) Applicability. Any person who commences to manufacture or import a new chemical substance for a commercial purpose for which that person previously submitted a section 5 notice under this Part must submit a notice of commencement of manufacture or import.
>
> (b) When to report. (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on the first day of such manufacture or import. [17]

Unlike the proposed rule which had been published some four (4) years and four (4) months before, the new "final" rule did not use the term "non-exempt." Instead, it referred to manufacture "for a commercial purpose" without any specific exemption or exclusion. Hence, in this regard, it reflected the interim policy statement of May 15, 1979.

On July 11, 1983, EPA published a notice postponing the effective date of the final rule from July 12, 1983 to September 10, 1983. [18] On September 6, 1983, EPA further postponed the effective date of the final rule to October 26, 1983 (with the exception of certain sections, not pertinent here, for which the

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[17] Id. at 21753.

[18] 48 F.R. 31641 (July 11, 1983).

effective date was stayed). [19] At the same time, EPA announced a "nonsubstantive amendment" of § 720.102(b)(1) concerning the timing of the submission of the NOC for commercial production begun after the effective date of the rule. [20] It was revised to read: "If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days after, the first day of such manufacture or import." Thus, where the manufacture of a chemical substance for commercial purposes began on or after October 26, 1983, the NOC was to be submitted no later than 30 days after manufacture began rather than "on the first day" such manufacture began.

In the supplementary information to this amendment of § 720.102(b)(1), EPA explained a purpose of the NOC requirement. "[I]t is important that new chemical substances be entered on the TSCA Inventory promptly after the first commercial manufacture... so that subsequent manufacturers can know that they are not subject to PMN requirements and to prevent unnecessary EPA review of duplicative PMN's . . . ." [21]

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[19] 48 F.R. 41132 (September 13, 1983).

[20] Id. at 41140.

[21] Id.

On October 26, 1983, 40 C.F.R. § 720.102 became effective. [22] It provided, in pertinent part:

> § 720.102 Notice of commencement of manufacture or import.
>
> (a) Applicability. Any person who commences to manufacture or import a new chemical substance for a commercial purpose for which that person previously submitted a section 5 notice under this Part must submit a notice of commemcement of manufacture or import.
>
> (b) When to report. (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture or import.
>
> (2) If manufacture or import for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.

Thus, the "final" version of § 720.102 drew no distinction between exempt and nonexempt commercial manufacture of chemical substances.

Moreover, under the definition of "manufacture or import for commercial purposes" new chemical substances which had been manufactured under the TME could be considered as having been manufactured for commercial purposes. "Manufacture or import for commercial purposes" was defined in the "final" rule as meaning to

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[22] Id. at 41132.

"produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer . . . and includes, among other things, 'manufacture' of any amount of a chemical substance or mixture . . . [f]or commercial distribution, including for test marketing . . . ." [23]

On (CBI Deleted) Hercules submitted a TME for Chemical A and on (CBI Deleted) the TME was approved. Thereafter, Hercules began to manufacture Chemical A "for commercial purposes," in this case, "for test marketing." This initial production was, of course, exempt from the PMN requirements [24] and, hence, exempt from the NOC requirements, [25] because it was produced and distributed under a TME. In other words, even though Chemical A was being manufactured for commercial purposes, as that phrase had been defined in the regulation, the NOC requirement did not apply because Hercules had a TME where the production was for the limited purpose of test marketing.

On (CBI Deleted) Hercules submitted a PMN pursuant to § 5(a) of the Act. It is clear from the legislative history of TSCA that the § 5 PMN requirements were probably the most important and significant feature of the Act. Section 5 provides " a mechanism to insure that that information with respect to health and environmental effects of chemicals can be collected from manufacturers

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[23] 48 F.R. 21744.

[24] See supra, p. 10.

