IN THE MATTER OF SANDOZ PHARMACEUTICALS CORPORATION

RCRA Appeal No. 91–14

ORDER DENYING REVIEW IN PART AND REMANDING IN PART

Decided July 9, 1992

Syllabus

Sandoz Pharmaceuticals Corporation seeks review of certain corrective action requirements in the federal portion of a RCRA permit issued to Sandoz by U.S. EPA Region II for Sandoz' manufacturing and research facility in East Hanover, New Jersey. Sandoz challenges: (1) the adequacy of the RCRA Facility Assessment; (2) the regulation of five "Areas of Concern," where underground storage tanks were once situated; (3) the Region's failure to establish action levels in the permit; (4) the inclusion of generic, boilerplace investigation requirements that are based on suspected (as opposed to confirmed) releases; and (5) the time constraints imposed by the permit for various activities.

Held: The first issue listed above has not been preserved for review. With respect to the second issue, the proceeding is remanded to the Region, which is directed to supplement its response to comments by explaining why, in light of the remediation already performed by Sandoz on the Underground Storage Tank sites, further investigation of those sites is required by the permit. With respect to the third issue, the Agency has indicated that, where possible, action levels should be specified when the permit is first issued. The proceeding is remanded to the Region to explain why it deviated from this approach. On the other two issues, review is denied.

Before Environmental Appeals Judges Ronald L. McCallum, Edward E. Reich, and Timothy J. Dowling (Acting).

Opinion of the Board by Judge Dowling:

Sandoz Pharmaceuticals Corporation seeks review of certain corrective action requirements in the federal portion of a permit issued to Sandoz by U.S. EPA Region II under the Hazardous and Solid Waste Amendments (HSWA) to the Resource Conservation and Recovery Act of 1976 (RCRA), for Sandoz' manufacturing and research

facility in East Hanover, New Jersey.[1] Sandoz challenges: (1) the adequacy of the RCRA Facility Assessment (RFA) and the permit conditions based thereon; (2) the regulation of five "Areas of Concern," where underground storage tanks were once situated; (3) the Region's failure to specify action levels in the permit; (4) the inclusion of generic, boilerplate investigation requirements, as well as requirements for suspected (as opposed to confirmed) releases; and (5) the time constraints imposed by the permit for various activities. As requested by the Judicial Officer, the Region filed a response to the petition for review.[2] For the reasons set forth below, we conclude that the first issue listed above has not been preserved for review. With respect to the second and third issues, this proceeding is remanded to the Region for further consideration. On the other two issues, review is denied.

I. *BACKGROUND*

In fashioning the permit under review, the Region relied on a RCRA Facility Assessment (RFA) performed by the New Jersey Department of Environmental Protection (NJDEP) in May and June of 1987. The RFA included a preliminary review and a visual site inspection. In addition to the RFA, the Region reviewed an NJDEP Underground Storage Tank Registration Questionnaire for Sandoz, a Construction Plan of Waste Equalization Tanks at Sandoz' facility, a New Jersey Pollutant Discharge Elimination System (NJPDES) permit issued to Sandoz on January 1, 1990, and a surface map of Sandoz' underground tanks. The Region also relied on notes of telephone conversations with Sandoz representatives. On the basis of these materials, the Region issued a draft permit to Sandoz on October 2, 1990. After public notice and comment, a final permit was issued on April 11, 1991.

The final permit identifies twelve present and former storage units at the facility as either solid waste management units ("SWMUs") or Areas of Concern ("AOCs").[3] Of the twelve, eleven

[1] The non-HSWA portion of the permit was issued by the State of New Jersey, an authorized State under RCRA § 3006(b), 42 U.S.C. § 6926(b).

[2] At that time, the Agency's Judicial Officers provided support to the Administrator in his review of permit appeals. On March 1, 1992, all cases pending before the Administrator, including this case, were transferred to the Environmental Appeals Board. *See* 57 Fed. Reg. 5321 (Feb. 13, 1992).

