

Administrator to use this list of HAPs to develop and publish a list of source categories for which NESHAP will be developed. EPA must list all known categories and subcategories of "major sources."

The term major source is defined in paragraph 112(a)(1) to mean any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate 10 tons per year (tons/yr) or more of any HAP or 25 tons/yr or more of any combination of HAPs. The term stationary source, from section 111 of the CAA, means any building, structure, facility, or installation that emits or may emit any air pollutant. The term area source, as defined in section 112(a)(2), means any stationary source of HAPs that is not a major source.

Notice of the initial list of categories of major and area sources of HAPs was published on July 16, 1992 (57 FR 31576), under authority of section 112(c). This notice listed pharmaceutical manufacturing as a category of major sources of HAPs. Notice of the schedule for the promulgation of emission standards for the listed categories, under authority of section 112(e), was given on December 3, 1993 (58 FR 63941). Under this notice, emission standards for the pharmaceutical production industry would be promulgated no later than November 15, 1997.

Section 112(d) of the CAA directs the Administrator to promulgate emission standards for each category of HAP sources listed under section 112(c). Such standards are applicable to both new and existing sources and must require the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new and existing sources in the category or subcategory to which such emission standard applies. See 42 U.S.C. 7412(d)(2).

Section 112(d)(3) provides that the maximum degree of reduction in emissions that is deemed achievable for new sources shall not be any less stringent than the emission control that is achieved in practice by the best controlled similar source. For existing sources, the standards may not be less stringent than the average emission limitation achieved by the best

performing 12 percent of existing sources in each category of 30 or more sources.

Once this minimum control level (referred to as the floor) has been determined for new or existing sources for a category, the Administrator must set a standard based on maximum achievable control technology (MACT) that is no less stringent than the floor. The Administrator may set MACT standards that are more stringent than the floor if such standards are achievable considering the cost, environmental, and other impacts listed in section 112(d)(2). Such standards must then be met by all sources within the category.

#### *C. Resource Conservation and Recovery Act (RCRA)*

Subtitle C of RCRA, 42 U.S.C. 6921–39b, directs EPA to establish a comprehensive "cradle to grave" system regulating the generation, transport, storage, treatment and disposal of hazardous wastes. The hazardous wastes subject to this comprehensive management scheme include any solid waste, or combination of solid wastes, that because of its quantity, concentration, or physical, chemical, or infectious characteristics may cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed. 42 U.S.C. 6903(5).

RCRA defines "solid waste" to include any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material. 42 U.S.C. 6903(27). The Act does not specify what characteristics of a waste render it hazardous to human health or the environment; instead, it directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. 42 U.S.C. 6921. Pursuant to this directive, EPA has adopted a two track scheme for identifying hazardous wastes. So-called "characteristic wastes," regulated under 40 CFR 261.20–24, exhibit at least one of four specified characteristics: ignitability, corrosivity, reactivity, or toxicity. Such wastes are deemed automatically subject to regulation under RCRA subtitle C, and retain the

designation of hazardous waste until they cease to exhibit any of the characteristics. See 40 CFR 261.3(d)(1).

The other type of hazardous wastes, "listed wastes," comprises wastes specifically classified as hazardous by EPA rule. See 40 CFR 261.11 (setting out criteria EPA considers in determining whether a solid waste should be a listed hazardous waste). Under EPA regulations, a listed hazardous waste retains that classification, even if has been treated in some fashion, until the waste has been demonstrated to be no longer hazardous. See 40 CFR 261.3(c)–(d) (the "derived-from" rule).

Once a waste has been identified or listed by EPA, RCRA permits its disposal on the land if the waste has been treated to meet standards established by EPA pursuant to 42 U.S.C. 6924(m). Section 6924(m)(1) instructs EPA to specify those levels or methods of treatment, if any, that substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized. EPA has concluded that requiring hazardous wastes to be treated in accordance with the best demonstrated available technology ("BDAT") is sufficient to satisfy this criterion. See 51 FR 40,572, 40,578 (1986). These standards can apply even after a characteristic waste no longer exhibits a characteristic. 40 CFR 261.3(d)(1).

In addition to meeting treatment standards before land disposal, hazardous wastes are also subject to cradle-to-grave control from point of generation to point of final disposition. Generators prepare manifests to assure proper tracking of all hazardous wastes. Facilities treating, storing or disposing of such wastes are subject to design and operating standards established by EPA. Such standards ordinarily are embodied in an operating permit issued by EPA to the facility. In addition to meeting design and operating standards, facilities must commit sufficient money to assure that the facility will be properly closed, or that proper post-closure care of the wastes will occur.

#### *D. Pollution Prevention Act of 1990*

In the Pollution Prevention Act of 1990 (42 U.S.C. 13101 *et seq.*), Congress declared pollution prevention the national policy of the United States. The Pollution Prevention Act declares that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled or reused in an