

PARTIAL ACCELERATED DECISION

Under consideration is respondent's motion to dismiss for failure to state a claim upon which relief can be granted, or , in the alternative, for accelerated decision, filed February 13, 1998 and complainant's cross-motion for accelerated

decision and opposition to motion to dismiss, filed March 13, 1998. (1) Respondent argues that it did not violate premanufacture reporting requirements (PMN), as alleged in the complaint, because the information provided was accurate to the extent it was known to or reasonably ascertainable by respondent at the time of the filing and when the information provided to the agency in the PMN changed, it did not require further notice because it was not material "within the plain meaning of 40 C.F.R. § 720.40 (f)." In addition, respondent urges that EPA "never suggested" that it interpreted its regulations to require the information cited in the complaint.

The complaint alleges that the respondent violated 40 C.F.R. § 720.45 and Sections 15 (1) (C) and 15 (3) (B) of the Toxic Substances Control Act (TSCA). Respondent filed premanufacturing notices on December 19, 1994 for chemicals A and B, December 23, 1995 for chemical C and January 9, 1996 for chemical D. The PMNs did not notify EPA that the chemicals would be manufactured at respondent's Marshall Laboratory in Philadelphia, Pennsylvania. Instead, respondent reported on the PMNs that the chemicals would manufactured at other locations in other states.

The premanufacture requirements of Part 720 require that no person may manufacture a new chemical substance for a commercial purpose unless that person submits a notice to EPA at least 90 days before such manufacture. 40 C.F.R. §§ 720.22, 720.40 (b). A new chemical substance is a chemical substance which is not on EPA's TSCA Inventory. 40 C.F.R. § 720.24 (a). The person who makes the filing must provide in the notice the sites controlled by the submitter and the identity of the sites where the new substance will be manufactured, processed, or used. 40 C.F.R. §§ 720.3 (v), 720.45 (g). If new information becomes available that materially changes the information provided in PMN, the person submitting the PMN must submit the change no later than 5 days before the end of the review period, or, if the information changes within five days of the end of the review period, notice of the change must be made by telephone to the notice contact at EPA.

Following submission of the premanufacture notice, any person who commences manufacture of a new chemical substance for commercial purposes must submit notice of commencement of manufacture of that substance to EPA on or no later than 30 days after the first day of such manufacture. 40 C.F.R. § 720.102.

Respondent offers business reasons why it decided to manufacture chemicals A, B, C and D in Philadelphia instead of the locations for which it gave notice. It does not argue that it notified EPA at least 90 days before commencing manufacture of chemicals A, B, C, and D in Philadelphia. Although, respondent does argue that no information was required to be filed about chemical C because it is exempt from notice pursuant to 40 C.F.R. § 720.30 (h) (7). Respondent relies instead on its self-assessment that there was "no change" in the environmental and health effects associated with the manufacture of chemicals A, B, C and D by moving the location of their manufacture to Philadelphia.

Respondent argues that it was not given notice that it had to submit new information regarding changes in the site of manufacture of chemicals A, B, C and D when "the changes do not increase any of the associated health and environmental effects," the complaint does not state that change in the production site is material new information, and the regulations do not specifically indicate that notice of a change of site was required. Respondent supports these arguments by urging that the information was accurate at the time it was submitted, it could not have violated any regulation with regard to chemical C since it did not have to

submit a premanufacture notice for that chemical, $\frac{(2)}{2}$ and the change of site was not material.

Essentially, respondent's materiality argument is premised on its own review of the information that should have been provided in the notice for its Philadelphia manufacturing site. Respondent concludes that only material changes need be reported and because the Philadelphia site had no material impact on the human and ecological environment, it need not have reported that manufacturing location in its premanufacture notice.

Whatever the merits of respondent's environmental assessment, it was not up to respondent to make the assessment. Section 720.45 provides a list of eight items that must be reported on the premanufacture form. The initial paragraph of the rule states that the information relates to the manufacture, processing, distribution, use and disposal of the new chemical substances. One of the principal elements of § 720.45 is the identification of manufacture sites, the process to be used at the sites, including a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance, worker exposure information, and information on release of the new substance. It is apparent from the face of the rule that eight items of information in § 720.45 -- which are all enumerated in separate alphabetical sections of the rule -- are material to the premanufacture review. The notice issuing the rule explained in detail the elements that would be important. See Premanufacture Notification, Premanufacture Notice Requirements and Review Procedures 48 Fed. Reg. 21722 (May 13, 1983). The rule itself and the notice issuing the final rule state in clear direct language that the manufacturing site is a key factor in determining exposure of a new chemical to human and ecological populations.