[3] The permit lists the following seven SWMUs and five AOCs:

#1—two clay-lined wastewater lagoons (SWMU)

#2—inactive wastewater skimming tank (SWMU)

#3—active skimming tank (SWMU)

are subject to corrective action requirements under the federal portion of the permit. As part of the RCRA Facility Investigation ("RFI"), the permit requires a soil investigation for eleven units, and a groundwater investigation for six units.

II. *DISCUSSION*

Under the rules that govern this proceeding, a RCRA permit ordinarily will not be reviewed unless it is based on a clearly erroneous finding of fact or conclusion of law, or involves an important matter of policy or exercise of discretion that warrants review. *See* 40 CFR § 124.19; 45 Fed. Reg. 33412 (May 19, 1980). The preamble to § 124.19 states that "this power of review should be only sparingly exercised," and that "most permit conditions should be finally determined at the Regional level * * *." *Id.* The burden of demonstrating that review is warranted is on the petitioner.

A. *The RFA*

Sandoz first argues that the RFA is incomplete and inadequate, and that the permit conditions based thereon that require corrective action are therefore defective. The Region responds that this issue has not been preserved for review because Sandoz did not raise it during the public comment period even though it was ascertainable at that time. If an issue is reasonably ascertainable during the public comment period, the issue must be raised at that time if it is to be preserved for review. *See* 40 CFR §§ 124.13 & 124.19(a). Adherence to this requirement is necessary to ensure that the Region has an opportunity to address potential problems with the draft permit before the permit becomes final.[4] In this case, the alleged inadequacies

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#4—removed underground caustic storage tank (AOC)

#5—removed underground fuel storage tank (AOC)

#6—removed underground fuel storage tank (AOC)

#7—removed underground wastewater storage tank (SWMU)

#8—removed underground fuel storage tank (AOC)

#9—three removed underground fuel storage tanks (AOC)

#10—container storage area (SWMU)

#11—removed above-ground alkaline waste storage tank (SWMU)

#12—removed above-ground alkaline waste liquid storage tank building (SWMU)

The container storage area (#10) is a RCRA-regulated unit operating under the State portion of the permit and is not subject to the corrective action requirements of the federal portion.

[4] *See In re Shell Oil Company,* RCRA Appeal No. 88–48, at 3 (March 12, 1990) ("These rules help to ensure that the Region has an opportunity to address any

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of the RFA were reasonably ascertainable at the time of the public comment period, but Sandoz did not raise the issue in its comments on the draft permit. *See* Letter dated November 19, 1990 from Keith E. Lynott to Laura J. Livingston (Exhibit E of Appendix to Sandoz' Petition). The issue has not been preserved for review, and review is therefore denied.[5]

B. *Areas of Concern*

AOCs 4, 5, 6, 8, and 9 consist of areas where seven underground storage tanks (USTs) were once situated. (AOC 9 contained three separate underground fuel and gasoline tanks.) Sandoz asserts, and the Region does not dispute, that the seven USTs were used to store raw material or fuel and never contained solid or hazardous waste. Sandoz states that four of the fuel oil tanks were leaking when they were removed from the ground, but it represents that: (1) releases from the leaking tanks (with one exception) have not caused contamination at concentrations exceeding NJDEP action levels; (2) Sandoz has appropriately remediated all releases in accordance with its NJPDES Permit and with the oversight of the NJDEP; and (3) any contamination not remediated by Sandoz is encapsulated in a dense glacial till which, according to Sandoz, serves as a protective barrier against migration of any release into the aquifer.

Sandoz argues that, for two reasons, the sites of the removed USTs are not SWMUs and therefore do not fall within the ambit of the Agency's corrective action authority under RCRA § 3004(u), which is limited to releases from SWMUs.[6] First, Sandoz contends

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concerns raised by the permit, thereby promoting the Agency's longstanding policy that most permit issues be resolved at the Regional level."); *In re Texaco Refining and Marketing, Inc. (Anacortes, Washington),* RCRA Appeal No. 89–12, at 3 (Nov. 6, 1990) (same).

