9/14/89

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

9/14/89 A9:02

IN THE MATTER OF	)	
	)	
B.F. GOODRICH COMPANY,	)	Docket No. TSCA-89-H-07
	)	
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 referred to as Chemical A. The complaint which contains the CBI material is filed with the Headquarters 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	)	
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B.F. GOODRICH COMPANY,	)	Docket No. TSCA-89-H-07
	)	
Respondent	)	

TSCA; PREMANUFACTURE NOTIFICATION: NOTICE OF COMMENCEMENT (NOC) OF MANUFACTURE:

The notification requirements for the commencement of manufacture 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 1983 sold, for commercial processing, a surplus quantity of a new chemical substance which had been manufactured for "exempt" research and development (R&D) purposes and who filed an NOC within thirty (30) days after the sale but did not file a second NOC after the first "non-exempt" commercial production began in 1984.

APPEARANCES:

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BEFORE: Henry B. Frazier, III
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 March 16, 1989 by the United States Environmental Protection Agency ("EPA" or "Complainant" or "Agency"), under Section 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 Section 15 of the Act, 15 U.S.C. § 2614.[2/] The violations of Section 15 alleged in the complaint were violations of rules promulgated under Section 8, 15 U.S.C. § 2607. More specifically, the complaint alleged that the B.F. Goodrich Company ("Respondent" or "BFG") had violated the rule in 40 C.F.R. § 720.102 requiring any person who commences the manufacture or import of a new chemical substance for a nonexempt

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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 such 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...."

commercial purpose to submit a notice of commencement of manufacture or import to EPA on, or no later than thirty (30) calendar days after, the first day of such manufacture or import. As a result, the complaint concluded that BFG's alleged conduct was in violation of 15 U.S.C. § 2614(1)(C) and 15 U.S.C. § 2614(3)(B).

B. Proposed Penalty

For the alleged violation, EPA proposed a civil penalty of $10,000.00.

C. Stipulation of Facts

Subsequent to the filing of the complaint and answer, the parties "stipulated that the following facts may be assumed by either party to be true for the purpose of this case":[3/]

1. Between November 11 and November 27, 1982, BFG manufactured eight charges of a chemical which, for the purposes of this action, is referred to as "Chemical A." One of those charges, designated Lot No. K6, met commercial quality standards. All eight charges were manufactured pursuant to the "research and development" exemption of TSCA, and the material was packaged and warehoused.

2. In March, 1983, BFG filed a premanufacture notification (PMN) for Chemical A. The 90-day review period was observed pro-

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3/ Letter from B.F. Goodrich to Hearing Clerk (June 30, 1989); Letter from EPA to Presiding Officer (July 7, 1989).

perly and expired before the end of June 1983, subsequent to which BFG was free to manufacture Chemical A for commercial purposes.

3. On July 27, 1983, 350 pounds of Chemical A (produced as Lot No. K6 in November 1982) were sold to a BFG customer for unrestricted commercial use. Chemical A is used in the manufacture of textile printing ink and presumably Chemical A was processed for further distribution to commercial users and/or customers.

4. By letter, dated August 17, 1983, BFG submitted a notice to the EPA reporting "commencement of manufacture" regarding Chemical A and stating that "[t]he first commercial shipment occurred on July 27, 1983."

5. BFG's "notification of commencement of manufacture" (NOC) was received by the EPA and the chemical was included on the list of chemical substances maintained by EPA pursuant to Section 8 of TSCA, 15 U.S.C. § 2607(b)(1), (the "Inventory").

6. The first post-PMN commercial batch of Chemical A was produced in August 1984. Thereafter, substantial quantities of Chemical A were produced by BFG and distributed in commerce.

7. In October 1987, the EPA conducted an inspection at BFG's Calvert City, Kentucky facility to determine compliance with TSCA Section 5 and 8 requirements.

8. Pursuant to an EPA request, BFG sent EPA a letter, dated October 20, 1987, setting forth the facts concerning the development and production of Chemical A, designated therein as Carbopol® 1030.