[25] See infra, p. 27.

and processors of chemical substances prior to manufacture." [26] The "premarket notification for new chemical substances . . . is probably the most important provision of the act, for it will enable us to limit chemical threats before they become manifest, not after." [27] "[T]hrough its testing and premarket notification provisions, the bill provides for the evaluation of the hazard-causing potential of new chemicals before commercial production begins." [28] Finally, the conferees recognized "that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins." [29]

When Hercules filed a PMN for Chemical A pursuant to the statute, EPA was properly afforded the opportunity to evaluate the "hazard-causing potential" of Chemical A and to take action to

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[26] Senate Consideration of S. 3149 [Excerpt from the Congressional Record, Mar. 26, 1976, Senate, pp. S4397-S4432] reprinted in Legislative History of the Toxic Substances Control Act . . . Prepared by the . . . Library of Congress for the House Comm. on Interstate and Foreign Commerce, 207-208 (Comm. Print 1976).

[27] Id. at 216.

[28] H.R. Rep. No. 1341, 94th Cong., 2d Sess. 1, reprinted in Legislative History of the Toxic Substances Control Act . . . Prepared by the . . . Library of Congress for the House Comm. on Interstate and Foreign Commerce, 409 (Comm. Print 1976).

[29] H.R. Rep. No. 94-1679, 94th Cong. 2d Sess. 65-66, reprinted in Legislative History of the Toxic Substances Control Act . . . Prepared by the . . . Library of Congress for the House Comm. on Interstate and Foreign Commerce, 678-679 (Comm. Print 1976).

protect human health and the environment against any potential adverse effects before commercial production began. As the parties stipulated, Hercules filed a PMN for Chemical A and the 90-day review period "expired without incident." After the expiration of the review period, Hercules was free to manufacture Chemical A for "full-scale commercial production" [30] as distinguished from commercial manufacture for "test marketing activity" [31] because EPA had taken no regulatory action to ban or otherwise regulate the substance and no Federal court had banned production. Thus, the reporting and notice requirements of § 5 of TSCA, which are designed to provide EPA with early warning so that the potential for harm can be prevented, were fully met by Hercules.

On (CBI deleted) Hercules received a commercial order for 5 gallons of Chemical A. Hercules filled the order from an excess quantity of Chemical A which had been produced during the now-expired TME period. This shipment of Chemical A was made by Hercules for unrestricted commercial use by the purchaser. Chemical A is used by the semiconductor industry and Chemical A is presumed to have been processed for further distribution to commercial users and/or consumers.

The issue which must be resolved in this case first manifested itself to Hercules at this time. Having now sold commercially a quantity of the excess Chemical A for nontest

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[30] See 40 C.F.R. § 720.38(b)(5) for the source of the term.

[31] Id.

marketing purposes, i.e., for unrestricted commercial use, including presumably, processing for further distribution, should Hercules file an NOC within 30-days thereafter?

In an overabundance of caution, to insure that it was not acting without full notice to EPA, Hercules filed an NOC within thirty (30) days of the sale of Chemical A for nonexempt purposes. The TME had previously expired on (CBI deleted). The quantity of Chemical A being shipped for unrestricted commercial use had been "manufactured for commercial purposes" as that phrase was defined in the EPA regulations. Section 720.102 required the submission of an NOC whenever a new chemical substance was being manufactured for a commercial purpose and a PMN had previously been submitted. The distinction between exempt and nonexempt manufacture had been dropped from the regulation. Moreover, § 8(b)(1) of TSCA requires the Administrator to maintain an Inventory of each chemical substance which is manufactured or processed in the United States. Hercules' sale to a customer was for unrestricted commercial use, presumably to be processed for further distribution to commercial users and/or consumers. Since processors had no duty to file a notice of introduction of the chemical substance into commerce, [32] the requirements of the statute would be met in that, without the NOC, Hercules' customer could have processed Chemical A for nonexempt commercial purposes without Chemical A having been added to the Inventory. Nevertheless, EPA would have me now conclude

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[32] 48 F.R. 21727 (May 13, 1983).

that Hercules filed a "false" NOC because it did not begin "full scale commercial production" of Chemical A within "any period permitted under § 5(a)(1) of the Act."

On April 22, 1986, EPA published a final rule revising certain provisions in Part 720, including "a non-substantive amendment to § 720.102(a) to further clarify the timing of submission of the notification of commencement of manufacture."[33]

In order to reflect this clarification § 720.102(a) was revised as follows:

> (a) Applicability. Any person who commences the manufacture or import of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice under this Part must submit a notice of commencement of manufacture or import.