[5] Our determination that Sandoz failed to preserve the RFA issue extends only to the alleged formal defects in the RFA (*e.g.*, the Region's alleged failure to prepare a separate written report, or to conduct sampling). Sandoz' challenge to the Region's use of the RFA to justify corrective action for potential (as opposed to confirmed) releases is addressed in Section D below.

[6] RCRA § 3004(u) provides:

> Standards promulgated under this section shall require, and a permit issued after November 8, 1984, by the Administrator or a State shall require, corrective action for all releases of hazardous waste or constituents from any *solid waste management unit* at a treatment, storage, or disposal facility seeking a permit under this subchapter, regardless of the time at which waste was placed in such unit. Permits issued under section 6925 of this title shall contain schedules of compliance for such corrective action (where such corrective action cannot be completed prior to issuance of

that the USTs contained fuel or raw materials, not solid or hazardous waste. Second, Sandoz argues that, notwithstanding the passive leaks from the tanks, there were never any routine and systematic releases from the tanks that would render the sites SWMUs.

Sandoz is correct that the term "solid waste" as defined in RCRA generally does not extend to stored raw materials or fuel.[7] The investigation requirements at issue here, however, are directed to potential releases or spills of the stored materials, not to the materials in their original condition of storage. A spill or release of stored materials into the surrounding area would generally constitute "solid waste" under RCRA. *See In re Amerada Hess Corporation, Port Reading Refinery,* RCRA Appeal No. 88–10, at 2 (August 15, 1989).

Even though a release from a tank to the surrounding area is "solid waste," to invoke RCRA § 3004(u) it is still necessary to determine that the area is a "solid waste *management unit.*" The term "solid waste management unit" includes areas contaminated by routine and systematic releases, but not by a one-time, accidental spill or a passive leak. *See* 55 Fed. Reg. 30809 (July 27, 1990). Sandoz argues that there is no evidence of any routine or systematic releases from the USTs. The Region, however, does not argue that the UST sites are SWMUs, but instead cites the statutory and regulatory omnibus provisions as legal authority for imposing corrective action requirements on non-SWMUs.[8]

It is well established that RCRA § 3005(c)(3) provides authority to require corrective action for certain non-SWMUs. *See In re Morton International, Inc. (Moss Point, Mississippi),* RCRA Appeal No. 90–7, at 13–14 (February 28, 1992); *In re American Cyanamid Co.,* RCRA

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the permit) and assurances of financial responsibility for completing such corrective action.

42 U.S.C. § 6924(u) (emphasis added).

[7] The term "solid waste" is defined as:

> any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities * * *.

RCRA § 1004(27), 42 U.S.C. 6903(27).

[8] The statutory omnibus provision reads as follows:

> Each permit issued under this section shall contain such terms and conditions as the Administrator (or the State) determines necessary to protect human health and the environment.

RCRA § 3005(c)(3), 42 U.S.C. § 6925(c)(3). The regulatory omnibus provision essentially tracks the language of the statute. *See* 40 CFR § 270.32(b)(2).

Appeal No. 89–8, at 13 (August 5, 1991); *In re LCP Chemicals-North Carolina, Inc.,* RCRA Appeal No. 90–4, at 3–4 (February 14, 1991).[9] This authority, however, is not unlimited; by its own terms, § 3005(c)(3) authorizes only those permit conditions necessary to protect human health or the environment. Accordingly, the Region may not invoke its omnibus authority unless the record contains a properly supported finding that an exercise of that authority is necessary to protect human health or the environment.