D. Respondent's Answer

In its answer, BFG contends that the facts do not constitute a violation of TSCA, that the amount of the penalty proposed is inappropriate and excessive and that Respondent is entitled to judgment as a matter of law.

In further answer as to its liability in this matter, Respondent raises several affirmative defenses, namely that:

- Respondent's sale and shipment of lot # K6 on or about July 27, 1983 was tantamount to the manufacture of a new batch of Chemical A and constituted commencement of manufacture for commercial purposes;

- Respondent's sale and distribution in commerce of Chemical A on July 27, 1983 constitutes the activity the "notice of commencement" regulation was designed to cover, and notification of such activity fulfilled the objectives and requirements of 40 C.F.R. § 720.102 and TSCA;

- The requirements of 40 C.F.R. § 720.102, as interpreted by EPA, are unlawful, arbitrary and capricious, and are contrary to the objectives of TSCA as applied to Respondent in the circumstances of this case in that BFG would be prohibited from notifying EPA when an R&D chemical is sent out for commercial processing;

- The complaint fails to state a claim on which relief can be granted because no regulation was in effect which made BFG's notice of commencement unlawful or untimely when filed, and

no provision of TSCA requires the filing of a notice of commencement or made BFG's filing unlawful; and

- The action is barred by the statute of limitations.

In addition, the Respondent raised certain additional defenses which bear primarily or exclusively on the question of the appropriateness of the penalty, namely:

- Respondent acted in a timely and good faith manner to comply with all requirements of the regulation;

- There was no harm or potential for harm from an alleged early notification of commencement of manufacture;

- EPA's proposed penalty is excessive and inappropriate and contrary to EPA's General TSCA Civil Penalty Policy, dated September 10, 1980;

- EPA's policy and procedure for assessing civil penalties against Respondent in this case deny Respondent due process of law and are contrary to the requirements of TSCA and the Administrative Procedure Act; and

- EPA cannot maintain its alleged claims against Respondent to the extent that the filing of the complaint and the proposed penalty are based upon unpublished and/or internal memoranda that were not the subject of formal rulemaking.

E. Background - Processing of the Case

On June 7, 1989, EPA filed a motion to strike all of Respondent's affirmative defenses and, in anticipation that the motion to strike would be granted, a motion for an accelerated

decision on all matters of liability. On July 12, 1989, BFG filed a cross-motion for an accelerated decision dismissing the complaint. Both sides have filed memoranda in support of their respective motions and in opposition to the other's motions.

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."

EPA states that "there are no facts in dispute in this case"[4/] because "the relevant facts have been agreed to"[5/] by the parties and "agrees that...an evidentiary hearing is not necessary since the parties agree to the facts as presented in B.F. Goodrich's Statement of the Case."[6/] Respondent agrees that

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4/ Complainant's "Motion for Accelerated Decision on all Matters of Liability," (June 7, 1989) at 1.

5/ Complainant's "Consolidated Memorandum in Support of Motion to Strike Affirmative Defenses and Motion for Accelerated Decision on All Matters of Liability," (June 7, 1989) at 6.

6/ Letter from EPA to Presiding Officer, (July 7, 1989).

"there are no material facts in dispute in this case"[7/] as "the parties have agreed by stipulation to the facts...."[8/]

The first question to be resolved under 40 C.F.R. § 22.20(a) and which I will consider is whether Respondent's motion to dismiss the complaint should be granted. In their submissions, the parties have elected to postpone extensive briefing on the substance of Respondent's affirmative defenses.[9/] ("If neither motion for an accelerated decision is granted, the parties intend to submit all issues on liability...by more extensive briefs....") If Respondent's motion should be granted, the complaint will be dismissed. If Respondent's motion should be denied, the Complainant's motion to strike all affirmative defenses next must be considered. If that motion should be granted, Complainant's motion for an accelerated decision would then be considered.

