BACKGROUND DOCUMENT

RESOURCE CONSERVATION AND RECOVERY ACT

SUBTITLE C - HAZARDOUS WASTE MANAGEMENT

SECTION 3001 - IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

§261.10 - Criteria for Identifying Characteristics of Hazardous Waste

§261.11 - Criteria for Listing Hazardous Waste

§260.22 - Petitions to Amend Part 261 to Exclude a Waste Produced at a Particular Facility

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OFFICE OF SOLID WASTE
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INTRODUCTION

The purpose of this document is to describe the basis and purpose that the Agency used in establishing final (1) criteria for identifying characteristics of hazardous waste, (2) criteria for listing hazardous waste and (3) procedures for delisting hazardous wastes. This document refers to §§250.12 and 250.15 of the Proposed Rules published on December 18, 1978, and to §§261.10, 261.11, and 260.22 of the Final Rules. The document also relates to Sections 3001(a) and 1004(5) of the Resource Conservation and Recovery Act, as amended, (RCRA).

Section 3001(a) of RCRA requires the Administrator to "develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, which should be subject to the provisions of this subtitle (Subtitle C - Hazardous Waste Management), taking into account toxicity, persistence, degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness and other hazardous characteristics." This statutory requirement to establish criteria for characteristics of hazardous waste and for listing hazardous waste is non-discretionary. Provision for delisting hazardous wastes is not explicitly mentioned in the statute. The discretionary authority for establishing procedures for delisting is based on Section 2002(a)(1) of RCRA which authorizes the Administrator "to prescribe .... such regulations as are necessary to carry out his functions under this Act."

Section 1004(5) of RCRA defines "hazardous waste" to mean "a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may:

(1) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating

reversible, illness; or

(2) pose a substantial present or potential hazard to human health or the environment, when improperly treated, stored, transported, or disposed of, or otherwise managed."

This definition, together with the factors delineated in Section 3001(a), provides the statutory test that is to be used by the Agency in developing criteria for characteristics and listing of hazardous waste under Section 3001(a) of RCRA.

SYNPOSIS OF PROPOSED RULES

The Proposed Rules established separate criteria for identifying characteristics of hazardous waste and listing of hazardous waste (see §§250.12 (a) and (b), respectively, of the Proposed Rules). The criteria for identifying characteristics required (1) that the characteristic be defined in terms of specific physical, chemical, toxic, infectious or other hazardous properties of a solid waste and (2) that such properties be measurable by available, standardized testing protocols. These criteria explicitly required that a characteristic be quantitative and specific and that it be determinative through standardized, readily available testing methods. Section 250.10(d)(1) of the Proposed Rules made it clear that generators of solid wastes were required to use characteristics to determine whether their solid wastes were hazardous wastes. Section 250.14 of the Proposed Rules stated that the Agency also would use characteristics to list hazardous wastes.

As indicated above, the term "characteristic(s) of hazardous waste(s)" takes on a very special meaning in the Proposed Rules (and in the Final Rules).

It denotes a hazardous property or set of properties that are highly quantifiable and readily measurable or otherwise determinable so that they can be readily and confidently used by generators of solid wastes to determine whether their solid wastes are hazardous wastes. This meaning is much more specific and narrowly drawn than the traditional meaning of the term, or even the meaning that the term takes in a few parts of the legislative history where "characteristic" appears to be a synonym for "properties") and does not carry the connotation of quantitativeness, specificity, measurability or generator usability that has been attached to this term in the regulations. In short, as used in these regulations, a characteristic is a hazardous property or a set of hazardous properties that can be used by generators in evaluating his wastes. Hazardous properties which cannot be used in this way, or which the Agency believes should not be used in this way, are called "factors" in this document and in the Final Rules.

The criteria for listing a hazardous waste required either (1) that the waste possess one or more of the established characteristics or (2) that the waste meet the definition of hazardous waste given by Sections 1004(5) of RCRA. The Agency elected to establish a rebuttable presumption for listing wastes which met these criteria. Types or classes of waste were listed, rather than individual wastes from individual sources, and a presumption was created that all individual wastes within the type or class listed were hazardous wastes. The delisting mechanism (discussed later) enabled an individual waste of a listed type or class of waste to be delisted thus rebutting the presumption with respect to the individual waste.

Under the criteria for listing, listed hazardous wastes would be regulated unless or until delisted (individual waste only). Wastes that were not listed would be hazardous waste if found (primarily by generators) to possess one or more of the characteristics. Implicit in this approach is the certainty that attaches to the listing of hazardous wastes. The regulated community, as well as the regulating agencies (EPA and the States), would face no doubts about the status of a waste if it is listed as a hazardous waste. No testing or other complex determinations of hazardousness would be required relative to listed hazardous wastes. The hazardous status of unlisted wastes would be uncertain until tested or assessed against the established characteristics.

The requirements for delisting (see §250.15(a) of the Proposed Rules) were essentially the inverse of the basis for listing. Where a waste was listed because it possessed a characteristic, the requirement for delisting was demonstration that the waste did not possess the characteristic. Where a waste was listed for reasons other than a characteristic (i.e., the waste met the definition of the Act), the requirement of delisting was demonstration that the waste did not possess the properties (e.g., chronic toxicity) that caused it to be listed by EPA. In addition, the requirements for delisting prescribed (1) the information to be submitted as part of a demonstration, (2) the procedures the Agency would use in approving or disapproving a demonstration and in allowing a demonstration to become effective, and (3) certain due process procedures.

RATIONALE FOR THE PROPOSED RULES

The proposed criteria for characteristics and listing and the requirements for delisting were based on a regulatory strategy that assumed that (1) characteristics defining all of the intrinsic hazardous properties of solid waste (e.g., ignitability, corrosivity, reactivity, toxicity, genetic activity, bioaccumulation potential and radioactivity) could eventually be established and would be used by generators to self-determine whether their solid wastes are hazardous wastes and (2) EPA would list classes or types of hazardous wastes where it had good reason to believe that all or most individual wastes in the listed class possess one or more of the established characteristics. Under this approach, characteristics would capture all solid wastes, even those not listed as hazardous wastes, deemed to be hazardous under the statute. Accordingly, even those solid wastes for which the Agency had insufficient data or knowledge to support a listing would be brought into the hazardous waste management system through self-determinations by generators of solid wastes. The objective of this strategy was to establish a system that assured broad coverage of hazardous wastes in the absence of the Agency's listing of hazardous wastes.

The listing of hazardous wastes, under this regulatory strategy, was intended to provide a high degree of certainty for the generators of solid wastes, the public and the regulating agencies about which solid wastes were hazardous. Listing, therefore, had the purpose of reducing or eliminating the burden on generators and the regulating agencies of having to test or otherwise determine whether certain solid wastes were hazardous wastes. As such, listing was a refinement of, not a substitute for, the basic element of the regulatory strategy--case-by-case application of characteristics by generators.

Under this approach, the burden of determining which solid wastes were hazardous would initially fall largely on generators through application of the characteristics because EPA would initially only be able to list a limited number of wastes. Over time, this burden would be reduced by the Agency's listing of more and more wastes. The principal burden on EPA would be to define, establish and revise characteristics (as appropriate). A secondary burden on the Agency would be to initially list and, over time, extend the listing of hazardous wastes.

The strategy recognized that the listing of wastes would not be perfect. For administrative efficiency, classes or types of wastes, rather than the wastes from individual sources, would be listed for the most part (although listing of individual waste streams would be permissible). The Agency recognized that some individual wastes within a listed class or type of waste, might not be hazardous wastes, because of different raw materials or manufacturing processes used or because of other atypical factors. Consequently, provision for delisting of fundamentally different individual wastes within classes or types of listed hazardous wastes was embodied in the Proposed Rules.

In developing the Proposed Rules, the Agency was unable to fully effect the above described regulatory strategy. Characteristics could only be developed and proposed for some of the hazardous properties of wastes. These were characteristics for ignitability, corrosivity, reactivity and toxicity (limited to toxicity caused by contaminants governed by Interim Primary Drinking Water Standards). With respect to these characteristics,

the above described regulatory strategy was incorporated in the Proposed Rules. With respect to other hazardous properties (chronic organic toxicity to humans, aquatic toxicity, phytotoxicity, genetic activity, 1/ bioaccumulation potential, radioactivity, and infectiousness), EPA was unable to propose characteristics because it lacked sufficient information and data to support such characteristics and their associated test protocols. The Agency believed, however, that such characteristics eventually could be developed and established and, toward that end, the Agency published an Advance Notice of Proposed Rulemaking on December 18, 1978, to initiate their development. Because of this belief, the Agency elected to follow the above-described regulatory strategy, but with an important, temporary deviation: the listing of wastes for which characteristics had not yet been established.

Although characteristics were not established for wastes listed for radioactivity, genetic activity, organic toxicity, bioaccumulative potential and infectiousness, the Agency, in fact, did follow a set of characteristic-like

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1/ Where used in this document, "genetic activity" refers to carcinogenicity, mutagenicity and teratogenicity.

criteria, together with the consideration of other factors, to list such wastes. Although these criteria were not delineated in the criterion for listing hazardous wastes under §250.12(b)(2), they were implicitly reflected in the delisting requirements of §250.15(a)(5) and (6). These criteria were:

1. For wastes listed because of radioactivity, the criterion was that the waste contained less than 5 picocuries per gram of radium-226, if a solid-state waste, or contained less than 50 picocuries per liter of radium-226 and radium-228 combined, if a liquid-state waste.
2. For wastes listed because of genetic activity, the criterion was that the extract of the waste (as derived by the proposed Extraction Procedure) contained less than one milligram per liter of any compound on the Controlled Substance List in Appendix IX of the Proposed Rules or gave a positive response in any one of a series of tests specified in §250.15(a)(6)(i) of the Proposed Rules.
3. For wastes listed because of bioaccumulative potential, the criterion was that the extract of the waste (as derived by the proposed Extraction Procedure) gave a positive response in the Bioaccumulation Potential Test prescribed in Appendix XI of the Proposed Rules.
4. For wastes listed because of organic toxicity, the criterion was that the extract of the waste (as derived by the proposed Extraction Procedure) contained an organic substance having a calculated human LD50 of less than 800 milligrams per kilogram at a concentration in milligrams per liter greater than or equal to 0.35 times its LD50 expressed in units of milligrams per kilogram.

In addition, for delisting infectious wastes, the waste would have to be shown not to contain microorganisms or helminths of CDC (Center for Disease Control) Classes 2 through 5 of Etiologic Agents (see §250.14(b) of the Proposed Rules).

The important feature of this interim approach was that it clearly placed the burden on EPA to bring a large number of the most hazardous wastes into the hazardous waste management system through listing, as opposed to placing this burden on generators through application of characteristics. The principal advantages and disadvantages of this approach were well recognized by the Agency. Clearly, for many wastes, principally toxic organic wastes, generators would be relieved of the burden of waste testing which they would find expensive, difficult and objectionable. EPA, however, would be saddled with the burden of testing and evaluating the broad array of industrial solid wastes to determine which should be listed as hazardous waste. This would require considerable resources and, to the extent that resources likely would be limited, listing of all or most hazardous wastes would require several years. Until such listing was completed, desired regulatory coverage of hazardous wastes would be incomplete. This would constitute initial and temporary under-regulation.

Regulatory Strategy. A number of commenters expressed differing points of view on the regulatory strategy authorized by the Act for identifying hazardous wastes. Some felt that wastes could only be listed as hazardous wastes against established characteristics. These commenters seemed to argue for a three level system: criteria for characteristics, characteristics, and listing against characteristics, similar to the system proposed for ignitable, corrosive, reactive and certain toxic wastes. These commenters made little or no distinction between characteristics and criteria for listing hazardous waste, apparently believing them to be one and the same. In fact, they referred to the legislative history (H.R. Report 94-1491) which spoke about the "bifurcation of developing the criteria.... separate from the identification and listing of hazardous wastes." Most of these commenters also argued that listing was the only statutorily authorized approach for identifying hazardous wastes, thereby agreeing with the comments summarized next.