Thus, to clarify the NOC requirement, EPA revised § 720.102(a) by returning to the "exempt/non-exempt" commercial purpose concept and reinserting the qualifying adjective "non-exempt" which term had been used in the proposed regulation in 1979 [34] but which had been dropped from the interim policy statement [35] and from the "final" regulation. [36] While the preamble to this final rule explained this clarification, revision

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[33] 51 F.R. 15096 (April 22, 1986).

[34] Supra at pp. 11-12.

[35] Supra at pp. 12-13.

[36] Supra at pp. 13-14.

and amendment primarily within the context of the R&D exemption, the language of the revision, amendment and clarification is clearly not limited to situations where the manufacturer intends to begin nonexempt commercial activities with quantities of the new chemical substance previously produced for purposes of R&D. The langauge of the revision, amendment and clarification is not cast in terms of any particular exemption to the PMN requirement. Instead, it is cast in general terms and "requires persons to submit a notification of commencement of manufacture within thirty (30) days of the start of non-exempt commercial manufacture of a new substance" thereby impliedly excluding all exempt forms of commercial manufacture.

On June 28, 1989, EPA filed the complaint herein against Hercules for allegedly violating, in (CBI deleted), 40 C.F.R. § 720.102, as that regulation subsequently had been clarified, revised and amended by EPA on April 22, 1986. Thus, Complainant would hold Respondent liable for having filed a "false" NOC when neither the Respondent nor the public-at-large had notice of the appropriate timing for filing an NOC in the special and particular circumstances of this case until the revision, amendment and clarification were published after the filing of the NOC in April 1986. The special and particular circumstances to which I refer are those in which the manufacturer intends to begin commercial sale of a new chemical substance with excess quantities previously produced for exempt purposes and the manufacturer intends to commence nonexempt commercial manufacture sometime later. EPA's

requirement that the NOC should be filed in such special circumstances only after the start of nonexempt commercial manufacture and not when the manufacturer initially begins the unrestricted commercial sale of the excess exempt product was reflected in the 1986 clarification/revision/amendment which reintroduced the exempt/nonexempt dichotomy.

In other words, EPA would now hold Respondent liable for misinterpreting a regulation in (CBI deleted), which regulation later proved so incomplete, unclear and ambiguous that EPA itself issued a clarification, revision and amendment in 1986. Moreover, the clarification, revision and amendment were issued by EPA to address factual situations posed in cases similar to this case.

The retrospective application of the 1986 revision and clarification of § 720.102(a) cannot be justified simply because EPA called the 1986 revision "a non-substantive amendment." Legal questions cannot be decided on the basis of labels which a party elects to use to describe its actions. EPA issued an "amendment," i.e., it "revised" § 720.102(a) to "clarify" the timing of submission of an NOC. Electing to call the amendment "non-substantive," or to call the revision a technical revision, does not answer the question of whether § 720.102(a), as amended, revised and clarified, should be applied retroactively to Hercules in the circumstances of this case.

Where retroactivity is used to describe a rule which alters the <u>past</u> legal consequences of <u>past</u> actions (as opposed to a rule with exclusively future legal effect which nevertheless can affect

past transactions - sometimes described as "secondary retroactivity"), the Supreme Court has ruled in the Bowen case:

> It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress . . . .
>
> Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result . . . . By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms . . . . Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant. [37]

Section 8 of TSCA, 15 U.S.C. § 2607, which establishes the Administrator's power to promulgate rules regarding the reporting and retention of information, contains no express authorization of retroactive rulemaking. Thus, there is no statutory authority to promulgate rules pertaining to the establishment and maintenance of the Inventory which would alter the past legal consequences of past actions by Respondent here. Therefore, § 720.102(a), as clarified, revised and amended in 1986, cannot alter the past legal consequences of actions taken by Respondent in filing an NOC prior to that time. To the extent that Complainant now would apply this

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[37] Bowen v. Georgetown University Hospital, 488 U.S. ___, 102 L.Ed. 2d 493, 499-500 (1988). For a discussion of the distinction between retroactivity and "secondary retroactivity" see the concurring opinion of Justice Scalia at 507.

provision not merely to affect past actions by Respondent but to change what the rule was in the past, such application would be contrary to the holding of the Supreme Court.