II. Respondent's Motion for Accelerated Decision Dismissing Complaint

A. Introduction.

The basic issue in this case is whether the Respondent

7/ Respondent's "Motion for Accelerated Decision Dismissing the Complaint," (July 7, 1989).

8/ Respondent's "Memorandum in Support of Respondent's Motion for Accelerated Decision and in Opposition to Complainant's Motion for Accelerated Decision and to Strike Affirmative Defenses," (July 7, 1989) at 10.

9/ Respondent has waived its defense that the action in this case is barred by the statute of limitations. Respondent's Letter to Hearing Clerk, (June 30, 1989).

met the requirement for filing a timely NOC for Chemical A.

During November 1982, BFG manufactured Chemical A under the research and development exemption[10/] to the PMN requirements. In March 1983, BFG filed a PMN and properly observed the 90-day review period. Thereafter, BFG was free to manufacture Chemical A for commercial purposes. On July 27, 1983, BFG sold 350 pounds of Chemical A which had been manufactured under the research and development exemption. An NOC was filed on August 17, 1983, within thirty (30) days after the sale. The first post-PMN commercial batch of Chemical A was produced in August 1984, approximately one year after the NOC was filed.

1. Complainant's Contentions:

EPA alleges in the complaint that these facts constitute a violation of 40 C.F.R. § 720.102(b) and Section 15(1)(C) and (3)(B) of TSCA, in that Respondent failed to submit a timely NOC to the Administrator of EPA within thirty (30) days of commercial manufacture as required.

In Complainant's subsequent submissions wherein it explains in more detail its theory of the alleged violation, EPA advances dual or alternate theories of the case. That is, EPA initially contends that both the filing of the NOC on August 17, 1983 constituted a violation and the failure to file an NOC on or after the date commercial production began in August 1984 constituted a violation.

10/ 15 U.S.C. § 2604(h)(3); 40 C.F.R. § 720.36.

EPA maintains, in its submission of June 7, 1989, that the facts constitute a violation "as a matter of law" because an NOC is not supposed to be given on or after the shipment of an R&D batch, but rather within thirty (30) days after the commencement of commercial manufacture.[11/] EPA insists that "it is not a requirement nor an objective to have chemicals on the TSCA Inventory that should not be on the Inventory."[12/] In EPA's view, BFG's notification to EPA was premature and hence a violation of governing regulations and statutes warranting a $10,000.00 penalty. As EPA puts it: "[t]he NOC sent on August 7, 1983 was clearly sent at the wrong time. The NOC should properly have been sent on or no later than 30 days after the date of first non-exempt commercial manufacture, which for this chemical was August 1984....To have sent the notice nearly a year too early is a violation."[13/]

In its later submission of July 21, 1989, EPA emphasizes its alternate theory of the alleged violation, namely that BFG's failure to file an NOC after commercial production began in August 1984 constituted a violation of the NOC requirement. As EPA expresses it, "[t]he undisputed facts are that Respondent... first manufactured the chemical in question for commercial pur-

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11/ Complainant's "Consolidated Memorandum in Support of Motion to Strike Affirmative Defenses and Motion for Accelerated Decision on All Matters of Liability," (June 7, 1989) at 2.

12/ Id. at 17.

13/ Id. at 17-18 (emphasis supplied).

poses in August 1984. The regulation governing the duty of BFG to file an NOC at that time...said, as it says today, that an NOC must be filed 'on, or no later than 30 calendar days, after the first day of such manufacture...' BFG failed to do this. Therefore, the Complainant, EPA, asserts that this constitutes a violation of the NOC requirement."14/

In its most recent submissions, EPA abandons the theory that the submittal in August 1983 was a violation and relies upon the theory that the failure to submit an NOC after the first post-PMN commercial batch of Chemical A began in August 1984 was a violation. EPA states that BFG "does not understand...that they have been charged with failure to file a timely notice of commencement of commercial manufacture in August 1984....The 1983 NOC submission was in violation of the Interim Policy....[and] in violation of the May 1983 final rule, which, although it was not yet effective, was the most recent guidance from the Agency on when to file an NOC....[T]he United States does not seek, in this enforcement action, to enforce the interim policy. EPA is enforcing the regulation which was clearly in effect in August 1984."15/