A number of commenters felt that the characteristics should be used only by EPA for listing hazardous wastes and should not be imposed on the regulated community to determine the hazardous status of unlisted wastes. These commenters were concerned about the burden placed on generators to employ costly, sophisticated and perhaps imprecise tests to evaluate unlisted solid wastes. Some of the commenters felt that the tests were costly, that the burden of testing properly rested on the regulating agencies (EPA or the States). Others felt that many generators, particularly small generators, would avoid testing because of the high costs and complexity of the tests or because of their incapacity to perform the tests. Consequently, these commenters felt that small generators would designate marginally hazardous or non-hazardous wastes as hazardous wastes in order

to "be safe" and avoid possible civil or criminal penalties that could attend errors in testing. These commenters felt that this would lead to over-regulation, would be costly to industry and would aggravate the disposal capacity problem.

At the other end of the spectrum, several commenters contended that characteristics should be used for both listing of hazardous wastes by EPA and case-by-case designation of unlisted wastes as hazardous wastes by generators. These commenters felt that this would assure the broadest possible regulatory coverage of hazardous wastes (until it was possible for EPA to list all hazardous wastes) and that such broad coverage was environmentally essential.

In summary, there was wide disagreement as to what Congress intended in Section 3001(a) of the Act. Importantly, virtually all of these comments were directed at the proposed regulatory strategy covering the listing of hazardous wastes for which characteristics were not proposed (primarily those listed for organic toxicity, genetic activity, bioaccumulation potential, radioactivity and infectiousness).

The Agency disagrees with those commenters who argued that characteristics should be used only for listing wastes and should not be imposed on generators to self-determine if their unlisted wastes are hazardous wastes. It further disagrees with commenters who contended that the statute does not authorize these two approaches for designating hazardous waste. The Agency believes that the statutory language plainly contemplates two distinct mechanisms for bringing a waste into the hazardous waste system. Section 3010 provides

that "Not later than ninety days after promulgation or revision of regulations under Section 3001 identifying by its characteristics or listing any substance as a hazardous waste subject to this subtitle....." (emphasis added), any generator or transporter of hazardous waste or operator of a hazardous waste facility shall file notice with the Administrator providing information about the "identified or listed hazardous waste..." This language explicitly envisions either of two methods for determining whether a given waste is hazardous: (1) identification in accordance with the characteristics or (2) listing. Similarly, Section 3001(c) provides that "...the Governor of any State may petition the Administrator to identify or list a material as a hazardous waste." (emphasis added). Additionally, Sections 3002, 3003, 3004 and 3005 refer to generators, transporters and treatment facility operators of "hazardous waste identified or listed under this subtitle..." (emphasis added). Thus, Congress indicated clearly that there are two distinct mechanisms for bringing waste into the hazardous waste system.

Given that the statute authorizes (and, presumably, expects) the use of two mechanisms, it is left to the discretion of the Agency to fashion the nature and content of each mechanism. Even here, however, that statute provides implicit guidance on the intended nature for these two mechanisms. The intended nature of the listing mechanisms seems to be clear and obvious. Under this mechanism, the Agency is to list

particular hazardous wastes[1/] or classes or types of hazardous waste based on data and information it has collected about the wastes and based on its determination that these particular wastes are hazardous in accordance with the statutory definition of hazardous waste. Once listed, the generator's responsibility is simple and straight-foreward: to designate, as a hazardous waste, any and all wastes that meet the descriptions of the wastes listed.

The nature of the identification mechanism also appears reasonably apparent in the statute. Under this mechanism, the Agency is to establish characteristics of hazardous wastes and hazardous wastes are to be identified by these characteristics.[2/] Admittedly, the statute does not explicitly indicate who is to identify individual wastes by their characteristics. If Congress had intended EPA to determine whether wastes met the characteristics, however, then there would have been no point in making a distinction between the two mechanisms. Furthermore, if the Agency (and authorized States) were obligated to perform identification against established characteristics, that would entail an extensive, resource intensive monitoring and testing program, literally involving the sampling and testing of each and every solid waste not listed as a hazardous waste. This could encompass individual sampling and testing of hundreds of thousands of solid wastes and, in many cases, repeated sampling and testing of these wastes because of their variability over time.

1/ See Section 3001 (b) of RCRA.

2/ See Section 3010 of RCRA.

The Agency does not believe that the Congress contemplated such an absurd result. Rather, the Agency believes that the Congress contemplated just the opposite: the sampling and testing of solid wastes by generators (and by owners or operators of hazardous waste treatment, storage and disposal facilities). Section 3002 (1) of RCRA explicitly prescribes that requirements be placed on generators to perform "recordkeeping practices that accurately identify the quantity of such hazardous wastes generated, the constituents thereof which are significant in quantity..." Such record-keeping cannot be accomplished without first sampling and testing of the wastes. Section 3002(4) requires generators to "furnis(h)...information on the general chemical composition of such hazardous waste to persons transporting, treating, storing, or disposing of such wastes." Finally, Section 3005 (1) requires applicants for hazardous waste management permits to supply "estimates with respect to the composition, quantities, and concentrations of any hazardous waste..." Taken together, these requirements clearly indicate that the statute contemplates (and, in fact, directs) that the regulated community carry a responsibility to sample and test or otherwise determine the quantity and composition of the hazardous wastes that they generate and manage. It is thus wholly reasonable to conclude that the Congress contemplated that these same responsibilities were to be assumed by the regulated community in the identification of hazardous wastes for which characteristics have been established.

Such a reading of the statute not only places responsibility for identifying unlisted hazardous wastes or those parties who generate them--a fundamental purpose of the statute in the Agency's view-but also capitalizes on the advantage of the "division of labor" in identifying such wastes. Whereas the

the Agency and the authorized States will not have the resources to sample and test all unlisted wastes, the Agency believes that the large number of generators do have this capacity (within limits as discussed below) and can and should be expected to assume this responsibility. In simple terms, assigning responsibility for identifying unlisted hazardous wastes to generators spreads this responsibility to an estimated 67,000 generators[1/] rather than 51 entities, the Agency and the authorized States.[2/] Clearly, this approach has considerable merit from the standpoint of administrative efficiency. Moreover, generators of hazardous wastes are "continually on the scene," so to speak and therefore, are capable of intimately knowing their various solid wastes, knowing and predicting the variability of these wastes and readily and efficiently sampling these wastes. To expect the Agency and the authorized States to have such "on the scene" capacity in order to efficiently and effectively identify unlisting wastes is clearly unrealistic. In summary, the Agency concludes that practicality and a reasoned reading of the statute argue for the implementation of the identification mechanism by generators.

Based on the foregoing, EPA has retained, in the Final Rules, the same two mechanisms for designating wastes that were reflected in the Proposed Rules. Where appropriate, certain characteristics are established and are required to be used by generators to identify hazardous wastes (they may be and, in fact, are used also by EPA to list wastes known to possess one or more of these

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1/ Accounting for the exemptions for small quantity generators in §261.5 of the Final Rules, the Agency estimates that 67,000 generators will be covered by the Subtitle C regulation.

2/ The number of 51 entities will inevitably be smaller (probably 35 to 45) because only a portion of the 50 States will be authorized to assume responsibility for the program.

characteristics). Hazardous wastes are also listed, using the criteria for listing established in the Final Rules.

The Agency clearly recognizes that the identification mechanism has its limitations and must be used with considerable care. First and foremost, this mechanism must only employ characteristics which, in and of themselves, sufficiently define the properties of a waste that cause the waste to meet the definition of hazardous waste prescribed in Section 1004(5) of RCRA. In other words, a solid waste that possesses the property or properties described in an established characteristic must meet the statutory definition of hazardous wastes without consideration of any other properties of or factors about the waste or its constituents. Where properties or factors outside of those defined in the characteristic must be considered to reach a determination that a waste meets the statutory definition of hazardous waste, a characteristic is not sufficient for the purpose of designating a hazardous waste. In those cases where multiple factors are required to determine the hazardous status of a waste, the Agency has employed the listing mechanism to designate the waste. This represents a change in regulatory strategy from that advanced in the Proposed Rules; a change which is in response to comments. Basically, the Agency has concluded that the intended characteristic for organic toxicity, genetic activity, bioaccumulation potential, radioactivity, and infectiousness, that were discussed in the Proposed Rules (and were preliminarily proposed in the Advance Notice of Proposed Rulemaking) are not, in and of themselves, capable of identifying wastes as hazardous without consideration of additional properties and factors outside of those defined in those characteristics.[1/]

1/ Further discussion of this conclusion is presented later in this document. Suffice it to say at this point however, that the subject characteristics as proposed in the ANPR did not take into consideration all relevant factors necessary to substantiate the hazardousness of wastes.

Consequently, the Agency has deferred establishment of these characteristics and has decided, at this time, to use the listing mechanism to designate hazardous wastes that possess properties of toxicity not covered in the EP toxicity characteristic, namely genetic activity, bioaccumulation potential, radioactivity, or infectiousness.

At the same time, the Agency has concluded that the characteristics of ignitability, corrosivity and reactivity are sufficient to use in the identification i.e., self-testing mechanism because they define a degree and nature of hazardousness that meets the statutory test of hazardous wastes, without considering outside factors (substantiation of this conclusion is presented in separate background documents covering these characteristics). With respect to the proposed toxicity characteristic, the Agency has concluded that a modified version of this characteristic[1/] can be used in the identification mechanism because it, too, defines a degree and nature of hazardousness that meets the statutory definition (substantiation of this conclusion is presented in a separate Background Document covering this characteristic which has been re-named "Characteristic of EP Toxicity" in the Final Rules). In summary, the Final Rules establish four characteristics (for ignitability, corrosivity, reactivity and EP toxicity) that are required to be used by generators of solid wastes to self-determine if their unlisted wastes are hazardous.

A second factor that the Agency considered in the use of the identification mechanism was that of the implementability of characteristics that would have to be used by generators. The Agency concluded that characteristics should be definitive and determinative if they were to be properly and successfully used

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1/ The concentration limits of contaminants that define this characteristic have been increased ten-fold in the Final Rules.

by the diverse group of generators that would have to use them. Also, characteristics should be reasonably simple and straightforward and should not require complex determinations. Finally, the test protocols included in characteristics should be standardized and readily available to generators (or the private-sector laboratories that might serve them) and should be within the performance capability of generators (or private-sector laboratories). Although EPA intends to use the listing mechanism to eventually list most, if not all, hazardous waste, the identification mechanism initially and, to some extent, always will play a very important role in bringing into the hazardous waste management system waste for which EPA does not have sufficient information to list. It is therefore in the Agency's interest, and in the interest of generators and the public at large, that the characteristics used in the identification mechanism be highly definitive, determinative, and usable by generators so that they avoid both overregulation and underregulation.

The factor of implementability was carefully considered by the Agency, both in response to the many comments on this matter and as a result of Agency initiative. In part, these factors also helped EPA reach the decision to defer characteristics for organic toxicity, genetic activity, bioaccummulation potential, radioactivity, and infectiousness. Aside from the insufficiency of these characteristics in incorporating all relevant properties and factors necessary to the determination of hazardousness (discussed above), these characteristics, as preliminarily proposed in the ANPR, were, for the most part complex and required the use of test methods that are not yet fully standardized or widely available. On the other hand, the Agency concluded that these factors of implementability did not impair the characteristics for ignitability, corrosivity, reactivity and EP toxicity established in the Final Rules. The Agency believes that these characteristics

are definitive, determinative, and reasonably simple and that their test protocols are standardized, available and within the performance capacity of generators or private-sector laboratories (substantiation of these contentions are presented in the separate Background Documents covering these characteristics).

With respect to comments on the burden of characteristics on small generators of hazardous wastes, §261.5 of the Final Rules, with a few exceptions, excludes from the regulation the hazardous wastes generated by persons who generate or accumulate less than 1,000 kilograms of hazardous waste in any calendar month.1/2/ An estimated 693,000 generators are excluded from regulation under this provision. A detailed description and discussion of this exclusions are presented in a separate Background Document. The Agency believes that this

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1/ However, this exclusion level will eventually be reduced to 100 kilograms in any calendar month.