As noted, however, EPA described the clarification, revision and amendment of § 720.102(a) as "a non-substantive amendment." This appellation may have been intended as a signal that, because the amendment was not considered to be a substantive change in the rule, it did not constitute a change in past law. If the rule itself is considered unchanged, its retroactive application to Respondent would constitute "secondary retroactivity" by affecting only the consequences of Respondent's past actions. As Justice Scalia pointed out in his concurring opinion in Bowen, "[i]n reference to such situations, [of "secondary retroactivity"] there are to be found in many cases statements to the effect that '[w]here a rule has retroactive effects, it may nonetheless be sustained in spite of such retroactivity if it is reasonable.'"[38]

In sum, if one views the 1986 clarification, revision and amendment of § 720.102(a) as a change in past law, its application to Respondent in the circumstances of this case could be considered to constitute impermissible retroactivity in the sense of altering the past legal consequences of past actions. In the alternative, if one considers the 1986 clarification, revision and amendment of § 720.102(a) as a non-substantive change in the rule, its retroactive application to Respondent must be viewed as merely affecting

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[38] Id. at 507.

Respondent's past actions and not as constituting a change in past law. This alternative would require the traditional analysis to which Justice Scalia refers and which is applied in cases of "secondary retroactivity."

To determine whether the retroactive application of the 1986 amendment, revision and clarification of § 720.102 to Respondent is reasonable under this alternative analysis, I must balance the public interests and statutory ends to be achieved with the effects of retroactive application on the Respondent.

The requirement that the manufacturer must submit an NOC is not a specific requirement of TSCA itself but of the EPA regulations issued pursuant to § 8(a) to assist the Administrator in meeting his duty under § 8(b) of the Act to establish and maintain the Inventory. Hence, the 1986 amendment, revision and clarification did not constitute an interpretation of a statutory requirement as such. Instead, it reflected a change in the impact on past actions of the rules previously published by the Agency to impose the NOC reporting requirement on manufacturers.

The retrospective application of newly adopted administrative rules or interpretations of agency regulations is not, per se, unlawful in such circumstances. [39]

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[39] Pasadena Hospital Ass'n, Ltd. v. U.S., 618 F.2d 728, 735 (U.S. Ct. Cl. 1980); E.L. Wiegand Division v. N.L.R.B., 650 F.2d 463, 471 (3rd Cir. 1981), cert. denied, 455 U.S. 939 (1982).

However, such retroactive measures, whether promulgated by a legislature or an administrative agency, have traditionally been subjected to stricter scrutiny than have prospective measures. [40]

Generally speaking, such retrospective application of agency rules, like retroactive statutes, will be valid if reasonable, but invalid if the retrospective application is unreasonable in the circumstances. [41]

Retroactive application of an administrative promulgation is deemed unreasonable when the ill effects of retroactive application outweigh the need of such application, or when the hardship on affected parties will outweigh the public ends to be achieved.[42]

In determining whether the retrospective application of an administrative promulgation is reasonable, consideration must be given to such factors as whether such application will result in manifest injustice to a party, [43] whether the party had fair notice of the retroactive application of an interpretation, [44] whether the party's conduct would have differed if the rule in

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[40] Daughters of Miriam Center for the Aged v. Mathews, 590 F.2d 1250, 1259 (3rd Cir. 1978).

[41] Pennzoil Co. v. U.S. Dept. of Energy, 680 F.2d 156, 175 (Temp. Em. App. 1982), cert. dismissed, 459 U.S. 1190 (1983); K. Davis, Administrative Law Treatise, § 7:23, at 109 (2nd ed. 1979).

[42] Iowa Power and Light Co. v. Burlington Northern, Inc., 647 F.2d 796, 812 (8th Cir. 1981), cert. denied, Burlington Northern, Inc. v. U.S., 455 U.S. 907 (1982).

[43] Saint Francis Memorial Hospital v. Weinberger, 413 F. Supp. 323, 332-33 (N.D. Cal. 1976).