14/ Complainant's "Reply Memorandum in Opposition to Respondent's Motin for Accelerated Decision Dismissing the Complaint," (July 21, 1989) at 1-2. EPA does not abandon its earlier theory because it continues to assert that "BFG should not have sent an NOC for this R&D batch and is in violation of TSCA for having done so." Id. at 7.

15/ Complainant's "Surreply to Reply Memorandum of Respondent," (August 17, 1989) at 1-2.

2. Respondent's Contentions:

BFG asserts that 40 C.F.R. § 720.102 had not been promulgated at the time BFG submitted the NOC and that such submission did not violate any statute or regulation.

As for BFG's failure to file another NOC in 1984, when the first non-R&D commercial batch was produced, Respondent states that it had already submitted an NOC in August 1983 and EPA had already put the chemical on the Inventory. Therefore, Respondent pleads: "What possible reason would there be for BFG to submit another notice in 1984? BFG had already fulfilled its duty to notify EPA, and EPA had fulfilled its duty to put the chemical on the inventory. This was the only purpose of the NOC requirement. To re-notify EPA would have been a useless act."16/

B. Application of Statutory and Regulatory Framework

Under Section 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 or import the substance unless EPA has taken regulatory action under section 5(e) or section 5(f) to ban or otherwise regulate the substance.

16/ Respondent's "Reply Memorandum in Support of Respondent's Motion for Accelerated Decision," (August 3, 1989) at 5-6.

There are certain exceptions to the Section 5(a) PMN requirement. Section 5(h) provides an exemption for chemical substances manufactured only "in small quantities" solely for purposes of research and development provided that certain conditions are observed.

Under Section 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 Section 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 person may produce the substance without giving notice to EPA under Section 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.[17]/

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...[i]n small quantities solely for research and development...."[18]/ Therefore, under the rules as proposed in early 1979, an NOC was not required when a person commenced to manufacture a new chemical substance in small quantities solely for research and development purposes.

On May 15, 1979, EPA published a Statement of Interim Policy on the premanufacture notification requirements under Section 5 of TSCA[19]/ wherein it also set forth an interim policy for the implementation of Section 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

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[17]/ 44 F.R. 2278 (January 10, 1979).

[18]/ Id. at 2265.

[19]/ 44 F.R. 28564 (May 15, 1979).

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."20/ 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. There was no specific exclusion of exempt commercial purposes, such as research and development, 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 Section 5 of TSCA.21/ It said, in pertinent part, that "[p]rovisions of the May 15 notice which are not addressed in

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20/ Id. at 28567.

21/ 45 F.R. 74378.

this statement will remain in effect as published on May 15, until the final rules are promulgated."22/ 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."23/

In that same month, November 1982, BFG produced the eight (8) charges of Chemical A under the research and development exemption of Section 5(h) of TSCA. Thereafter, BFG decided to manufacture Chemical A for commercial purposes. At that point in time, the PMN requirements of Section 5(a) came into play.

It is clear from the legislative history of TSCA that the Section 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 and processors of chemical substances prior to manufacture."24/ The "premarket notification for new chemical sub-

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22/ Id. at 74379.

23/ Id. at 74378.

24/ 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).

stances...is probably the most important provision of the act, for it will enable us to limit chemical threats before they become manifest, not after."25/ "[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."26/ 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."27/

In March 1983, BFG filed a PMN for Chemical A pursuant to the statute and the revised interim policy. EPA was properly afforded the opportunity to evaluate the "hazard-causing potential" of Chemical A and to take action to protect human health and the environment against any potential adverse effects before commercial production began. As the parties stipulated, BFG filed a PMN for Chemical A and the 90-day review period was observed properly. After the expiration of the review period, before the

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25/ Id. at 216.

