

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

APRIL 10, 1989

Ms. Karen Florini
Attorney
Environmental Defense Fund
1616 P Street, NW
Washington, DC 20036

Dear Ms. Florini:

Thank you for your recent letter regarding the scope of medical wastes covered in regulations implementing the Medical Waste Tracking Act of 1988. I understand your concerns, and I believe that this letter will clarify several areas of the issue of determining which medical wastes should be subject to this demonstration program.

Section 11002(a) of the Medical Waste Tracking Act lists eleven categories of wastes potentially subject to the demonstration tracking program. The first five categories are mandatory and must be included. Categories six through ten are optional, and may be excluded upon a finding that they do not pose a substantial present or potential hazard to human health or the environment. Category eleven may be used to regulate other health care wastes, upon a finding that those wastes pose a threat to human health or the environment.

There is considerable overlap between the ten waste categories listed in the Act. In developing the medical waste regulations, our goal has been to regulate all medical wastes that pose a substantial threat to human health or the environment. In determining specifically which waste categories should be covered, we assessed whether they could cause infection, could be physically harmful (e.g., puncture the skin), or caused serious aesthetic degradation of the environment (e.g., were responsible for beach closings). On that basis, we have determined that the following waste classes should be regulated:

Waste Class

(1) Cultures and
Stocks

(2) Pathological
Wastes

(3) Human Blood
and Blood
Products

(4) Sharps

Description

Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

(1) Liquid waste human blood; (2) products of blood; (3) items saturated and/or dripping with human blood; or (4) items that were saturated and/or dripping with human blood that are now caked with dried blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing, and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.

Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents).

(5) Animal Wastes

(6) Isolation
Wastes

(7) Unused Sharps

Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

Biological waste and discarded materials contaminated with blood,

excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly

communicable diseases.

The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

As can be seen from the above classes of waste that will be regulated, EPA is regulating all medical wastes described in Section 11002(a)(1) through (5) and many wastes in (6) through (9). For example, discarded laboratory glassware containing cultures and stocks of infectious agents, specifically mentioned in the statute as an example of laboratory wastes (source-based waste category 7), is covered in our regulations under waste type 1. Surgery wastes from waste category 6 could contain human body parts (described in waste category 2), human blood (described in waste category 3), and sharp implements, such as scalpel blades (described in waste category 4). The regulation has been expanded further so that it also covers other surgery, laboratory, and dialysis waste items. If a given item is saturated or dripping with human blood, for instance, or caked with dried blood, it will be covered under the regulation as written. Thus, although the regulation does not contain ten waste classes, it does cover many items in the waste categories listed in Section 11002(a)(6)-(9). We have determined that those items that we are not regulating do not pose a substantial threat to human health and the environment.

The determination to exclude some of the wastes mentioned in waste categories (6) through (9) is based on consultation with the Centers for Disease Control (CDC), the National Institutes of Health, numerous state public health officials, and infection control experts. A combination of the following factors must be present in order for disease to be transmitted: (1) the presence of a pathogen of sufficient virulence, (2) an adequate dose, (3) a portal of entry, and (4) a susceptible host. Because of the combination of factors that must be present, epidemiological information is necessary to verify disease transmission. The experts consulted have emphasized repeatedly that no epidemiological evidence exists relating mismanagement of medical wastes generally to disease transmission, despite repeated and thorough searches of the literature and worker compensation records. Detailed examples of EPA's reasoning are given in the Background Document Resource Conservation and Recovery Act, Subtitle J Section 11002. This is available in the public docket along with other background materials.

With regard to waste category 10 the authority in Section 11002(a)(10) does not allow EPA to regulate all wastes generated from the care of patients with diseases, such as Hepatitis B; the authority extends only to certain wastes from patients isolated to protect others from communicable diseases. For the same reasons given in the previous paragraph, we have been advised that the potential hazard posed by most isolation wastes appears to be minimal. Thus, on advice of infection control experts, have chosen to regulate only certain wastes generated by patients isolated because they have contracted highly communicable diseases (e.g., those listed in classification 4 by the CDC in Classification of Etiologic Agents on the Basis of Hazard (1974).

This demonstration project, along with other actions EPA and States are taking, will help abate the degradation of our coastal areas. We will evaluate the medical waste tracking system throughout the

demonstration period. An important part of this evaluation will be the adequacy and appropriateness of the list of wastes that are regulated.

I hope that this letter clarifies the scope of our medical waste tracking and management regulations. If you have further questions, please contact Devereaux Barnes at (202) 382-4637.

Sincerely,

Sylvia L. Lowrance, Director
Office of Solid Waste