2/ Pesticide containers and residues employed and generated by farmers are not subject to regulation if they are disposed of in specified ways. As provided in §262.51, farmers who triple-rinse pesticide containers and dispose of pesticide residues in accordance with the pesticide label instructions are not subject to Subtitle C regulations with respect to these wastes. Other hazardous wastes generated by farmers are not excluded unless they are generated or disposed of in quantities less than 1,000 kilograms in any 30-day period.

exclusion addresses many of the concerns of commenters on this matter. Admittedly, there are some small and many medium-size generators who will not be affected by this exclusion. However, with respect to these generators, the Agency believes that the four characteristics established in the Final Rules are not unreasonably costly,[1/] difficult to employ, imprecise or beyond the performance capacity of these generators or the private-sector laboratories that are available to serve them. It is probably inevitable, as suggested by some commenters, that some of these generators will avoid self-determination of unlisted wastes by merely declaring their solid wastes to be hazardous wastes, in order to "be safe" and avoid any possibility of criminal or civil penalties. This is permissible under the requirements of §262.11 which requires generators to determine whether their unlisted solid wastes are hazardous but does not require them to test their wastes to make this determination. The Agency believes that these instances will be reasonably few because considerations of the regulatory obligations attaching to hazardous wastes management will discourage overinclusive hazardous wastes destinations. In any case, the Agency does not believe it would be justified in eliminating the characteristics merely to avoid the excessive designation of hazardous

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1/ The cost of testing for all four characteristics is estimated to be less than $1,000 (based on cost estimates by commercial laboratories) and, in many instances, the cost will be less because the generator can safely assume that his wastes do not possess some of the characteristics; e.g., the ignitability and reactivity characteristics. Sampling expenses will vary, but also deemed to be reasonable since generators ordinarily will use their own personnel to gather samples.

wastes by some small and medium generators. The quantities of the wastes that might be "overdesignated" as hazardous wastes will be small because of the small size of these generators. As a result, the additional costs and the impact on available disposal capacity will be modest, but the human health and environmental impacts could be significant.

The Agency disagrees with commenters who contended that hazardous waste should only be listed against established characteristics.[1/] It agrees that hazardous waste must be listed against criteria for listing (established in §261.11) and may be listed against characteristics (in which case the criteria for listing will provide for listing against characteristics). Section 3001(b) of the statute is quite explicit on the point that listing must be based on the criteria for listing required to be established under Section 3001(a).

The Agency is not unsympathetic to the concerns that probably lie behind the comments urging the listing of hazardous wastes only against characteristics; that concern being that the proposed criterion for listing (see §250.12(b)(2) of the Proposed Rules) was not very specific. In the absence of specific listing criteria in the Proposed Rules, the commenters quite naturally saw the need for characteristics which essentially would provide the missing criteria. The Agency has addressed this concern by substantially expanding the final criteria for listing (see §261.11 of the Final Rules). This expansion is discussed subsequently in this document.

1/ Where "characteristics" have the very specific and narrowly drawn meaning described on pp. 2 and 3.

Finally, the Agency recognizes that the regulatory strategy, in limiting the utilization of the identification mechanisms to the four characteristics established in the Final Rules and relying on the listing mechanism to bring all other wastes into the system, is in partial disagreement with those commenters who urged, for environmental reasons, broad use of the identification mechanism to cover hazardous waste for which the Agency now or in the future may not have sufficient information to list. This is the result of the balancing of two contradictory objectives: achieving broad coverage and keeping the burden of the identification mechanism on generators within attainable bounds. This has been a difficult balance for the Agency to make, but it believes it has achieved a reasonable result. Even so, the Agency is cognizant that the coverage of hazardous waste by the initial listing contained in the Final Rules is incomplete. To rectify this situation, the Agency intends to pursue a dedicated effort over the ensuing years to more completely characterize the solid wastes generated by industry and, through this, list additional hazardous wastes in future revisions of the Final Rules. With the initiation of this effort in FY 1980 and its planned funding for FY 1981 and FY 1982, the Agency will make a major effort to correct the short-comings in the initial listing.

Criteria for Identifying Characteristics. Only a few comments were received on the criteria for identifying characteristics (§250.12(a) of the Proposed Rules). One comment urged that site-specific or management-specific considerations be incorporated in the criteria as well as the characteristics in order to implement the "when improperly....managed" clause of the statutory definition of hazardous waste. The Agency agrees that possible and plausible scenarios of improper management should be

considered both in establishing characteristics and in listing hazardous wastes. To assure such consideration, it has explicitly added the statutory language, including the phrase "when...improperly managed", in the criteria for establishing characteristics (see §261.10(a)(1)(ii) of the Final Rules). However, EPA strongly believes that the initial determination of whether a waste is hazardous is not made on a site-specific basis (indeed, the statutory definition of hazardous waste seem conclusive on this point), so that site-specific and management-specific factors are not included in either the criteria or the characteristic. Furthermore, it is obviously impossible to incorporate actual site-specific or management-specific considerations in the characteristics or listed wastes without developing separate, individual characteristics or listing criteria for each of the many thousands of wastes. Such considerations are properly left to the issuance of permits for individual treatment, storage and disposal facilities and this, in fact, is provided for in Parts 264, 265 and 122 of the regulations.

Another comment contended that the criteria and characteristics should account for persistence and degradability in nature.

The Agency agrees that the properties of persistence and degradation[1/] should be considered, where appropriate, in identifying characteristics of hazardous waste. The Agency, in fact, did consider the properties of persistence and degradation in establishing the four characteristics of ignitability, corrosivity, reactivity and EP toxicity. However, it turns out that these

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1/ Persistence and non-degradation are synonymous but are used together to reflect the wording of the Act.

properties do not play a major role in these characteristics. The first three of these characteristics principally address properties of waste that may cause hazards in the initial management of a waste; therefore, persistence and degradation are not believed to be significant factors. In addition, the properties (e.g., flash point, oxidizing potential and pH) of these characteristics do not depend on degradable constituents and therefore their persistence does not change. In the EP toxicity characteristic, the hazardous constituents are either highly persistent, non-readily degradable pesticides or non-degradable persistent heavy metals.

Several commenters urged that the criteria allow for two classifications of hazardous wastes: very hazardous and less hazardous wastes. One such commenter suggested that this distinction be based on the distinction between paragraphs (A) and (B) of the statutory definition of hazardous waste. The Final Rules (§261.11) provide criteria for listing which distinguish between extremely hazardous waste and less (but still substantially) hazardous waste. Section 261.11(a)(2) provides the listing criterion for the former, while §261.11(a)(3) provides for the latter. The Final Rules do not, however, make such a distinction in the criteria for characteristics or in the characteristics themselves, because the Agency has not determined how this can be accomplished and, as discussed in another background document, the Agency does not feel that such a distinction adds much to the regulatory scheme created by the regulations. In a sense, the characteristic for reactivity defines extremely hazardous properties that comport with paragraph (A) of the statutory definition of hazardous waste and, in some regards, the characteristic of ignitability defines very hazardous properties. Consequently, some distinction between extreme and lesser hazardness is implicitly incorporated in the final characteristics.

A few commenters objected to the use of poorly documented and unrepresentative damage cases in EPA's files as the basis for the criteria and characteristics. Another commenter objected to the reliance on regulations of other agencies as the basis for criteria and characteristics because such regulations are not necessarily designed for environmental protection and therefore are not necessarily transferable. These comments on the use of damage cases and reliance on regulations of other agencies were in reference to a statement made in the preamble of the Proposed Rules (43 Fed. Reg. 243 at 58950) to the effect that these factors were used in developing a candidate set of characteristics.

The Agency believes that the commenters misunderstood the Agency's use of information from damage cases and its use of regulations of other agencies in establishing both criteria for characteristics and the characteristics. The Agency used these factors as "points of departure" in initially identifying candidate criteria and characteristics. Ultimately, however, the Agency based its development of criteria and characteristics primarily on relevant scientific and technical information and principles. However, data from damage cases have been used as secondary and supporting information where they are relevant. Regulations of other agencies also have been similarly used.

One commenter felt that test procedures should be validated for precision and accuracy before being used for regulatory purposes. This is also the policy of the Agency, as discussed earlier in this document, and as discussed in more detail in the Background Documents supporting the individual characteristics. All tests employed in the characteristics of hazardous waste have been standardized

or validated either by the Agency or other regulatory or standard-setting organization (e.g., the ASTM in the case of flash point). Standardization and validation of the Extraction Procedure has been completed since its proposal. This is more fully described in the Background Document for the EP toxicity characteristic and has, in part, been discussed in several studies which were made available, for public comment, since proposed rulemaking.

Finally, one commenter suggested that the criterion of "available" test protocols be expanded to reflect currently commercially available analytical methodology approved and disseminated by EPA. The Agency agrees that the criteria for characteristics should specify that test protocols be commercially available. It believes that point had been clearly expressed in the proposed rules. In order to further clarify this point, however, the final criteria for characteristics have been modified to specify that test protocols must be "reasonably within the performance capability and capacity of generators... or private-sector laboratories that are available to serve generators..." (see §261.10(a) (2)(i) of the Final Rules). With respect to the comment that test methods should be approved and disseminated by EPA, the Agency believes that prescription of a test protocol in the Final Rules constitutes EPA approval and that descriptions of the test protocol in the Final Rules, where they are not widely available in published literature, constitutes adequate dissemination.

Other than the changes mentioned above in response to comments, the final criteria for identifying characteristics have not been substantially changed from those proposed. It has been edited, however, to provide clearer exposition.

Comments on Criteria for Listing. A large number of commenters found the proposed criteria for listing hazardous wastes for which characteristics had not been established (§250.12(b)(2)) to be insufficient. Their arguments were many and varied. Many felt that the mere articulation of the statutory definition did not constitute establishment of the criteria required by Section 3001(a) of the Act. They contended that this approach was circular (a waste is a hazardous waste if it meets the definition of a hazardous waste) and was vague and non-specific. They felt that it constituted an abrogation of a non-discretionary duty under Section 3001(a) of the Act to establish criteria that do not expand on and further quantify the definition of hazardous wastes given in the Act. They argued that the real criteria appeared to be those characteristics presented in the Advance Notice of Proposed Rulemaking (ANPR--concurrently published with the proposed rules on December 18, 1978). As such, they contended that EPA was proposing to list hazardous wastes against criteria that had not been proposed and criteria that, in fact, were quite tentative by virtue of their publication in pre-proposal form in an ANPR. They found the criteria, when combined with the characteristic-like delisting rules (§250.15(a)), to be a capricious double standard, allowing EPA to assume a vague, ill-defined and perceivably light burden in listing wastes (apparently not using the delisting test protocols to support the listing of wastes) while requiring the regulated community to undertake a greater and inflexible burden of specific and sophisticated testing to delist such wastes. One commenter equated this approach to being declared guilty until proven innocent. These commenters felt that EPA should be held to the same rules for listing as required for

delisting. In summary, these commenters felt that EPA should not and legally could not list hazardous wastes against the proposed §250.12(b)(2) criteria unless or until these criteria were expanded and converted into highly specific characteristic-like criteria.

The Agency agrees that the proposed criterion for listing wastes for which no characteristics had been established was not explicit and it agrees that Section 3001(a) of RCRA clearly requires the Agency to establish specific criteria for listing hazardous wastes. Accordingly, the Agency has established a more specific and expanded set of listing criteria in §261.11 and these are discussed below. Because these criteria have been extensively expanded over the proposed listing criteria, they are being promulgated as Interim Final Rules and public comments are being invited on them. It is the Agency's intent to review and consider any public comments received and to promulgate §261.11 as a Final Rule, with any appropriate changes justified by public comments, by or before the effective date of Part 261.

The Agency admits that the implied criteria for listing wastes because of organic toxicity, genetic activity, bioaccumulation potential and radioactivity were largely the characteristics presented in the ANPR (however, other factors outside of these characteristics were also considered in the listing of these wastes). After consideration of the comments received on the ANPR and the Proposed Rules, and after considerable reassessment of the whole matter of listing criteria, the Agency has concluded that the characteristics presented in the ANPR are not sufficient either as characteristics or as criteria for listing. First, as currently constructed and presented in the ANPR, they fail to incorporate all of the multiple factors necessary to characterize the

hazardousness of wastes for the purpose of regulation under Subtitle C. This failing is seen in the subsequent discussion on the interim final listing criteria where multiple factors are incorporated therein. Secondly, with respect to their use as characteristics, most of the ANPR characteristics depended on testing methods that are not yet fully standardized and validated for wide use by a diverse regulated community or are not all widely used by or available to the regulatory community. Although the Agency intends to further develop and perfect the ANPR characteristics, it has concluded that they are not now sufficiently complete and sufficient for broad use as characteristics or as unaugmented criteria for listing.