The Region has arguably made a finding that the basis for invoking Section 3005(c)(3) exists with respect to the UST sites simply by designating them as "Areas of Concern." In the Region's Response to Comments, the Region explains that the term "Area of Concern" is defined in the permit as an area that the Region is regulating under its omnibus authority because of suspected but unconfirmed releases of hazardous waste:

> Pursuant to the authority granted by Sec. 3005(c)(3) of RCRA 40 C.F.R. § 270.32(b)(2) [sic], an area of concern is hereby defined for purposes of this permit to mean an area at the facility or an off-site area, which is not at this time known to be a solid waste management unit (SWMU), where hazardous waste and/or hazardous constituents are present or are suspected to be present as a result of a release from the facility. The term shall include area(s) of potential or suspected contamination as well as actual contamination. Such area(s) may require study and a determination of what, if any, corrective action may be necessary.

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[9] In the Subpart S proposal, the Agency notes that it has interpreted the "routine and systematic" criterion as not including areas where a one-time spill or "passive" leakage has occurred. The Agency then observes that its interpretation has the effect of removing some environmental problems at RCRA facilities from the reach of § 3004(u). The Agency notes, however, that it

> intends to exercise its authority, as necessary, under the RCRA "omnibus" provision (section 3005(c)([3])), or other authorities provided in RCRA * * * to correct such problems and to protect human health and the environment.

55 Fed. Reg. 30809 (July 27, 1990).

Sandoz cites *National-Standard Company v. Adamkus,* 685 F. Supp. 1040 (N.D. Ill. 1988), for the proposition that the Agency's corrective action authority does not extend to non-SWMUs. *Adamkus* does contain dicta to the effect that Section 3004(u) does not extend to non-SWMUs. *Id.* at 1050. Because the Region is not relying on § 3004(u) as authority for requiring investigations of the UST sites, however, *Adamkus* is inapposite.

(Region's Response to Comments, at 1–2, Exhibit B in Appendix supporting Petition for Review.) In view of the Region's reference to the omnibus provision, the designation of the UST sites as "Areas of Concern" could arguably be viewed as the Region's shorthand method of indicating that at least a preliminary investigation of those areas is necessary to protect human health and the environment.

It is not enough, however, for the Region to simply make a finding that a corrective action measure is necessary to protect human health and the environment. To justify an exercise of its omnibus authority, the finding must have a sufficient factual basis in the record. In this regard, we find the Region's response to comments to be inconsistent with the permit. Sandoz has described the steps it has taken under State supervision to remedy releases from the USTs at issue here, and the Region has not disputed Sandoz' account. When Sandoz raised those State-supervised remediation efforts during the comment period, the Region, in its response to comments, stated that such efforts "will be accepted." (Region's Response to Comments, at 2 and 7, Exhibit B of Appendix supporting Petition for Review.) The federal portion of the permit nonetheless requires Sandoz to investigate these units as part of the RFI. To correct this inconsistency, we are remanding this issue to the Region so that the Region may supplement its response to comments on the draft permit. On remand, the Region should provide a properly supported finding that the required UST site investigations are necessary to protect human health and the environment, and specifically address why the remedial steps already taken by Sandoz are insufficient. Alternatively, the Region may determine that Sandoz' past remedial efforts are adequate to protect human health and the environment for some or all of the units at issue and adjust the permit accordingly.

C. *Action Levels*

Under the permit, action levels will be used to trigger a Corrective Measures Study (CMS), but these levels will not be incorporated into the final permit until after Sandoz completes the RFI. Sandoz believes that the action levels should be set in the final permit *before* it is required to perform the RFI. Sandoz argues that the absence of specific, numerical action levels in the final permit impedes performance of the RFI.

In response, the Region states that the RFI only requires the comparison of actual contamination levels to background levels, and that the absence of action levels in the permit does not hamper

Sandoz' ability to make this comparison. The Region argues that it is appropriate to require a permittee to identify contamination based on background levels, leaving it to the Region to then specify the releases that require remediation.