Under the circumstances, respondent's argument that the change of site would not have affected the review is speculative since the correct information was not submitted and reviewed.

Whether a change of site in the manufacture is for the better or worse is not at issue in this proceeding. The issue is whether the manufacturing site is required

in order to the review the environmental impact of the manufacture of a new chemical. Respondent has supplied no information that indicates that the site is not a necessary and material element of the premanufacture form and review. Moreover, if respondent was uncertain, the rule points out that there is a reviewer that it could contact. $\frac{(3)}{(3)}$ The Notice states as follows: "A Notice Manager is assigned to each notice. The Notice Manager coordinates the review and serves as the EPA contact on all matters concerning the notice. Persons wishing to contact the managers of particular notices can obtain their names and telephone numbers from the Prenotice Communications Coordinator." 48 Fed. Reg. at 21,724 (1983) Far from being in the dark, the rule explains the information that is important and specifically sets out a scheme for changing the information provided. Moreover, the agency has appointed an official who answers questions for those in doubt.

Nor is respondent's violation with regard to chemical C excused just because it need not have filed a premanufacture notice. The requirements of the premanufacture form required that respondent identify the site of manufacture for all new chemicals for which it filed a premanufacture notice, preceding the initiation of manufacture. According to respondent, it did not know whether it should file a premanufacture form for chemical C. Instead of having the agency rule on that issue before submitting the premanufacture form, it submitted a premanufacture form for chemical C. That form failed to provide accurate information for the reviewer in violation of premanufacture notice rule. That respondent did not need to file does not cure a violation of withholding information required under the rule about the manufacturing site when a form is filed. Violation of a rule is not cured because it need not have been violated.

No genuine issue of material fact exists on the question of liability on counts I, II, III, and IV. The premanufacturing notices which respondent filed on December 19, 1994 for chemicals A and B, December 23, 1995 for chemical C and January 9, 1996 for chemical D did not notify EPA that the chemicals would be manufactured at respondent's Marshall Laboratory in Philadelphia, Pennsylvania. That failure violates 40 C.F.R. § 720.45 and Sections 15 (1) (C) and 15 (3) (B) of the Toxic Substances Control Act (TSCA).

Several weeks ago two dates were suggested to the parties for the hearing in this matter. Both dates were apparently unacceptable to the parties and complainant stated that the parties would suggest dates that were acceptable. That has not been done. If the parties fail to designate an appropriate date for hearing the penalty issue, within five days of this order, a date will be selected without consultation with the parties.

ACCORDINGLY, IT IS ORDERED that the respondent's motion to dismiss for failure to state a claim upon which relief can be granted, or , in the alternative, for accelerated decision IS DENIED.

IT IS FURTHER ORDERED that complainant's cross-motion for accelerated decision and opposition to motion to dismiss IS GRANTED.

IT IS FURTHER ORDERED that respondent's failure provide premanufacture notice of the manufacturing of chemicals A, B, C, and D in Philadelphia, Pennsylvania (as alleged in counts I-IV of the complaint) violated 40 C.F.R. § 720.45 and Sections 15 (1) (C) and 15 (3) (B) of the Toxic Substances Control Act (TSCA).

Edward J. Kuhlmann Administrative Law Judge

March 30, 1998 Washington, D. C. 1. On March 25, 1998, the respondent filed a response to complainant's cross motion for accelerated decision, or in the alternative, motion for leave to reply.

2. Respondent states that it filed a premanufacture notice for chemical C because it was uncertain about whether it came within the exemption. It claims now that it is clear that it need not have filed a notice for chemical C and therefore it should be absolved for not filing accurate information.

3. When § 720 was issued in final form, on May 13, 1983, the agency explained that the "notice review program [] employs a Prenotice Communications Coordinator to assist persons preparing a notice or considering the submission of a notice. The Prenotice Communications Coordinator provides guidance on a wide variety of topics, and refers persons to the appropriate EPA staff members for guidance on other questions. Topics for prenotice inquiries include the scope of TSCA and this rule, the contents of the TSCA Chemical Substance Inventory, the notice form, section 5 exemptions, premanufacture testing, confidentiality and generic name development, and notice review procedures." Premanufacture Notification, Premanufacture Notice Requirements and Review Procedures 48 Fed. Reg. 21722, 21724 (May 13, 1983). The next paragraph of the notice gives the telephone number and the address of the coordinator. Respondent's argument that it was unable to determine what it should do in this situation could have been solved if it took advantage of the assistance that was available.

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