A large number of commenters were more specific in pointing out the shortcomings of the proposed §250.12(b)(2) criteria or, alternatively, pointing to the specific provisions that should be incorporated in that criteria. Several found that the criteria gave no consideration to quantity and/or concentration. Others found it deficient in the consideration of synergistic effects, degradation potentials and degree of toxicity combined with potential exposure. Some believed that the criteria should account for typical or probable management practices and, in this same vein, one commenter thought that the criteria should consider the management aspects of commingling of incompatible wastes.

The Agency concurs with the comments that urged that the criteria for listing hazardous waste where an explicit characteristic has not been established, must consider multiple factors including quantity, concentration, degree and nature of toxicity, persistence, degradation, and possible and plausible improper management practices. The Agency recognizes that the

proposed criteria for listing hazardous waste did not specifically provide for consideration of multiple factors; however, it did not preclude their consideration.

The Agency does not agree that the criteria for listing can or should explicitly consider synergistic effects or the commingling of incompatible wastes. These factors are very site specific and the Agency has concluded that they are best considered in the management standards under Parts 264 and 265 and in the issuing of hazardous waste management facility permits under Part 122.

A few commenters believed that the criteria should be structured so as to avoid listing wastes that would be adequately managed in facilities meeting the guidelines promulgated under Subtitle D of the Act. The Agency does not agree with this comment and the reasons are discussed in the following section in relation to the statutory mandate to employ a criterion of "improper management" in listing wastes.

A few believed that the criteria should account for small quantities; some of these contending that the criteria should provide coverage of all small quantities of very hazardous wastes and others contending that it should serve to exclude small quantities. One commenter was concerned about the inclusion of small quantities of municipal wastes. The Agency has given considerable attention to the regulation of small quantities and these are discussed in a separate background document covering the applicability of the Final Rules to small quantity generators (also see §261.5 of the Final Rules). Coverage of municipal wastes (household wastes) is discussed in the preamble to Part 261.

The Agency agrees with most of these comments, and these comments, have resulted in a re-development of the criteria for delisting. These substantive delisting criteria are found in §§260.22(c)(d) and (e) and are being promulgated as Interim Final Rules because their counterpart criteria for listing hazardous wastes are being promulgated as Interim Final Rules.

The substantive delisting criteria are, very simply, the inverse of the listing criteria of §261.11. For those wastes listed because they exhibit any of the characteristics of hazardous waste, the criterion for delisting is to demonstrate that the waste from an individual facility does not exhibit the characteristic which caused the Agency to list the waste (see §260.22(c) of the Interim Final Rule). For those wastes listed because they meet the listing criterion of §261.11(a)(2)--Acutely Hazardous Wastes having the Hazard Code "H"--the delisting criterion (see §260.22(e)) is to show that the waste does not meet the listing criterion of §261.11(a)(2)--that is, that it is not acutely toxic--and that it does not meet the criterion of §261.11(a)(3) when considering the factors listed therein. The latter showing is necessary because, even though a waste may be found not to be acutely hazardous in accordance with §261.11(a)(2), it may still be less acutely toxic or chronically toxic in accordance with §261.11(a)(3). When the Agency lists a waste under §261.11(a)(2), it presumes that the waste also meets §261.11(a)(3).

Finally, for wastes listed because they meet the listing criterion of §261.11(a)(3)--Toxic Wastes having the Hazard Code "T"--the delisting criterion (see §260.22(d)) is to show that the waste either does not have the hazardous constituent(s) that caused the Agency to list the waste or that consideration of the factors listed in §261.11(a)(3) argue against listing the waste as a hazardous waste.

The basic rationale for these delisting criteria is the same as that of the Proposed Rule in the sense that delisting is a means of showing that an individual generator's waste is fundamentally different from the class or type of hazardous waste listed and therefore should not be listed. In fact, the delisting procedure is actually put in the form of a rulemaking procedure. Thus, delisting petitions will be treated as rulemaking and a successful petition will result in an actual modification of the listing description; e.g., Subpart D would be modified to show that the listing is no longer "waste A from process B" but instead "waste A from process B except those wastes generated by the XYZ plant."

The rationale for the substantive criteria, however, has changed significantly from that employed in the Proposed Rule. The interim final criteria are no longer based on specified testing[1/] but, as stated above, are based instead on a showing against the same considerations that went into the listing of a waste. This change has been necessitated by the changes made in the criteria for listing. The Agency reasoned that persons who petition for delisting a waste should be held to the same showing that the Agency made in listing the waste and should not be held to a specific testing regime that may or may not have been used in listing the waste. Accordingly, delisting petitions should show why and how the factors considered by EPA in listing a waste do not apply to the individual waste for which delisting is requested. For each

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1/ Except in the case of delisting wastes that are listed because of characteristics.

waste, the showing for delisting will vary because the factors considered in listing each waste varies.

The Agency believes that the delisting criteria are fully consistent with the listing criteria and are appropriate and equitable in the sense of requiring consideration of the same factors that went into the initial listing determination. The Agency believes that these features meet the concerns of most of the commenters.

Many comments were received on the procedural aspects of delisting. These have been carefully considered and are discussed in Section VII C of the preamble to Part 261. Consideration of these comments and the Agency's own reconsideration of the Proposed Rule have led to restructuring and modifications which are reflected in §§260.20 and 260.22, and are also discussed in the preamble to Part 261.

A fair number of commenters were concerned about the inadequacy or potential inadequacy of disposal capacity and argued that the criteria should operate to list only the most hazardous wastes and avoid listing the less hazardous and certainly the non-hazardous wastes to avoid exceeding a limited disposal capacity throughout many parts of the country. In a variant on this theme, one commenter thought that the identification and listing of wastes under Section 3001 of the Act (and even the generator requirements under Section 3002) should be deferred until after the management requirements of Section 3004 are promulgated and well in place. These issues are discussed in the preamble to Part 261. In brief, the Agency does not have the statutory authority to avoid listing wastes because of potential disposal incapacity. It can, however, and does intend to consider capacity problems in its implementation of the regulations and in the

scheduling and issuing of permits.

Several commenters expressed concern about the stigma that would attach to hazardous wastes and believed that the criteria should take this factor into account, particularly with respect to wastes that have re-use or recycling potential. These commenters contended that the stigma of the hazardous waste label would serve to dissuade the beneficial re-use or recycling of many marginally hazardous wastes which were listed. The issue of regulating hazardous wastes that are re-used or recycled, including the subsidiary stigma issue, is fully discussed in the preamble to Part 261.

Several commenters were concerned that the listing of classes or types of waste could encompass non-hazardous members of the class (wastes that are fundamentally different than other members of the listed class of wastes). These commenters believed that the criteria should consider this aspect of listing. This is discussed in the following section.

Finally, one commenter pointed out that the statutory definition of hazardous was based on terms of "substantial....hazard" not "may cause harm" as stated in the preamble of the proposed rules. The Agency concurs and has been careful to base the interim final criteria for listing on the "substantial hazard" test of the statute (see discussion in next section).

Reconsideration of the Criteria for Listing In consideration of the public comments, the Agency has provided a much more expanded set of criteria for listing hazardous waste than proposed and has devoted a complete section of the Final Rules (§261.11) to these criteria. In overview, §261.11 provides the following:

- §261.11(a)(1) provides the criterion for listing hazardous wastes because they exhibit any of the characteristics identified in Subpart C
- §261.11(a)(2) provides the criterion for listing hazardous wastes because they are acutely toxic or acutely hazardous wastes and may be fatal to humans in low doses
- §261.11(a)(3) provides the criterion for listing hazardous wastes because they contain one or more of the hazardous constituents listed in Appendix VIII and may pose substantial present or potential hazard to human health or the environment when improperly managed
- §261.11(b) provides for listing types or classes of hazardous wastes as opposed to individual hazardous wastes
- §261.11(c) provides for the establishment of exclusion limits for hazardous wastes listed in Subpart D, where such exclusion limits are applicable to the special requirements for small quantity generators under §261.5(c)

In addition, Appendix VIII of the Final Rules provides a list of toxic and genetically active constituents which are employed in the criterion for listing Toxic Wastes under §261.11(a)(3).

The three criterion of §261.11(a) all draw heavily on the statutory definition of hazardous waste found in Section 1004(5) of RCRA. The criterion in §261.11(a)(2) is based on part (A) of the statutory definition, and the §261.11(a)(3) criterion is based on part (B) thereof, read in conjunction with Section 3001. The following discussion describes the Agency's thinking in establishing these three criteria.

1. Criteria for Listing Wastes Possessing a Characteristic

EPA's first criteria for listing is if a waste exhibits the characteristic of ignitability, corrosivity, reactivity, or EP Toxicity. The listing determination is quite straight forward, showing whether or not the waste in fact possesses the appropriate characteristic.

2. Criteria for Listing Wastes Which are Acutely Hazardous

This criteria implements part (A) of the statutory definition of hazardous waste which provides that wastes are hazardous if they "may cause, or significantly ontribute to an increase in serious irreversible, or incapacitating illness." The Agency believes that this language is intended to provide the basis for wastes that are acutely toxic or otherwise acutely hazardous and may pose a direct hazard to human health.

The Agency believes that part (A) of the statutory definition was intended to cover wastes that are acutely hazardous to human health (whereas §261.11(a)(3) addresses wastes which may pose chronic as well as acute effects, and may pose a substantial adverse hazard to humans and environmental receptors other than humans). Use of terms such as "increase in mortality", "increase in serious irreversible...illness" and "increase in serious...incapacitating reversible illness" seem to connote that the focus of this provision was on human health. The Agency interprets these terms to apply to acute effects as opposed to chronic effects, because long-term chronic effects generally necessitate some consideration of environmental fate and waste management, which are not mentioned in the definition (see discussion below). Furthermore, consideration of chronic effects are covered by part B of the hazardous waste definition, and the Agency believes Congress intended part A of the definition to have some independent force (see H.R. Rep. No. 94-1491, 94th Cong., 2d Sess. 25).

The Agency also believes that for this class of wastes, environmental fate and waste management techniques are not considerations in determining hazard. The Agency believes that the environmental fate factors of persistence, degradation potential and bioaccumulation potential in Section 3001(a) have little or no importance because the language of 1004(5)(A)

describes a type of hazard which is acute and therefore may be operative before these factors can manifest their effects. Moreover, the Agency believes that the factor of improper management is not important under this element because the language connotes a type of hazard that is capable of operating under a wide range of management conditions from improper conditions up to conditions that would constitute proper management for other wastes. In fact, whereas the phrase "improperly...managed" is an integral element of part (B) of the statutory definition of hazardous wastes, the absence of this phrase in part (A) of the definition signifies that improper management is not an important factor.

Accordingly, the §261.11(a)(2) criterion provides for listing wastes that are "found to be fatal to humans in low doses." Recognizing however, that acute effects data on humans is limited to scattered epidemiological observation and do not begin to cover the chemicals and wastes that very clearly are acutely hazardous to human, the §261.11(a)(2) criterion provides for use of surrogate acute effects data, viz., oral LD50, inhalation LC50 and dermal LD50 toxicity data as measured, respectively, with the rat, the rat and the rabbit as test animals. The Agency is confident that the

values used -- respectively, less than 50 milligrams for kilogram, less than 2 milligrams per liter and less than 200 milligrams per kilogram -- are levels that will produce definite acute effects -- increased mortality and increased serious illness -- in humans even though the data derive from animal studies. These values are selected with reference to values used by groups such as the Department of Transportion, Consumer Product Safety Commission, and National Academy of Sciences use in determining if substances are poisonous or acutely toxic.

These surrogates serve to enable the use of the §261.11(a)(2) criterion to list acutely toxic wastes. The Agency believes it is also essential to list wastes that are acutely hazardous to humans for reasons other than acute toxicity; e.g., wastes that are highly reactive and produce acute hazards by virtue of their explosivity or generation of acutely hazardous vapors, or wastes containing substantial concentrations of potent carcinogens. To reach these wastes, the §261.11(a)(2) criterion incorporates the verbatim language of part (A) of the statuory definition of hazardous wastes.