On July 27, 1990, the Agency proposed a comprehensive set of regulations for the implementation of RCRA § 3004(u), the Subpart S proposal. *See* 55 Fed. Reg. 30798 (July 27, 1990). The Subpart S proposal constitutes the Agency's most recent, comprehensive statement of its views regarding corrective action under RCRA § 3004(u). The preamble to the Subpart S proposal makes clear that action levels should be specified when the permit is first issued. For example, at one point in the preamble, the Agency states:

> Action levels will, whenever possible, be incorporated in the permit. The Agency believes it is advantageous to identify action levels in the permit so that the public and the permittee will know in advance what levels will trigger the requirement to conduct a CMS. This approach also minimizes the need for permit modifications later in the process, which could delay ultimate cleanup.

55 Fed. Reg. at 30814. In another passage, the preamble contains the following statement:

> Requirements for the remedial investigation would be specified by the Agency in a schedule of compliance in the facility's permit. The schedule would typically identify the SWMUs and environmental media that required more detailed investigation as well as the types of investigations required; it would also typically require the owner/operator to develop a plan for conducting these investigations. The permit would also include "action levels" for specific constituents in specific media under investigation. If subsequent investigation indicated that these action levels had been exceeded, a Corrective Measure Study could be required by the Agency.

Id. at 30810.

It is certainly conceivable that, in certain cases for site-specific reasons, a Region will be justified in deviating from this approach, but Region II has not offered any site-specific reasons for such a

deviation here. On remand, the Region should explain why a deviation from the approach delineated in the Subpart S proposal is appropriate in this case. Alternatively, if the Region determines that the permit should be revised to include action levels, it should adjust the permit accordingly.

D. *The RFI Requirements*

Sandoz argues that, under the corrective action program developed by EPA, an RFI is performed only if the Agency determines, based on evidence obtained in the RFA, that releases of hazardous wastes or hazardous constituents from a SWMU have occurred or are likely to occur in the future. Sandoz believes that the RFA performed by the Region in this case was inadequate to justify many of the corrective action requirements because it does not show that a release has occurred or is likely to occur from certain units. Sandoz also argues that, because the information obtained from the RFA was inadequate, the Region was forced to rely on boilerplate requirements that have been designed to apply to every type of treatment, storage, and disposal facility regulated under RCRA. Sandoz argues that such requirements are contrary to EPA's policy favoring phased, site-specific corrective action requirements that reflect the unique characteristics of regulated facilities.

The Region disputes the assertion that the RFI requirements in the permit are "generic." It gives instances in which it tailored the requirements to site-specific conditions. It also argues that there is nothing wrong with certain boilerplate requirements, and that to preclude the Agency from using such requirements would be imprudent given the number of facilities for which corrective action is required and the limited resources of the Agency. The Region points out that the RFI Management Plan, which is a component of the RFI work plan, accommodates the need for site-specific tailoring.

To the extent this issue is a restatement of the first issue discussed above concerning the adequacy of the RFA (*see* note 5), we conclude that the issue has not been preserved for review for the reasons given above. But the Petition raises two additional points that need to be addressed. Sandoz' first point is that the Agency does not have authority to require an RFI for an area unless it has definitively determined that a release has occurred or is likely to occur in the future. In other words, Sandoz believes that the Agency does not have authority to require an investigation of a suspected release. It is well established, however, that the Agency does

have authority to require at least a preliminary investigation where it is likely that hazardous constituents have been released, even if there is no definitive confirmation of the release.[10]

The second point that needs to be addressed is Sandoz' assertion that the permit imposes boilerplate RFI requirements that are not tailored to site-specific conditions at the facility. Sandoz is correct that corrective action requirements should be tailored to site-specific conditions at the facility. *See American Cyanamid Company,* RCRA Appeal No. 89–9, at 7 (August 5, 1991) ("EPA guidance documents emphasize the importance of tailoring RCRA corrective action requirements to site-specific conditions in order to avoid imposing unnecessary or inappropriate burdens upon the permittee."). A permit must contain "some minimum measure of site-specificity to avoid imposing unnecessary requirements on the permittee." *Id.* at 9 n.19. In this regard, the Region represents that, based on site-specific data, it eliminated from its list of SWMUs and AOCs requiring investigation a septic tank and some sand filter beds. Moreover, as the Region correctly points out in its Response, the Region concluded for site-specific reasons that a

> full RFI for all media is not required for any of the SWMUs or AOCs. Soils and ground water investigations are required for six of the SWMUs/AOCs; soil investigations only are required for five of the SWMUs/AOCs; no investigation is required as to SWMU #10, the container storage area.