[44] Pennzoil Co. v. U.S. Dept. of Energy, 680 F.2d at 173.

issue had applied from the start, [45] or whether retroactive application will avoid a result which is contrary to statutory design or to legal and equitable principles. [46]

Hercules filed a PMN for Chemical A thereby properly affording EPA the opportunity under TSCA and Part 720 of the Rules to evaluate the hazard-causing potential of Chemical A and to take any necessary action to protect human health and the environment against any potential adverse effects before commercial production began. Thus, the reporting and notice requirements of § 5 of TSCA, as implemented in Part 720, which are designed to provide EPA with early warning so that the potential for harm can be prevented, were fully met by Hercules. [47]

Turning next to the maintenance of the Inventory by EPA under § 8 of TSCA, even though Hercules' timing in submitting the NOC was not in accord with EPA's 1986 revised, amended and clarified regulation, a primary purpose of the NOC requirement was met by Hercules' submission. That is, subsequent manufacturers had notice through the listing of Chemical A on the Inventory that the PMN requirements for Chemical A had been met and therefore duplicative PMN submissions and review by EPA were not required. [48]

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[45] Daughters of Miriam Center for the Aged v. Mathews, 590 F.2d at 1262.

[46] E.L. Weigand Division v. N.L.R.B., 650 F.2d at 471.

[47] Supra, pp. 17-19.

[48] Supra, p. 15.

However, Complainant asserts that such notification to other potential manufacturers or importers of the same chemical is not a primary purpose of the NOC requirement. Complainant argues that the essential focus of the statute is upon the actual manufacture of a new chemical substance. Complainant maintains that the "submission of an NOC without actual manufacture commencing may result in the processing, distribution, or use of a new chemical substance in the United States by other persons, under other circumstances, which may result in unanticipated harm to human health or the environment."

This argument must be rejected because it is not consistent with the regulatory scheme which EPA has put in place to implement the PMN and NOC requirements and because it is not consistent with the explanation of those procedures which EPA published in the preamble to the final rule on September 13, 1983.

Under § 720.102(a) of the EPA regulations, only those persons who have previously submitted a PMN for a new chemical substance must file an NOC. Under § 720.22(a)(1) any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a PMN. A new chemical substance is defined in § 3(9) of the Act, 15 U.S.C. § 2602(9)," as any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) . . . ." Thus, 40 C.F.R. § 720.25(a) states that a new chemical substance is a chemical that is not on the Inventory. Therefore, only where a chemical is <u>not</u> on the Inventory must a potential manufacturer

submit a PMN and subsequently, an NOC. If the chemical is on the Inventory, there is no requirement that any subsequent manufacturer file a PMN or an NOC even where there is a potential that the new manufacturer may process, distribute or use the same chemical substance, "under other circumstances, which may result in unanticipated harm to human health or the environment." Were there some validity to Complainant's argument as to the primary purpose of §§ 5 and 8 of TSCA, I am certain that EPA would have made provision for additional PMN reviews and/or additional NOC's of a chemical already on the Inventory whenever subsequent manufacturers would produce, process or use the chemical "under other circumstances, which may result in unanticipated harm to human health or the environment." But, EPA did not establish such a requirement. The regulatory scheme requires only one PMN, and hence, only one NOC, regardless of the circumstances of manufacture. Once a chemical is on the Inventory, subsequent manufacturers are not limited to manufacturing the chemical under the same circumstances as those under which the initial manufacturer operates. As noted previously, [49] EPA said in the preamble to the September 13, 1983 rules, "it is important that new chemical substances be entered on the TSCA Inventory promptly after first commercial manufacture (so that subsequent manufacturers can know they are not subject to PMN requirements and to prevent unnecessary EPA review of duplicative PMN's) . . . ." For these reasons I must reject Complainant's

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[49] Supra, p. 15.

contentions that this is not a primary purpose of the NOC requirement.

I conclude that the purposes and design of TSCA will not be undermined by a decision not to apply the 1986 amendment, revision and clarification of 40 C.F.R. § 720.102(a) retroactively to Respondent in the circumstances of this case.

When the Final Rule which revised, amended and clarified § 720.102(a) was published in the Federal Register on April 22, 1986, it contained no notice that § 720.102(a), as so revised, amended and clarified, would be applied retroactively. The first notice that Respondent received of such retroactive application was the receipt of the complaint in this proceeding in June 1989.