In the interim final listing of wastes in Subpart D, the §261.11(a)(2) criterion has been used exclusively to list commercial products that appear in §261.33(e). The use of this criterion for this listing is discussed in the background document covering §261.33. This limited use of this criterion is not intended, however, to denote that the criterion cannot

be used to list wastes in §§261.31 or 261.32. It merely denotes that the Agency does not now have data that supports the listing of generic or process wastes because of acute hazardousness.

The effect of the §261.11(a)(2) criterion is to create a class of listed wastes that are clearly more immediately hazardous than the other wastes listed. The higher class of hazardous wastes created by the §261.11(a)(2) criterion is reflected in two other provisions of Part 261. Under §261.5(c), much lower exclusion limits than 1000 kilograms per month are created for small quantity generators that produce or accumulate wastes listed under this criterion and, under §261.33(c), containers that have held wastes listed under this criterion are, as a class, listed as hazardous wastes.

3. Criteria for Listing Toxic Wastes

a. Overall Methodology in Applying the Criteria

§261.11(a)(3) of the Interim Final Rule provides the criterion for listing Toxic Wastes, i.e., wastes that are hazardous wastes because they contain toxic or genetically active constituents and are not appropriately listed under the criteria of §§261.11(a)(1) or 261.11(a)(2).[1/] This criterion is used to list most of the hazardous wastes listed in §§261.31 and 261.32 of Subpart D and, as such, is probably the most important of the listing criteria. This criterion provides that a solid waste is a hazardous waste if it contains any of the hazardous constituents listed in Appendix VIII unless the Agency, after considering one or more of the factors delineated in the criterion, determines that the waste does not meet part (B) of the statutory definition of hazardous waste. The factors that the Agency may consider include:

- the nature of the toxicity of the hazardous constituent listed in Appendix VIII

1/ Section 261.11(a)(2) provides the criterion for listing acutely toxic and otherwise acutely hazardous wastes. Acutely toxic wastes, therefore, are not appropriately listed under §261.11(a)(3). Section 261.11(a)(1) provides the criterion for listing wastes that possesses any of the characteristics identified in Subpart C including the characteristic of EP toxicity. A waste that possesses EP toxicity could be listed under either §261.11(a)(1) or §261.11(a)(3) and, where this is the case, the Agency will use §261.11(a)(1). However, a waste that does not possess the characteristic of EP toxicity and cannot be listed under §261.11(a)(1) may still be hazardous because, as discussed in the EP Toxicity background document and the preamble, the EP toxicity characteristic does not necessarily encompass all those wastes which possess hazardous concentrations of the constituents delineated in the EP toxicity characteristic. In addition, factors other than those taken into account by the characteristic may justify such listing.

- its concentration in the waste
- its potential to migrate or otherwise escape from the waste
- its persistence and potential for degradation in the waste
- its bioaccumulation potential
- the plausible and possible types of improper management to which the waste may be subjected
- other appropriate factors

These factors, their importance, and their application, are discussed in more detail below.

The first consideration is whether the waste contains a constituent listed in Appendix VIII. Appendix VIII lists 387 toxic and constituents that have been shown to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms and clearly "may pose substantial present or potential hazard to human health or the environment", or "cause or significantly contribute to an increase in mortality or...serious...illness." Appendix VIII includes most of the toxic constituents listed under Section 307(a) of the Clean Water Act and many of the constituents listed under Section 311 of that Act. It also includes those constituents regulated under section 112 of the Clean Air Act and, in addition, covers the constituents regulated under the Primary Drinking Water Standards of the Safe Drinking Water Act, Finally, it includes genetically active constituents which the Agency's Cancer Assessment Group has evaluated and determined to present sufficient threat to human health to warrant appropriate

regulation under the several regulatory programs managed by the Agency and it includes the most acutely toxic substances listed in the NIOSH Registry or regulated by the Department of Transportation as a transportation hazard. In short, Appendix VIII tracks the several lists of hazardous constituents being used by the Agency. For each constituent listed in Appendix VIII, the Agency also has prepared a Health and Environmental Effects Background Document.1/ Each document describes and evalutes the adverse effects of the constituent to humans and other life forms and substantiates that the constituent poses a substantial hazard to human health or the environment.2/

If the waste contains one or more of the hazardous constituents listed in Appendix VIII, the waste is presumed to be hazardous, unless after considering other factors, EPA concludes that the waste is not capable of posing a substantial present or potential hazard to health or the environment

1/ These Background Documents will be made available for public comment when the Part 261 rules are promulgated. This will be in conjunction with the invitation for public comments on the criteria for listing (§261.11), Appendix VIII and the listing of hazardous wastes (Subpart D) which are being promulgated as Interim Final Rules. The Agency intends to consider any comments received on these Interim Final Rules and the Background Documents and to make appropriate changes in the rules, including Appendix VIII, prior to promulgation of Final Rules for these segments.

2/ The Agency recognizes that Appendix VIII is far from a complete list of all hazardous constituents. It includes only those constituents for which the Agency has sufficient data or has been able to review the available data in order to make listing determinations. It will be the Agency's intent to amend Appendix VIII as it has information and capacity to do so.

when improperly managed. Very simply, the first determination, if affirmative, creates a presumption that the waste is a hazardous waste. The second determination serves to confirm or reject this this presumption. If the presumption is confirmed, the Agency will list the waste as a hazardous waste. If rejected, the Agency will not list the waste as a hazardous waste.

The Agency believes this approach to be fully in accord with the statutory scheme. Under section 1004(5)(B), a waste is hazardous if it "may pose a substantial present or potential hazard to human health or the environment when improperly managed." (Emphasis added.) This is obviously a broad standard which affords the Agency considerably discretion. Thus, use of the conditional "may", reinforced by the reference to "potential" hazard, indicates that the administrative focus is to be on those wastes capable of causing substantial harm. Further, wastes are hazardous if they could cause substantial harm if managed improperly, whether or not they are in fact handled in such a way as to minimize or obviate the risk of danger. In the toxicity listing criteria, the Agency therefore has focused on waste's potential capacity for harm by identifying particular constituents which clearly pose substantial hazard to human health or the environment. It is reasonable to suspect or presume that any waste that contain any of these substances may pose substantial hazard.

There is ample evidence that the hazardous constituents contained in wastes often can migrate or otherwise escape from the waste and enter into the environment where they can pose a substantial hazard. Further, there is ample evidence that wastes often are improperly managed and, when so managed, the migration or escape of hazardous constituents into the environment is highly probable.[1/]

As noted, once it is determined that a waste contains one or more of the Appendix VIII constituents, it will be presumed to be hazardous unless, often considering certain designated factors listed in 261.11(a)(3)(i) - (xi), EPA determines that it does not meet the definitions of hazardous waste in Section 1004(5)(B). The specific factors (discussed in detail below) are drawn from Sections 1004(4) and 3001 of the Act, or are otherwise deemed probative to the issue of hazardousness. Congress in fact directed the Agency to consider multiple factors when listing as hazardous any waste not found to be "hazardous per se" (in the Agency's interpretation, not meeting the criteria of §261.11(a)(2)):

> The listing of any substance not found to be hazardous per se should be accompanied by an explanation as to when such wastes are considered hazardous. Such explanation should relate to the quantity, concentration,...toxicity, persistence and degradability in nature, potential for accumulation in human tissue and other factors..." (H.R. Rep. 94-1491 at 25).

1/A further advantage to the Agency's approach is that it effectively alerts the interested public to the wastes the Agency is considering listing, and thus provides an opportunity to the public to make appropriate plans.

It should also be mentioned that the companion Senate bill to RCRA contained a scheme very close to the present §261.11(a)(3). It provided that at a minimum the Administrator should designate as hazardous each mixture of solid waste which contained a toxic or hazardous substance listed in section 112 of the Clean Water Act or sections 307(a) and section 311(b) of the Clean Water Act unless consideration of listing criteria indicated the waste was not hazardous. S.Rep. No. 94-988, 94th Cong., 2d sess. 14. The Senate bill thus envisioned a presumption for listing based on the presence of a toxic constituent, which presumption may be rebutted by consideration of further factors. Although this bill was not ultimately adopted, the concept was never rejected, and again suggests that the Ageny's overall listing methodology reflects congressional intent.

b. Discussion of Factors to be Considered in Determining the Validity of the Presumption of Hazardousness Based on Presence of an Appendix VIII Constituent.

§261.11(a)(3) requires consideration of the following factors before a final listing determination is made:

-- The nature of the toxicity presented by the constituent.

-- The concentration of the constituent in the waste;

-- The potential of the constituent or any toxic degradation product of the constituent to migrate from the waste into the environment under the types of improper management considered.

-- The persistence of the constituent or any toxic degradation product of the constituent;

-- The potential for the constituent or any toxic degradation product of the constituent to degrade into non-harmful constituents and the rate of degradation;

-- The degree to which the constituent or any degradation product of the constituent bioaccumulates in ecosystems;

-- The plausible types of improper management to which the waste could be subjected;

-- The quantities of the waste generated at individual generation sites or on a regional or national basis;

-- The nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes containing the constituent;

-- Actions taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent.

-- Such other factors as may be appropriate.

These factors generally involve the waste's inherent potential for causing harm (the nature of the toxicity presented by the constituent(s) of concern, and whether the constituent(s) is present in significant concentrations, and whether the waste is generated in large quantities and the environmental fate and transport mechanisms to which waste constituents are subject (whether waste constituents may migrate from the waste if improper management occurs, persist in the environment, and reach environmental receptors so as to pose a potential substantial hazard). In certain cases, actual damage incidents involving the waste or waste constituents demonstrate empirically that waste constituents may migrate, persist, and cause substantial harm if mismanaged.

As explained more fully in the preamble to the Section 3001 regulations, in weighing these various factors, the Agency's principal focus is on the identity of and nature of toxicity of the waste's constituents, and whether the constituents are present in significant concentrations; in other words, on the waste's potential capacity to cause harm. This approach, as already noted, is justified by the conditional wording of the hazardous waste definition, which commands implicitly that the listing mechanism be aggressive enough to bring into the hazardous waste management system any waste that might pose a substantial potential hazard if mismanaged.

Environmental fate and transport issues are certainly relevant

in determining whether substantial hazard could result from waste mismanagement. The Agency does not, however, seek to demonstrate that waste constituents will migrate and persist in sufficient concentrations to cause substantial hazard. Instead, fate and transport information is considered to determine if the potential for harm inherent in the waste by virtue of its composition will not eventuate. There thus must be fairly strong assurance that mismanaged waste constituents will not migrate and persist to cause substantial hazard before the Agency will choose not to list a waste on this basis. The degree of assurance required also increases as the relative toxicity of waste constituents increases, or as waste constituents comprise a higher percentage of the total waste.[1/]

The following discussion explains in more detail the relevance of the particular factors used in determining whether the listing presumption (based on the presence of Appendix VIII constituents) is valid. The nature of the toxicity of the waste constituent(s) is clearly important. The more dangerous the waste constituent, the likelier the Agency is to list the waste. Carcinogens are of special concern, since one single exposure may result in substantial hazard. (See EPA Water Quality Criteria, 44 FR 15926, 15930 (March 15, 1979)).

1/Needless to say, the relative balancing of these factors varies with each waste, as explained in the background documents covering each individual listing determination.

The concentration of the hazardous constituent in the waste is an important factor. Obviously, higher concentrations enhance the possibility that the constituent will pose substantial hazard.