(Region's Response to Petition, at 19 n.8.) In light of these representations, which are supported by the record, we conclude that the permit as written has the requisite minimum measure of site-specificity. Accordingly, review of this issue is denied.

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[10] *See Shell Oil Company,* RCRA Appeal No. 88–48, at 6 (March 12, 1990); *Marathon Petroleum Company,* RCRA Appeal No. 88–24, at 3–4 (November 16, 1990); *see also,* 40 CFR §270.14(d)(3) (Region may require a permit applicant to conduct verification monitoring where necessary to fill data gaps and to allow Region to make initial release determination); 52 Fed. Reg. 45,788–89 (December 1, 1987) (same).

Early Agency guidance on corrective action, and permit appeal decisions based thereon, state that a mere "suspected" release is sufficient to require further investigation. *See e.g.,* RCRA Facility Investigation Guidance, at p. 1–6 (Interim Final; EPA Office of Solid Waste, May 1989); *Shell Oil, supra.* The more recent Subpart S proposal would authorize the required remedial investigations if the Agency determines that hazardous constituents are "likely to have been" released from a SWMU. 55 Fed. Reg. 30874 (July 27, 1993) (§264.510) (emphasis added).

E. *Unreasonable Time Frames*

Sandoz argues that the final permit establishes unreasonable time frames for action by Sandoz. Sandoz represents that it cannot complete the actions required by the final permit within the time frames established in the permit because: (1) the time frames do not allow enough time for customary laboratory turn-around times; (2) Sandoz needs more time to review drafts of submissions prepared by its consultants; and (3) the pace of Sandoz' preparation of the various plans and submissions required by the final permit will be contingent in part on timely review and response by the NJDEP and EPA. The Region responds that the final permit allows for modification of the compliance schedule when unforeseen circumstances necessitate a change.

We note that, when this issue was raised during the comment period, the Region responded by revising twenty-three deadlines in the permit to give Sandoz more time to fulfill its obligations under the permit. (Region's Response to Comments, Exhibit B to Appendix supporting Petition for Review, at 10–13.) The Region's obvious willingness to accommodate Sandoz' concerns about time constraints, as evidenced by its revisions to the draft permit, convinces us that Sandoz' concerns are adequately addressed by the permit provision allowing for modification of the compliance schedule when unforeseen circumstances require a change. Accordingly, review of this issue is denied.

III. *CONCLUSION*

The issue relating to the adequacy of the RFA has not been preserved for review, and review is accordingly denied. The issues relating to the former UST sites and to action levels are hereby remanded to the Region for further proceedings consistent with this order.[11] All contested conditions and non-severable conditions (to be identified by the Region) shall remain stayed on remand. The Region should give public notice of this remand under 40 CFR § 124.10. Appeal of the remand decision will not be required to exhaust administrative remedies under § 124.19(f)(1)(iii) of the rules. Review of the

[11] Although § 124.19 of the rules contemplates that additional briefing will be submitted upon the grant of a Petition for Review, a direct remand without additional submissions is appropriate where, as here, it does not appear that further briefs on appeal would shed light on the issues to be addressed on remand. *See, e.g., In re Chemical Waste Management, Inc.*, RCRA Appeal No. 87–12, at 5 (May 27, 1988).

other two issues raised by Sandoz is hereby denied for the reasons set forth above.

So ordered.