26/ 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).

27/ 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).

end of June 1983, BFG was free to manufacture Chemical A commercially 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 Section 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 BFG.

On May 13, 1983, EPA published the "final" rule for the PMN requirements and procedures under Section 5 of TSCA.[28/] Its effective date was announced as July 12, 1983.[29/] Section 720.52 of the 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.

28/ 48 F.R. 21722 (May 13, 1983).

29/ Id.

> (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.[30]

Unlike the proposed rule which had been published some four years and four 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. The date on which the NOC was to be filed under the "final" rule depended upon whether manufacture for commercial purposes began before or after the effective date of the rule. For manufacture for commercial purposes which began before the effective date of the rule, the NOC must have been submitted "by the effective date" of the rule. As EPA said in explanation:

> EPA proposed this requirement in January 1979 and believes that most notice submitters to date have notified EPA when they began manufacture or import. However, any persons who already have begun to manufacture or import a chemical substance after undergoing notice review, but who have not yet submitted a notice of commencement or manufacture, must submit the notice by the effective date of this rule to allow EPA to update the Inventory.[31]

30/ Id. 21753.

31/ Id. 21736.

On July 11, 1983, EPA published a notice postponing the effective date of the final rule from July 12, 1983 to September 10, 1983.[32/]

On July 27, 1983, BFG sold 350 pounds of Chemical A which had been produced under the research and development exemption to a BFG customer for unrestricted commercial use.

On August 17, 1983, BFG filed an NOC with EPA. As noted previously, while EPA at one point in these proceedings contended that the filing of this notice was a violation,[33/] it subsequently abandoned that theory.[34/]

When BFG filed the NOC on August 17, the interim policy required, without any specific exemption, that an NOC be filed "on or about the date when manufacture...commences." Although the manufacture of Chemical A had been conducted some nine months earlier under the research and development exemption from the PMN requirements of Section 5, and hence no PMN and no NOC had been required at that earlier time, BFG was in somewhat of a quandary: could it now sell, for commercial purposes, Chemical A so manufactured under the R&D exemption after filing the required PMN but without filing an NOC? Or would an NOC be required? No specific provision in the interim policy statement or the not-yet-

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32/ 48 F.R. 31641 (July 11, 1983).

33/ Supra pp. 8-9.

34/ Supra pp. 10-11.

effective final rule directly addressed this question. However, the preamble to the final rule which was to become effective the following month did provide some guidance in the passage quoted above: "[h]owever, any persons who already have begun to manufacture or import a chemical substance after undergoing notice review, but who have not yet submitted a notice of commencement of manufacture, must submit the notice by the effective date of this rule to allow EPA to update the Inventory."35/

BFG had begun to manufacture Chemical A in November 1982, before the effective date of the "final" rule. While it was manufactured under the R&D exemption, it nevertheless could be considered as having been manufactured for commercial purposes. "Manufacture or import for commercial purposes" had been defined in the "final" rule as meaning to "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 use by the manufacturer, including use for product research and development...."36/ BFG had submitted a PMN but had not submitted an NOC. The preamble appears to have instructed those manufacturers in such a position to submit the NOC by the effective date of the rule. When BFG submitted the NOC to EPA on

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35/ Supra, pp. 18-19.

36/ 48 F.R. 21744.

August 17, 1983 "pursuant to 40 C.F.R. § 720.102," it was clearly submitted by the September 10, 1983 effective date of the "final" rule.

Moreover, given the absence of any final rules or regulations to implement Section 8(b)(1) of TSCA, BFG argues that one should look to the statute itself for guidance as to whether BFG should have submitted an NOC at that time. Section 8(b)(1) requires the Administrator to maintain an Inventory of each chemical substance which is manufactured or processed in the United States. BFG's 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,[37/] BFG contends that by filing an NOC, the requirements of the statute would have been met in that, without the NOC, BFG's customer could have processed Chemical A for non-exempt commercial purposes without Chemical A having been added to the Inventory.