The potential for the hazardous constituent to migrate or otherwise escape from the waste and enter into the environment is an important factor. By and large, hazardous constituents that do not migrate from the waste do not cause hazardous effects because direct exposure of humans and other life forms to wastes is limited.2/ For example, humans rarely do directly ingest, inhale or otherwise come into intimate contact with the waste to suffer the consequences of the toxic effects of its constituents. For the most part, the concern about the waste is the migration of the hazardous constituents into groundwaters, surface waters or air where human or other life-form exposure can take place. Accordingly, the migratory potential of waste constituents via each realistically - occurring exposure pathway must be considered. Migration and transport mechanisms include solubilization of the hazardous constituents in aqueous solutions and the

2/ This is not always the case. Occasionally, humans and other life forms are directly exposed to wastes containing hazardous constituents and the toxic effects of the constituents are direct. Some real examples are where the waste is inadvertently mixed with human or animal foods, where hazardous waste containers are re-used for a variety of purposes and where children, workmen and animals come into direct contact with the wastes, usually unknowingly (children and animals at Love Canal) or accidently (personnel handling the waste).

attendant leaching of these constituents into groundwaters or draining into surface waters; the volatilization or sublimation of these constituents and the attendant migration into the atmosphere; the incomplete thermal destruction of the hazardous constituents when the waste is burned and the attendant escape of these constituents into the atmosphere. In addition, migratory potential of the toxic degradation products of waste constituents (if formed) also must be considered, since the migration or escape of these by-products into the environment can be as important as the migration or escape of the parent hazardous constituent.

The persistence, or alternatively, the degradation potential of the hazardous constituent(s) also is important. Obviously, the hazardousness of a hazardous constituent is of much less concern if it rapidly degrades in the waste or in the environment, since the likelihood of exposure is reduced. There are some organic constituents which degrade rapidly in water, (in hours, days or weeks), while at the other end of the spectrum, there are constituents that degrade very slowly or do not degrade at all (e.g., toxic heavy metals) and therefore are highly persistent. Clearly, the hazardousness of a persistent hazardous constituent is enhanced because there exists a longer opportunity to migrate to a receptor (a human or animal). Again, as above, the persistence or degradation potential of not only the hazardous constituent itself but also

the degradation by-products thereof can be of concern. For example, the parent hazardous constituent can be thermally destroyed at a given set of burning conditions (temperature, dwell time, etc.) but create highly toxic daughter products that escape into the atmosphere and pose substantial hazard to human health or the environment.

The potential for bioaccumulation can be an important factor. Frequently, the toxic effect of a hazardous constituent is significantly magnified (as much as several thousand-fold) through accumulation through the food chain so that the ultimate receptor (usually humans or food fish or animals) are subjected to very high constituent concentrations. The effects of PCB's, for example, are manifested largely because of bioaccumulation. Similarly, the hazardous constituent might bioaccumulate in the final receptor from low level exposure over a period of time. For example, cadmium can be accumulated in humans over a life-time of exposure to ultimately cause an injurious effect.

The various combinations of these factors also are important. A high concentration of a moderately toxic constituent may cause a waste to pose a substantial hazard. On the other hand, a low concentration of a highly toxic constituent may cause the waste to have such an effect. Other combinations may cause the Agency to reach a conclusion that confirms the presumption of hazardousness. These include but are not limited to: moderate to weak toxicity

and low concentrations but high persistency or high potential to bioaccumulate or both; moderate to weak toxicity but high concentration, high migration potential or high persistency; and low concentrations, but strong toxicity, high migration potential, high persistency or high bioaccumulation potential. In short, there are many combinations of the above discussed factors that influence the hazardous potential of a waste that contains any of the hazardous constituents listed in Appendix VIII.

In addition to the foregoing, the factors of quantity of waste and plausible and possible types of improper management to which the waste may be subjected are important. Obviously, higher quantities of wastes have the potential of releasing greater amounts of hazardous constituents (assuming that the constituents are capable of migrating from the waste), and thereby contaminating larger expanses of groundwater, increasing exposure and risk. Concern, however, is not confined to the quantities of wastes generated at individual facilities. In some cases, the aggregate quantities of wastes generated nationwide or in individual areas of the country may be important. Also, the aggregate quantities of different wastes containing the same hazardous constituents may be of concern. For example, the individual small quantities of degreasing solvents may not, as individual quantities, pose a substantial hazard, but the large aggregate national quantity and the large quantities generated in metropolitan areas present a

significant insult to air quality and contribute to substantial human health hazard.

Similarly, individual quantities of wastes may not pose a substantial hazard when disposed of separately, but do pose a substantial hazard when aggregated at a particular disposal site.

The improper management to which a waste may be subjected is often a very influential factor in defining the hazardousness of the waste. The statute of course mandates that improper management is a factor in listing (and identifying characteristics of) hazardous waste (except for very hazardous wastes listed under part (A) of the statutory definition of hazardous waste). The Agency also recognizes that it must be reasonable in selecting the standard; the statue requires that the potential hazard posed by the waste be substantial before a waste is hazardous. Hazardous arising from wholly unrealistic or improbable waste management, in the Agency's view, are not substantial.

In exercising its discretion, therefore, the Agency concludes that considerations of improper management should be limited to plausibly or possible - occurring mismanagement. Furthermore, there is no single standard of improper management; rather a scenario of improper management has to be developed for each waste, based upon the types of management the waste could normally undergo. Thus, for a waste which is typically

land disposed, a scenario of improper land disposal should be used; that is, a scenario that assumes little protection of groundwater or surface water contamination from the leaching or drainage of hazardous constituents from the waste. For a waste which is capable of being disposed by burning, a scenario of improper burning should be employed, a scenario that is based on comparatively low burning temperatures, dwell times and other conditions and is based on little or no air emission control. For a waste that might manifest its hazardous properties in transportation or storage, a scenario of improper packaging or containerizing and inadequate labeling should be assumed. In all cases, the scenario should be one that is reasonably possible and plausible, not one that very rarely would occur or is otherwise unrealistic.

It must be emphasized that the fact that a waste is properly managed by particular generators or particular classes of generators does not make the waste non-hazardous, as the statute requires the determination of hazardousness to consider potential dangers when improper management occurs. The Agency is quite aware of the fact that whether or not a waste may pose a substantial hazard depends heavily on how it is handled or managed. Undoubtedly, many of the wastes listed in Subpart D under the criteria for listing are sometimes managed in a manner that alleviates or even eliminates their hazardous risk. However, there is no guarantee that this

always is or will be the case and, in fact, there is ample evidence in recorded damage cases that it frequently is not the case. Consequently, the Agency believes that the statute mandates the listing of wastes against management scenarios that would result in the greatest hazardous risk, provided, of course, that such scenarios are not artificial or unrealistic and are reasonably plausible and possible for the given type of waste.

Additional Considerations

The Agency recognizes that there will be those who might wish to have the Agency use the criterion in a very broad or very narrow way, as will fit their particular interests. At one end of the spectrum, there will be those who will expect the Agency to exhaustively consider all possible factors to test the presumption of hazardousness and further, to reject the presumption on the slightest negative finding from any of the factors. At the other end of the spectrum, there will be those who will expect or will petition the Agency to initiate listing of a waste that has the slightest potential of containing any of the hazardous constituents listed in Appendix VIII and, further, to maintain the presumption and list the waste in the absence of data necessary to reasonably consider the potentially relevant factors. The Agency believes that both expectations would overreach the wise and reasonable use of the criterion. It believes, on one hand, that an exhautive consideration of all possible factors will rarely

be necessary. Instead, consideration of only those factors that reasonably can be expected to support or challenge the presumption is sufficient. It believes, on the other hand, that the public interest will not be well served by the listing of wastes on presumptions only, with little or no consideration of other factors. Many wastes contain one or more of the hazardous constituents listed in Appendix VIII but do not pose substantial hazard because of the low concentration or the low quantity of the waste or because of other factors or combinations thereof. Consequently, the Agency intends to use the §261.11(a)(3) criterion with considerable discretion to avoid abusive use.

Finally, the §261.11 (a)(3) criterion may be used to list wastes that contain any of the toxic metals or pesticides listed in Table 1 of the EP toxicity characteristic (§261.24) but which do not fail that characteristic and so cannot be listed under §261.11(a)(1). The EP toxicity characteristic is based on the concentration of any of these constituents in the extract of the waste exceeding 100 times the maximum concentration limits in the Primary Drinking Water Standards (PDWS). As such, this characteristic identifies wastes that have the capacity to release high concentrations of persistent hazardous constituents 1/ into the groundwater under a plausible scenario

1/ The toxic metals do not degrade and therefore are persistent. The toxic pesticides degrade very slowly and therefore are highly persistent.

of improper land disposal. The EP toxicity characteristic serves to identify only the most hazardous of those wastes that are hazardous because of their content of PDWS contaminants, since the characteristic is binding (i.e., a generator either passes or fails the test), so that there is some risk of over inclusiton if the test is too rigorous. The listing criterion of §261.11(a)(3) therefore is used to identify the remaining subset of those wastes, i.e., wastes, which after individualized consideration are shown to pose a substantial potential hazard if improperly managed, even though the EP extract of the waste contains less than 100 times the PDWS contaminants. When listing one of these wastes, the Agency usually identifies factors not measured by the EP Toxicity Characteristic which justify the listing, including the concentration of PDWS contaminants in the waste (as opposed to the waste extract), quantity of waste generated, damage incidents involving the waste, or indicia of actual waste mismanagement. Other factors are attenuative exposure pathways for the waste, such as exposure via surface water or air, scenarios of improper management, such as improper land treatment or land disposal where food crops are or may be grown, or improper burning. In the case of the first of these examples, lesser concentrations of the toxic constituents than defined by the EP toxicity characteristic may be sufficient to contaminate soils and permit food crop uptake of significant amounts of some of the toxic metals, such as

cadmium or lead, and thus pose a substantial hazard to human health through consumption of the contaminated food crop. In the case of burning, lesser concentrations than defined by the EP toxicity characteristic may result in significant atmosphere emission of the toxic metals that may pose substantial hazard to human health through inhalation where wastes may be plausibly mismanaged.

4. Listing of Classes or Types of Wastes

§261.11(b) of the Final Rules provides for listing of classes or types of waste, so-called generic listings, which encompass wastes generated in the production of a variety of products. It is the intent of the Agency to use this criterion primarily to list classes or types of wastes where the Agency determines that there is a high likelihood that most members of the class or type of waste are hazardous pursuant to the criteria. The legal justification for this approach is set out in the preamble to the Section 3001 rules. As with listings of wastes generated during production of particular products, the delisting mechanisms allows individual generators to show that their wastes are not hazardous.

It should also be noted that even where waste listings encompass only wastes from the production of a single product, the Agency typically will list a class or type of waste based on information from representative individual facilities within the class or type, and obiously not on information from all facilities generating the waste. Thus, even these

non-generic listings in a sense involve listing of classes or types of wastes. Again, the delisting mechanism is available to individual generators if their waste differs fundamentally from that described in the listing document.

5. Criteria for Listing and Small Generator Exclusion Limits

§261.11(c) provides for use of the listing requirements to establish, in §261.5(c), exclusion limits for specific hazardous wastes listed in Subpart D. The exclusion limits set forth in §261.5(c) apply to small quantity generators. Where the Agency believes that the general exclusion limits of 1000 kilograms per month is insufficient to protect human health or the environment with respect to certain wastes, it will set lower exclusion limits for such wastes. The considerations that go into the establishment of such exclusion limits are the same as those which go into a determination to list a hazardous waste. Consequently, the Agency reasoned that the same criteria could and should be used for both purposes. In effect, §261.11(c) only applies to the use of the criteria of §§261.11(a)(2) and 261.11(a)(3).

Delisting Procedures. Many commenters found the delisting requirements of §250.15(a) deficient. Many of these comments were similar to, linked to or flowed out of the comments summarized above under Comments on Criteria for Listing. Many contended that these requirements were vague, unworkable and infeasible, but specific reasons for or examples of these remarks were not given. Many found the requirements, particularly the test protocols, to be too burdensome on generators and beyond the performance capacity of many of them, particularly small generators. Some of these commenters called for elimination of these requirements. EPA presumes that these commenters would find the same problems, if not more problems, with the imposition of characteristics to cover unlisted wastes, given that such characteristics would impose involuntary testing requirements on the regulated community. Other commenters contended that the delisting requirements were too inflexible because delisting demonstrations could only use the limited number and types of tests specified by the requirements. These commenters argued for allowing other tests or submission of other (equivalent) information to support delisting. Some of these commenters pointed out that multiple factors and considerations, including consideration on how the waste is actually managed, govern the hazardousness of wastes and therefore should be considered in delisting. They contended that the proposed delisting requirements did not allow for consideration of multiple factors. These comments augmented those summarized above which pointed to deficiency in the listing criteria relative to multiple factors. Many commenters found the delisting requirements and particularly the test

protocols to be preliminary, evaluated and inappropriate because (1) EPA did not have sufficient confidence in them to propose them as listing criteria or characteristics, (2) EPA declared them (the test protocols, at least) to be unreliable in the preamble of the Proposed Rules and (3) EPA was concurrently initiating pre-rulemaking on these requirements and protocols through the concurrent publication of an Advance Notice of Proposed Rulemaking. These comments were clearly directed at the delisting requirements for organic toxicity, genetic activity, bioaccumulation potential and radioactivity. In most cases, they were linked to the comments summarized above that contended that delisting requirements, without companion listing criteria, constituted a capricious double standard. Some commenters believed the opposite, that the delisting requirements and test protocols, (that is, broadly applicable characteristic-like rules) were, in fact, not preliminary and unevaluated. They believed that those proposed delisting tests and others could be justifiably used in both listing and delisting to assure broad and essential protection of the environment. Finally, a few commenters suggested that the regulation should allow extending the delisting of an individual waste to other similar wastes or to classes or types of waste within the class of waste listed.

