9441.1995(06)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 21, 1995

MEMORANDUM

SUBJECT: Infectious and/or Genetically Engineered Waste

FROM: Michael Shapiro, Director
Office of Solid Waste

TO: Robert L. Duprey, Director
Hazardous Waste Management Division

Thank you for your memorandum in which you raised issues concerning RCRA and TSCA jurisdiction over infectious and/or genetically engineered waste. You have asked us to clarify EPA's authority to require submittal of information under RCRA section 3007 and to require corrective action for wastes which may have been disposed at the Dugway Proving Ground (DPG), a Department of the Army facility in Utah. We understand that the Region does not know the full extent and type of wastes produced at the facility, but that some possibilities are biological agents, genetically engineered organisms, and infectious wastes.

If biological, genetically engineered, or infectious wastes either are listed as hazardous wastes under 40 CFR Part 261 or exhibit a characteristic of hazardous waste, they are subject to hazardous waste management standards and interim status and permitting requirements in the same way as any other hazardous wastes listed or identified under Part 261.

Initially, the Region may gain access to the facility under section 3007 because it is a hazardous waste storage facility. Additionally, if materials do not meet the definition of hazardous waste under Part 261, they still would be subject to RCRA sections 3007 and 3013 if they meet the statutory definition of hazardous waste. This is broader than the regulatory definition in Part 261. 40 CFR 261.1(b)(20 provides that, even if a material is not a hazardous waste under Part 261, it may still be a solid and hazardous waste for purposes of RCRA sections 3007 and 3013 if EPA

has reason to believe that the material may be a solid waste within the meaning of RCRA section 1004(27), and a hazardous waste within the meaning of RCRA section 1004(5). The materials may also be addressed under section 7003 if the statutory elements are established. Regions have the authority to make case-by-case decisions on whether such material meets the statutory definition of hazardous waste. (see footnote 1)

Your letter also questioned whether section 3004(u) applies in this case. Section 3004(u) requires corrective action for releases of hazardous waste or constituents from any solid waste management unit at the facility. Since biological, genetically engineered or infectious wastes are solid wastes, SWMUs containing these wastes would be subject to section 3004 (u). In the proposed Subpart S rule, EPA interpreted "hazardous waste" for purposes of section 3004(u) to encompass the statutory definition of hazardous waste. Based on this interpretation, the Region could use section 3004(u) authority to require investigation of any SWMUs to determine whether there are releases of hazardous waste was defined under section 1004(5) or constituents. Because this interpretation of section 3004(u) is contained in a proposed rule that has not been finalized, the Region should be prepared to explain the interpretation as well as providing site-specific reasons why it is appropriate to require an investigation of this issue at the facility.

Note that section 3008(h) enforcement authority may be used in the same manner, since EPA's position is that the scope of that authority is no less broad than 3004(u). See memorandum from J. Winston Porter, "Interpretation of Section 3008(h) of the Solid Waste Disposal Act" (Dec. 16, 1985). If any aspect of the facility is classified, that is not a bar to EPA action unless the facility has a presidential exemption under section 6001, although inspectors may be required to obtain appropriate security clearances.

Your memorandum also raised questions regarding EPA's authorities to address this facility under the Toxic Substance Control Act (TSCA). Although TSCA may have mechanisms to address this type of materials in a remedial context, we believe the RCRA authorities outlined above would be more appropriate to address the facility in question in light of the fact that this is a RCRA facility.

Finally, you asked whether EPA's authority to address these wastes under RCRA is tied to any particular date. We do not believe that dates are relevant to the applicability of RCRA corrective action authorities, since sections 3004(u) and 3007 clearly have no such limitations.

We hope that you find this information helpful. Please contact David Fagan at (703) 308-8620 if you have any questions.

cc: M. Hale
D. Barnes
B. Pace

Footnotes

1. In addition, CERCLA section 104(e), which covers "hazardous substances", also could be used here.

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VIII
999 19TH STREET - SUITE 500
DENVER, CO 80202

October 13, 1994

MEMORANDUM

SUBJECT: Infectious and/or Genetically Engineered Waste

FROM: Robert L. Duprey, Director
Hazardous Waste Management Division

TO: Michael H. Shapiro, Director
Office of Solid Waste

We are requesting clarification of the extent of EPA's authorities pertaining to the Dugway proving Ground (DPG), Department of Army facility, in Tooele County, Utah. DPG is a Resource Conservation and Recover Act (RCRA) treatment, storage, and disposal facility going through closure and perhaps will receive a post closure permit. DPG has a RCRA storage permit and is subject to corrective action.

DPG had a mission to develop biological and chemical agents for use by the DOD. Waste material was produced by DPG in accomplishing this mission. Because of the classified nature of the work at DPG, we do not know the full extent and types of wastes it produced over the years. (About 30 years ago, DPG had several sheep kills from some type of experimentation it was conducting.) Chemical agents have been tested at DPG in experimental animals. We and the State of Utah have authority to address solid and hazardous wastes issues and releases from solid waste management units at the facility, and we are doing so.

Pathogens, non-pathogens, and other biological agents were probably experimented with at DPG. Waste from these experiments were disposed on-site and perhaps off-post. Under RCRA 1004 (5) the Agency has statutory authority to address infectious

characteristics waste, but no regulations have been developed by EPA. Infectious waste is considered by Region 8 to be solid waste. The Medical Waste Tracking Act, Subtitle J of RCRA, has expired, and so it is no longer germane to our concerns.

We are requesting clarification as to whether the Region has the authority to require the submittal of information from DPG under 3007 of RCRA, regarding the types of biological/infectious waste material handled and disposed by DPG. We also need confirmation that we do have the authority under 3004(u) and (v) and elsewhere in RCRA to address human health and environmental concerns from any improper or mishandling of these types of infectious waste materials.

Further, the Toxic Substances Control Act (TSCA) has given to EPA the authority to regulate genetically engineered organisms, even though our application of this authority has been minimal. DPG may have experimented with genetically engineered biological materials. Does TSCA provide EPA with authority to pursue investigation of the disposal of genetically engineered wastes? Can these materials be regulated under RCRA as an infectious waste? If yes, does our authority begin with the passage of RCRA in 1976 or with the inception of the hazardous waste program on November 19, 1980?

We recognize that we are asking difficult questions, but our concern is real. Even though DPG is in a remote, desert area in Utah, we still want to have the facility meet a clean-up standard that is protective of human health and the environment. If only chemical waste can be addressed by the Agency, then we may be leaving potential human health and environmental concerns unaddressed from biological and genetically engineered organisms. We don't know if DPG has any problem from the mismanagement of these types of waste materials, but we need clearly defined authority to be able to ask the questions and effect remediation as necessary.

Your assistance in clarifying the extent of these statutory authorities will be appreciated. Please call Larry Wapensky (303) 293-1509 if you have any questions.

cc: D. Downs UDEQ
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