On September 6, 1983, EPA postponed the effective date of the final rule to October 26, 1983 (with the exception of certain sections, not pertinent here, for which the effective date was stayed).[38/] At the same time EPA announced a "nonsubstantive

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37/ 48 F.R. 21727 (May 13, 1983).

38/ 48 F.R. 41132 (September 13, 1983).

amendment" of section 720.102(b)(1) concerning the timing of the submission of the NOC for commercial production begun after the effective date of the rule.[39/] 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 begun.

In the supplementary information to this amendment of section 720.102(b)(1), EPA explained the purpose of the NOC requirement. "It 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."[40/] BFG's action in filing the NOC in August 1983 clearly promoted this purpose because Chemical A was thereafter placed on the Inventory thereby relieving subsequent manufacturers (if any) of duplicative PMN paperwork and EPA of duplicative PMN reviews. Of course, as noted previously, BFG

39/ Id. at 41140.

40/ Id.

had filed a PMN in March 1983 thereby affording EPA an opportunity to review any potential threat Chemical A may have posed for human health and the environment.

On October 26, 1983, 40 C.F.R. § 720.102 became effective. 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 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, 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 non-exempt commercial manufacture of chemical substances. Moreover, it provided no clear answer to the quandary which had faced BFG on August 17, 1983.

In August 1984, BFG produced the first post-PMN commercial batch of Chemical A. Having previously filed an NOC in August 1983, BFG did not file one at this time. It is for the failure to file a second NOC at this time that EPA alleges that BFG is in violation of § 720.102 and Section 15 of TSCA.

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."[41/] In doing so, EPA addressed specifically for the first time the dilemma which BFG had faced nearly three years before.

In the preamble to this final rule, EPA acknowledged that in some cases manufacturers will have a surplus of a chemical substance produced for R&D after the R&D activities are complete.[42/] It explained that the regulations allow a manufacturer to use such R&D material for non-R&D commercial purposes after the submission of a PMN and the completion of the relevant review period.[43/] Then EPA got to the heart of the matter in the present case:

> EPA has received questions about the timing of notification of commencement of manufacture in cases where PMN review has been completed, but the manufacturer intends to begin non-exempt commercial activities with quantities of the new chemical substance previously produced for purposes of R&D.
>
> EPA requires persons to submit a notification of commencement of manufacture within thirty days of the start of non-exempt commercial manufacture of a new substance. If amounts of the new chemical produced for R&D already exist, a manufacturer or importer may use them for

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41/ 51 F.R. 15096 (April 22, 1986).

42/ Id. at 15097.

43/ Id. at 15097, 15100.

> non-exempt commercial purposes as soon as the PMN review is complete, but that person may not submit a notification of commencement of manufacture until actual non-exempt manufacture begins. Section 720.102(a) has been revised to reflect this. In addition, even after the PMN review period ends, the new substance may be manufactured solely for R&D or solely for export. In that case, the manufacturer or importer should submit no notice of commencement of manufacture until non-exempt manufacture occurs.44/

In order to reflect this clarification Section 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 requirement, EPA revised Section 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[45/] but which had been dropped from the interim policy statement[46/] and from the "final" regulation.[47/]

44/ Id. at 15101.

45/ Supra at pp. 14-15.

46/ Supra at pp. 15-16.

47/ Supra at pp. 17-18.

On March 16, 1989, EPA filed the complaint herein against BFG for allegedly violating, in August - September 1984, 40 C.F.R. § 720.102, as that regulation was clarified, revised and amended by EPA in April 1986. Thus, Complainant would retroactively hold Respondent to a requirement for filing a second NOC in August - September 1984 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 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 quantities previously produced for R&D purposes and intends to commence actual commercial manufacture sometime later. EPA's requirement that the NOC should be filed in such special circumstances only after the start of non-exempt commercial manufacture and not when the manufacturer initially begins the sale of the excess R&D product was reflected in the 1986 clarification/review/amendment.