In summary, the comments on the technical aspects of the delisting requirements were very similar to those submitted on the listing criteria and the regulatory strategy for identifying wastes. As already indicated, virtually all of these comments seemed to have been directed at the requirements for delisting toxic organic, genetically active, bioaccumulative and radioactive wastes. None seemed to be directed at the delisting requirements for wastes listed because they exhibited the characteristics of ignitability, corrosivity, reactivity and EP toxicity.

§261.10 Criteria for identifying the characteristics of hazardous waste

(a) The Administrator shall identify and define a characteristic of hazardous waste in Subpart C only upon determining that:

(1) A solid waste that exhibits the characteristic may:

(i) cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or

(ii) pose a substantial present or potential hazard to human health or the environment when it is improperly treated, stored, transported, disposed of or otherwise managed; and

(2) The characteristic can be:

(i) measured by an available standardized test method which is reasonably within the capability of generators of solid waste or private sector laboratories that are available to serve generators of solid waste; or

(ii) reasonably detected by generators of solid waste through their knowledge of their waste.

§261.11 Criteria for listing hazardous waste

(a) The Administrator shall list a solid waste as a hazardous waste only upon determining that the solid waste meets one of the following criteria:

(1) It exhibits any of the characteristics of hazardous waste identified in Subpart C.

(2) It has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. (Waste listed in accordance with these criteria will be designated Acute Hazardous Waste.)

(3) It contains any of the toxic constituents listed in Appendix VIII unless, after considering any of the following factors, the Administrator concludes that the waste is not capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed:

(i) The nature of the toxicity presented by the constituent.

(ii) The concentration of the constituent in the waste.

(iii) The potential of the constituent or any toxic degradation product of the constituent to migrate from the waste into the environment under the types of improper management considered in (vii) below.

(iv) The persistence of the constituent or any toxic degradation product of the constituent

(v) The potential for the constituent or any toxic degradation product of the constituent to degrade into non-harmful constituents and the rate of degradation.

(vi) The degree to which the constituent or any degradation product of the constituent bioaccumulates in ecosystems.

(vii) The plausible types of improper management to which the waste could be subjected.

(viii) The quantities of the waste generated at individual generation sites or on a regional or national basis.

(ix) The nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes containing the constituent.

(x) Actions taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent.

(xi) Such other factors as may be appropriate.

Substances will be listed on Appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms.

(Wastes listed in accordance with these criteria will be designated Toxic wastes.)

(b) The Administrator may list classes or types of solid waste as hazardous waste if he has reason to believe that individual wastes, within the class or type of waste, typically or frequently are hazardous under the definition of hazardous waste found in Section 1004(5) of the Act.

(c) The Administrator will use the criteria for listing specified in this Section to establish the exclusion limits referred to in §261.5(c).

§260.22 Petitions to amend Part 261 to exclude a waste produced at a particular facility

(a) Any person seeking to exclude a waste at a particular generating facility from the lists in Subpart D of Part 261 may petition for a regulatory amendment under this section and §260.20. To be successful, the petitioner must demonstrate to the satisfaction of the Administrator that the waste produced by a particular generating facility does not meet any of the criteria under which the waste was listed as a hazardous waste and, in the case of an acutely hazardous waste listed under §261.11(a)(2), that it also does not meet the criterion of §261.11(a)(3). A waste which is so excluded may still, however, be a hazardous waste by operation of Subpart C of Part 261.

(b) The procedures in this section and §260.20 may also be used to petition the Administrator for a regulatory amendment to exclude from §261.3(a)(2)(ii) or (c), a waste which is described in those sections and is either a waste listed in Subpart D, contains a waste listed in Subpart D, or is derived from a waste listed in Subpart D. This exclusion may only be issued for a particular generating, storage, treatment, or disposal facility. The petitioner must make the same demonstration as required by paragraph (a), except that where the waste is a mixture of solid waste and one or more listed hazardous wastes or is derived from one or more hazardous wastes, his demonstration may be made with respect to each constituent listed waste or the waste mixture as a whole. A waste which is so excluded may still be

a hazardous waste by operation of Subpart C of Part 261.

(c) If the waste is listed with codes "I", "C", "R", or "E" in Subpart D, the petitioner must show that demonstration samples of the waste do not exhibit the relevant characteristic defined in §§261.21, 261.22, 261.23 or 261.24 using any applicable test methods prescribed therein.

(d) If the waste is listed with code "T" in Subpart D, the petitioner must demonstrate that:

(1) Demonstration samples of the waste do not contain the constituent (as defined in Appendix VII) that caused the Administrator to list the waste, using the appropriate test methods prescribed in Appendix III; or

(2) The waste does not meet the criterion of §261.11(a)(3) when considering the factors in §261.11(a)(3)(i) through (xi).

(e) If the waste is listed with the code "H" in Subpart D, the petitioner must demonstrate that the waste does not meet both of the following criteria:

(1) The criterion of §261.11(a)(2).

(2) The criterion of §261.11(a)(3) when considering the factors listed in §261.11(a)(3)(i) through (xi).

(f) [Reserved for listed radioactive wastes.]

(g) [Reserved for listed infectious wastes.]

(h) Demonstration samples must consist of enough representative samples, but in no case less than four samples, taken over a period of time sufficient to represent the variability or the uniformity of the waste.

(i) Each petition must include, in addition to the information required by §260.20(b):

(1) The name and address of the laboratory facility performing the sampling or tests of the waste;

(2) The names and qualifications of the persons sampling and testing the waste;

(3) The dates of sampling and testing;

(4) The location of the generating facility;

(5) A description of the manufacturing processes or other operations and feed materials producing the waste and an assessment of whether such processes, operations or feed materials can or might produce a waste that is not covered by the demonstration;

(6) A description of the waste and an estimate of the average and maximum monthly and annual quantities of waste covered by the demonstration;

(7) Pertinent data on and discussion of the factors delineated in the respective criterion for listing a hazardous waste, where the demonstration is based on the factors in §261.11(a)(3);

(8) A description of the methodologies and equipment used to obtain the representative samples;

(9) A description of the sample handling and preparation techniques, including techniques used for extraction, containerization and preservation of the samples;

(10) A description of the tests performed (including results);

(11) The names and model numbers of the instruments used in performing the tests; and

(12) The following statement signed by the generator of the waste or his authorized representative: I certify under penalty of law that I have personally examined and am familiar with the information submitted in this demonstration and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

(j) After receiving a petition for an exclusion, the Administrator may request any additional information which he may reasonably require to evaluate the petition.

(k) An exclusion will only apply to the waste generated

at the individual facility covered by the demonstration and will not apply to waste from any other facility.

(l) The Administrator may exclude only part of the waste for which the demonstration is submitted where he has reason to believe that variability of the waste justifies a partial exclusion.

(m) The Administrator may (but shall not be required to) grant a temporary exclusion before making a final decision under §260.20(d) whenever he finds that there is a substantial likelihood that an exclusion will be finally granted. The Administrator will publish notice of any such temporary exclusion in the Federal Register.

APPENDIX I

REASON FOR INCLUSION OF HAZARDOUS CONSTITUENTS IN APPENDIX VIII

(1) Health and Environmental Effects Document
(2) NIPDWS Substance
(3) CAG Carcinogens
(4) Acute toxicity as listed in NIOSH Registry, Sax,or DOT regulations
(5) RPAR Substance

Reason(s)	Substance
(1)	Acetaldehyde
(4)	(Acetato)phenylmercury
(1)	Acetonitrile (I)
(4)	3-(alpha-Acetonylbenzyl)-4-hydroxycoumarin and salts
(3)	2-Acetylaminofluorene
(1)	Acetyl chloride (C)
(4)	1-Acetyl-2-thiourea
(4)	Acrolein
(1)	Acrylamide
(1),(3)	Acrylonitrile
(3)	Aflatoxins
(3),(4)	Aldrin
(4)	Allyl alcohol
(4)	Aluminum phosphide (R)
(3)	4-Aminobiphenyl
(3)	6-Amino-1,1a,2,8,8a,8b-hexahydro-8-(hydroxymethyl)-8a-methoxy-5-methylcarbamate azirino(2',3':3,4) pyrrolo(1,2-a)indole-4, 7-dione (ester) (Mitomycin C)

* The abbrevation N.O.S signifies those members of the general class "not otherwise specified" by name in this listing.

Reason(s)	Substance
(4)	5-Aminomethyl-3-isoxyzole
(4)	4-Aminopyridine
(3)	Amitrole
(1)	Antimony and compounds, N.O.S.*
(3)	Aramite
(2),(3)	Arsenic and compounds, N.O.S.
(3),(4)	Arsenic acid
(3),(4)	Arsenic pentoxide (R)
(3),(4)	Arsenic trioxide
(3)	Auramine
(3)	Azaserine
(1),(2)	Barium and compounds, N.O.S.
(4)	Barium cyanide
(3)	Benz[c]acridine
(1),(3)	Benz[a]anthracene
(3)	Benzene
(2)	Benzenearsonic acid
(4)	Benzenethiol
(3)	Benzidine
(3)	Benzo[b]fluoranthene
(3)	Benzo[j]fluoranthene
(3)	Benzo[a]pyrene
(1)	Benzotrichloride (C,R)
(1),(4)	Benzyl chloride
(1)	Bis(2-chloroethoxy)methane

Reason(s)	Substance
(1),(3)	Bis(2-chloroethyl) ether
(3)	N,N-Bis(2-chloroethyl)-2-naphthylamine
(1)	Bis(2-chloroisopropyl) ether
(1),(3),(4)	Bis(chloromethyl) ether
(1)	Bis(2-ethylhexyl) phthalate
(4)	Bromoacetone
(1)	Bromomethane
(1)	4-Bromophenyl phenyl ether
(4)	Brucine
(4)	2-Butanone peroxide
(1)	Butyl benzyl phthalate
(4)	2-sec-Butyl-4,6-dinitrophenol (DNBP)
(2),(3)	Cadmium and compounds, N.O.S.
(3)	Calcium chromate
(4)	Calcium cyanide (R)
(4)	Carbon disulfide (I)
(3)	Chlorambucil
(3),(5)	Chlordane (alpha and gamma isomers)
(1)	Chlorinated benzenes, N.O.S.
(3)	Chlorinated ethane(s), N.O.S.
(1)	Chlorinated naphthalene(s), N.O.S.
(1)	Chlorinated phenol(s), N.O.S.
(4)	Chloroacetaldehyde
(3)	Chloroalkyl ethers
(4)	p-Chloroaniline

Reason(s)	Substance
(1)	Chlorobenzene
(3),(5)	Chlorobenzilate
(4)	1-(p-Chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid
(1)	p-Chloro-m-cresol
(1)	1-Chloro-2,3-epoxybutane
(1)	2-Chloroethyl vinyl ether
(1),(3)	Chloroform (I)
(1)	Chloromethane (I)
(3)	Chloromethyl methyl ether
(1)	2-Chloronaphthalene
(1)	2-Chlorophenol
(4)	1-(o-Chlorophenyl)thiourea
(4)	3-Chloropropionitrile
(4)	alpha-Chlorotoluene
(4)	Chlorotoluene(s), N.O.S.
(2),(3)	Chromium and compounds, N.O.S.
(1),(3)	Chrysene
(3)	Citrus red No. 2
(4)	Copper cyanide
(1),(3)	Creosote
(1)	Crotonaldehyde
(4)	Cyanides (soluble salts and complexes), N.O.S. (R)
(4)	Cyanogen