Moreover, at the time Respondent filled this commercial order from the excess TME material in (CBI deleted), it clearly had no notice of EPA's revised, amended and clarified § 720.102(a) requirement which was published on April 22, 1986. Hence, it was not unreasonable that Hercules, in the exercise of considerable care, submitted an NOC when it began the unrestricted commercial sale of Chemical A.

Finally, Hercules' submission of the NOC, was consistent with a reasonable reading of the final rule published on October 26, 1983, as well as with § 8(b)(1) of TSCA. As EPA itself contends, "the importance of the Inventory's integrity stems from one of its

purposes being the compilation of all chemical substances manufactured or imported for commercial purposes in the United States."[50] Here Chemical A, which had been manufactured initially for an exempt purpose, was being distributed now for commercial purposes and ostensibly, for processing for further distribution to commercial users or customers. Clearly, as Respondent contends, its NOC filing alerted EPA, and the public, that Chemical A was now in commerce. This action, in and of itself, could not result in unanticipated harm to human health or the environment. Instead, it insured that the Inventory would include a chemical substance which was being commerically distributed for processing in the United States. As noted previously, § 8(b)(1) of TSCA requires the Administrator to maintain an Inventory of each chemical substance which is manufactured or processed in the United States. [51]

Complainant contends that Hercules shipped several free samples of the excess TME material to other potential customers after the TME and PMN had expired but before the NOC was filed. Hercules concedes that "[t]his fact is true." [52] Complainant contends that the "only apparent difference in the shipment of

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[50] Complainant's "Memorandum in Support of Complainant's Motion for Accelerated Decision Finding Liability and in Opposition of Respondent's Motion for Accelerated Decision" (January 19, 1990) at 1-3.

[51] Supra, p. 20.

[52] Respondent's "Reply Memorandum in Opposition to Complainant's Motion for Accelerated Decision Finding Liability and In Support of Respondent's Motion for An Accelerated Decision Dismissing the Complaint," (February 15, 1990) at 4.

Chemical A which prompted the filing of the NOC and the other earlier eight post-PMN shipments was that Hercules charged this customer for this sample." EPA argues that there is "no legal, equitable or environmental reason" which would support the defense that an NOC was appropriate only after the first post-PMN shipment of Chemical A for which payment was received.

In response, Hercules states that these shipments were distributed and intended for research and development purposes as opposed to distribution for commercial purposes. Hercules further argues that nothing in the regulations, now or at the time of the shipments, prohibited Hercules from distributing Chemical A, manufactured as exempt under a TME, to customers for research and development purposes after the TME expired. EPA does not refute Hercules' position and I find no basis to do so.

At the time of the submission of the NOC, Hercules clearly did not have the benefit of hindsight subsequently provided by the 1986 revision, amendment and clarification of the 1983 final rule. To hold Hercules liable in these circumstances for filing a "false" NOC, and to impose a monetary penalty for that filing through the retroactive application of a rule which EPA itself recognized was in need of clarification, revision and amendment some time after Hercules' action would impose a hardship on Hercules which is unreasonable and amounts to a manifest injustice. I conclude that the ill effects of such retroactive application and the hardship imposed on Hercules outweigh whatever public ends could conceivably be served by finding that Hercules filed a "false" NOC and violated

TSCA by submitting the NOC within thirty (30) days of the unrestricted commercial sale of excess TME material rather than submitting the NOC some four (4) months later when the first post-PMN nonexempt commercial production actually began.[53]

Accordingly, the question of the applicability of 40 C.F.R. § 270.102(a) having been resolved in Respondent's favor, Respondent is entitled to a judgment as a matter of law pursuant to 40 C.F.R. § 22.20.

ORDER

It is hereby ordered that the complaint be, and it is hereby, DISMISSED. [54]

Henry B. Frazier, III
Chief Administrative Law Judge

Dated: April 26, 1990
Washington, D.C.

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[53] See In the Matter of B.F. Goodrich Company, TSCA-89-H-07, Initial Decision (Sept. 14, 1989).

[54] Pursuant to 40 C.F.R. § 22.27(c), this accelerated decision shall become the final order of the Administrator within forty-five (45) days after the service upon the parties unless an appeal to the Administrator is taken by a party or the Administrator elects to review the accelerated decision upon his own motion. 40 C.F.R. § 22.30 sets forth the procedures for appeal from this accelerated decision.