In other words, EPA would now hold Respondent liable for misinterpreting a regulation in 1984, which regulation proved so incomplete, unclear and ambiguous that EPA itself issued a clarification, revision and amendment in 1986. Moreover, the explanatory clarification, revision and amendment were issued by EPA to address the precise factual situation posed in cases identical to this case.

The retrospective application of the 1986 revision and clarification of section 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" section 720.102(a) to "clarify" the timing of submission of an NOC. Whether one elects to call the amendment "non-substantive" (or for example, to call the revision a technical revision) does not answer the question of whether section 720.102(a) as amended, revised and clarified should be applied retroactively to BFG in the circumstances of this case.

To determine whether the retroactive application of the 1986 amendment, revision and clarification of section 720.102 to Respondent is reasonable in the circumstances of this case, 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 Section 8(a) to assist the Administrator in meeting his duty under Section 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 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.48/

However, retroactive measures, whether promulgated by a legislature or an administrative agency, have traditionally been subjected to stricter scrutiny than have prospective measures.49/

Generally speaking, the retrospective application of agency rules, like retroactive statutes, will be valid if reasonable, but invalid if the retrospective application is unreasonable in the circumstances.50/

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.51/

48/ 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).

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

50/ 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).

51/ 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).

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,[52] whether the party had fair notice of the retroactive application of an interpretation,[53] whether the party's conduct would have differed if the rule in issue had applied from the start,[54] or whether retroactive application will avoid a result which is contrary to statutory design or to legal and equitable principles.[55]

BFG filed a PMN for Chemical A in March 1983 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 Section 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 BFG.[56]

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

53/ Pennzoil Co. v. U.S. Dept. of Energy, 680 F.2d at 173.

54/ Daughters of Miriam Center for the Aged v. Mathews, 590 F.2d at 1262.

55/ E.L. Weigand Division v. N.L.R.B., 650 F.2d at 471.

56/ Supra, pp. 15-17.

Turning next to the maintenance of the Inventory by EPA under Section 8 of TSCA, even though BFG's timing in submitting the NOC was not in accord with EPA's 1986 revised, amended and clarified regulation, the purpose of the NOC requirement was met by BFG's 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.57/ The submission of a second NOC in 1984 by BFG would simply have confirmed the appropriateness of listing Chemical A on the Inventory. For BFG to submit a second NOC at that point in time would clearly have been redundant.

Therefore, 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 section 720.102(a) was published in the Federal Register on April 22, 1986, it contained no notice that section 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 March 1989.

57/ Supra, pp. 22-23.

Moreover, at the time Respondent produced the first post-PMN commercial batch in August 1984, it clearly had no notice of EPA's revised, amended and clarified section 720.102(a) requirement which was published nearly two years later. Hence, it was not unreasonable that BFG did not submit a second NOC at that time.

Finally, BFG's submission of the NOC on August 17, 1983, was consistent with a reasonable reading of the interim policy statement and the then not-yet-effective final rule as well as with Section 8(b)(1) of TSCA.[58/] At that time in 1983, BFG clearly did not have the benefit of hindsight subsequently provided by the 1986 revision, amendment and clarification of the 1984 final rule.

To hold BFG liable in these circumstances for a failure to file a second NOC, and to impose a monetary penalty for that failure through the retroactive application of a rule which EPA itself recognized was in need of clarification, revision and amendment some two years after BFG's failure, would impose a hardship on BFG which is unreasonable and amounts to a manifest injustice. I conclude that the ill effects of such retroactive application and the hardship imposed on BFG outweigh whatever public ends could conceivably be served by the filing of a second NOC in the circumstances of this case. Accordingly, the question

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58/ Supra, pp. 19-21.

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. § 20.22.

ORDER [59/]

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

Henry B. Frazier, III
Administrative Law Judge

DATED: September 14, 1989
Washington, D.C.

59/ 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.