Reason(s)	Substance
(4)	Cyanogen bromide
(4)	Cyanogen chloride
(3)	Cycasin
(1)	2-Cyclohexyl-4,6-dinitrophenol
(3)	Cyclophosphamide
(3)	Daunomycin
(1)	DDD
(1)	DDE
(1),(3)	DDT
(3),(5)	Diallate
(3)	Dibenz[a,h]acridine
(3)	Dibenz[a,j]acridine
(3)	Dibenz[a,h]anthracene (Dibenzo[a,h]anthracene)
(3)	7H-Dibenzo[c,g]carbazole
(3)	Dibenzo[a,e]pyrene
(3)	Dibenzo[a,h]pyrene
(3)	Dibenzo[a,i]pyrene
(3)	1,2-Dibromo-3-chloropropane
(3)	1,2-Dibromoethane
(1)	Dibromomethane
(1)	Di-n-butyl phthalate
(1)	Dichlorobenzene(s), N.O.S.
(1),(3)	3,3'-Dichlorobenzidine
(1)	1,1-Dichloroethane

Reason(s)	Substance
(1),(3)	1,2-Dichloroethane
(1)	trans-1,2-Dichloroethene
(1)	Dichloroethylene(s), N.O.S.
(1)	1,1-Dichloroethylene
(1)	Dichloromethane
(1)	2,4-Dichlorophenol
(1)	2,6-Dichlorophenol
(2),(4)	2,4-Dichlorophenoxyacetic acid (2,4-D)
(1)	Dichloropropane(s)
(4)	Dichlorophenylarsine
(1)	1,2-Dichloropropane
(1)	Dichloropropanol(s), N.O.S.
(1)	Dichloropropene(s), N.O.S.
(1)	1,3-Dichloropropene
(3),(4)	Dieldrin
(3)	Diepoxybutane (I)
(4)	Diethylarsine
(4)	0,0-Diethyl-S-(2-ethylthio)ethyl ester of phosporothioic acid
(3)	1,2-Diethylhydrazine
(1)	0,0-Diethyl-S-methylester phosphorodithioic acid
(4)	0,0-Diethylphosphoric acid, O-p-nitrophenyl ester
(1)	Diethyl phthalate
(4)	0,0-Diethyl-O-(2-pyrazinyl)phosphorothioate
(3)	Diethylstilbestrol

Reason(s)	Substance
(3)	Dihydrosafrole
(4)	3,4-Dihydroxy-alpha-(methylamino)-methyl benzyl alcohol
(4)	Di-isopropylfluorophosphate (DFP)
(4),(5)	Dimethoate
(3)	3,3'-Dimethoxybenzidine
(3)	p-Dimethylaminoazobenzene
(3)	7,12-Dimethylbenz[a]anthracene
(3)	3,3'-Dimethylbenzidine
(3)	Dimethylcarbamoyl chloride
(3)	1,1-Dimethylhydrazine
(3)	1,2-Dimethylhydrazine
(4)	3,3-Dimethyl-1-(methylthio)-2-butanone-O-((methylamino) carbonyl)oxime
(1)	Dimethylnitrosamine
(4)	alpha,alpha-Dimethylphenethylamine
(1)	2,4-Dimethylphenol
(1)	Dimethyl phthalate
(3)	Dimethyl sulfate
(1)	Dinitrobenzene(s), N.O.S.
(4)	4,6-Dinitro-o-cresol and salts
(1),(4)	2,4-Dinitrophenol
(1),(3)	2,4-Dinitrotoluene
(1)	2,6-Dinitrotoluene
(1)	Di-n-octyl phthalate
(3)	1,4- Dioxane

Reason(s)	Substance
(3)	1,2-Diphenylhydrazine
(3)	Di-n-propylnitrosamine
(4)	Disulfoton
(4)	2,4-Dithiobiuret
(4)	Endosulfan
(2),(4)	Endrin and metabolites
(1),(3)	Epichlorohydrin
(4)	Ethyl cyanide
(4)	Ethylene diamine
(3)	Ethylene bis dithiocarbamate (EBDC)
(3)	Ethyleneimine
(3)	Ethylene oxide (I)
(3)	Ethylenethiourea
(3)	Ethyl methanesulfonate
(1)	Fluoranthene
(4)	Fluorine
(4),(5)	2-Fluoroacetamide
(4),(5)	Fluoroacetic acid, sodium salt
(1),(3)	Formaldehyde
(3)	Glycidyl aldehyde
(1)	Halomethane(s), N.O.S.
(3),(5)	Heptachlor
(1)	Heptachlor epoxide (alpha, beta, and gamma isomers)
(1),(3)	Hexachlorobenzene

Reason(s)	Substance
(1),(3)	Hexachlorobutadiene
(1),(2),(3)	Hexachlorocyclohexane (all isomers)
(1)	Hexachlorocyclopentadiene
(3)	Hexachloroethane
(4)	1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-endo,endo-dimethanonaphthalene
(1)	Hexachlorophene
(4)	Hexachloropropene
(4)	Hexaethyl tetraphosphate
(3)	Hydrazine (R)
(4)	Hydrocyanic acid
(1)	Hydrogen sulfide
(3)	Indeno(1,2,3-cd)pyrene
(3)	Iodomethane
(4)	Isocyanic acid, methyl ester
(3)	Isosafrole
(3)	Kepone
(3)	Lasiocarpine
(1),(2)	Lead and compounds, N.O.S.
(1),(2),(5)	Lead acetate
(1),(2)	Lead phosphate
(1),(2)	Lead subacetate
(1)	Maleic anhydride
(1)	Malononitrile
(3)	Melphalan

Reason(s)	Substance
(1),(2)	Mercury and compounds, N.O.S.
(3)	Methapyrilene
(4)	Methomyl
(4)	2-Methylaziridine
(3)	3-Methylcholanthrene
(3)	4,4'-Methylene-bis-(2-chloroaniline)
(1)	Methyl ethyl ketone (MEK) (I)
(4)	Methyl hydrazine
(4)	2-Methyllactonitrile
(1)	Methyl methacrylate (R)
(3)	Methyl methanesulfonate
(4)	2-Methyl-2-(methylthio)propionaldehyde-o-(methylcarbonyl) oxime
(3)	N-Methyl-N'-nitro-N-nitrosoguanidine
(4)	Methyl parathion
(3)	Methylthiouracil
(3)	Mustard gas
(1)	Naphthalene
(1)	1,4-Naphthoquinone
(3)	1-Naphthylamine
(3)	2-Naphthylamine
(4)	1-Naphthyl-2-thiourea
(3)	Nickel and compounds, N.O.S.
(3),(4)	Nickel carbonyl
(3),(4)	Nickel cyanide

Reason(s)	Substance
(4)	Nicotine and salts
(4)	Nitric oxide
(4)	p-Nitroaniline
(1)	Nitrobenzene (I)
(4)	Nitrogen dioxide
(3)	Nitrogen mustard and hydrochloride salt
(3)	Nitrogen mustard N-oxide and hydrochloride salt
(4)	Nitrogen peroxide
(4)	Nitrogen tetroxide
(4)	Nitroglycerine (R)
(1)	4-Nitrophenol
(3)	4-Nitroquinoline-1-oxide
(3)	Nitrosamine(s)
(3)	N-Nitrosodi-n-butylamine
(3)	N-Nitrosodiethanolamine
(1),(3)	N-Nitrosodiethylamine
(1),(3)	N-Nitrosodimethylamine
(4)	N-Nitrosodiphenylamine
(1),(3)	N-Nitrosodi-n-propylamine
(3)	N-Nitroso-N-ethylurea
(3)	N-Nitrosomethylethylamine
(3)	N-Nitroso-N-methylurea
(3)	N-Nitroso-N-methylurethane
(3),(4)	N-Nitrosomethylvinylamine

Reason(s)	Substance
(3)	N-Nitrosomorpholine
(3)	N-Nitrosonornicotine
(3)	N-Nitrosopiperidine
(3)	N-Nitrosopyrrolidine
(3)	N-Nitrsosarcosine
(3)	5-Nitro-o-toluidine
(4)	Octamethylpyrophosphoramide
(4)	Oleyl alcohol condensed with 2 moles ethylene oxide
(4)	Osmium tetroxide
(4)	7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid
(4)	Parathion
(1)	Pentachlorobenzene
(1)	Pentachloroethane
(1),(3),(5)	Pentachloronitrobenzene (PCNB)
(4)	Pentachlorophenol
(3)	Phenacetin
(1)	Phenol
(4)	Phenyl dichloroarsine
(4)	Phenylmercury acetate
(4)	N-Phenylthiourea
(4)	Phosgene
(4)	Phosphine
(4)	Phosphorothioic acid, O,O-dimethyl ester, O-ester with N,N-dimethyl benzene sulfonamide

Reason(s)	Substance
(1)	Phthalic acid esters, N.O.S.
(1)	Phthalic anhydride
(3)	Polychlorinated biphenyl(s), N.O.S.
(4)	Potassium cyanide
(4)	Potassium silver cyanide (R)
(3)	Pronamide
(4)	1,2-Propanediol
(3)	1,3-Propane sultone
(4)	Propionitrile
(3)	Propylthiouracil
(4)	2-Propyn-1-ol
(1)	Pyridine
(3)	Reserpine
(3)	Saccharin
(1),(3)	Safrole
(2)	Selenious acid
(1),(2)	Selenium and compounds, N.O.S.
(1),(2),(3)	Selenium sulfide (R)
(4)	Selenourea
(1),(2)	Silver and compounds, N.O.S.
(4)	Silver cyanide
(4)	Sodium cyanide
(3)	Streptozotocin
(4)	Strontium sulfide
(4)	Strychnine and salts

Reason(s)	Substance
(1)	1,2,4,5-Tetrachlorobenzene
(3)	2,3,7,8-Tetrachlorodibenzo-p-dioxin
(1)	Tetrachloroethane(s), N.O.S.
(1),(3),(4)	1,1,1,2-Tetrachloroethane
(1),(4)	1,1,2,2-Tetrachloroethane
(1),(3)	Tetrachloroethene (Tetrachloroethylene)
(1)	Tetrachloromethane
(1)	2,3,4,6-Tetrachlorophenol
(4)	Tetraethyldithiopyrophosphate
(4)	Tetraethyl lead
(4)	Tetraethylpyrophosphate
(1)	Thallium and compounds, N.O.S.
(4)	Thallic oxide
(1)	Thallium (I) acetate
(1)	Thallium (I) carbonate
(1)	Thallium (I) chloride
(1)	Thallium (I) nitrate
(4)	Thallium selenite
(4)	Thallium (I) sulfate
(3)	Thioacetamide
(4)	Thiosemicarbazide
(3)	Thiourea
(4)	Thiuram
(1)	Toluene
(1)	Toluenediamine

Reason(s)	Substance
(3)	o-Toluidine hydrochloride
(1)	Tolylene diisocyanate
(1),(2),(3)	Toxaphene
(1)	Tribromomethane
(1)	1,2,4-Trichlorobenzene
(1),(2)	1,1,1-Trichloroethane
(1)	1,1,2-Trichloroethane
(3)	Trichloroethene (Trichloroethylene)
(4)	Trichloromethanethiol
(1)	2,4,5-Trichlorophenol
(1),(3)	2,4,6-Trichlorophenol
(5)	2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
(2)	2,4,5-Trichlorophenoxypropionic acid (2,4,5-TP) (Silvex)
(1)	Trichloropropane(s)
(1)	1,2,3-Trichloropropane
(1)	0,0,0-Triethyl phosphorothioate
(1)	Trinitrobenzene
(3)	Tris(1-azridinyl)phosphine sulfide
(3)	Tris(2,3-dibromopropyl) phosphate
(3)	Trypan blue
(3)	Uracil mustard
(3)	Urethane
(4)	Vanadic acid, ammonium salt
(4)	Vanadium pentoxide (dust)

Reason(s)	Substance
(3)	Vinyl chloride
(3)	Vinylidene chloride
(4)	Zinc cyanide
(4)	Zinc phosphide (R)