Chapter II. Comment Summaries and Responses on Retaining the Mixture and Derived-from Rules

The MDF codes identify all comments that address the issue of retaining the mixture and derived from (MDF) rules. Comments on the MDF issues were broken down further into the following specific issue codes:

MDF1	Legal authority for the MDF rules
MDF2	Necessity of the MDF rules
MDF3	Regulatory cost of the MDF rules
MDF4	Unintended consequences of the MDF rules
MDF5	Pollution prevention and treatment technology development under the MDF rules
MDF6	Mixture rules should be replaced by a general dilution prohibition
MDF7	MDF wastes should be regulated in the same way non-hazardous solid wastes are regulated (characteristics, supplemented by waste-specific listings, as warranted)
MDF8	Instead of revising the MDF rules, EPA should implement them more reasonably through directives to States
MDF9	Relationship of a concentration-based HWIR exemption to the MDF rules
MDF10	Relationship of delistings to MDF rules
MDF11	If MDF rules are finalized, EPA should identify when it believes any petitions seeking judicial review may be filed
MDF12	MDF rules should have a sunset provision of one year while being revised
MDF13	Exemptions are consistent with the RCRA statutory language and general principles of administrative law
MDF14	LDR Treatment Should be Required of Mixture-rule Process Wastes
MDF15	EPA Should Ensure that the Federal Revisions are Applicable in Authorized States

On the following pages, each MDF comment issue is summarized, and then followed by EPA's response. A list of all the specific MDF comments (including the comment number assigned by the EPA docket, the page, and the paragraph) that are linked to each comment issue summary is also included. The full text of these comments appear in Appendix A.

Issue Code: MDF1: Legal Authority for the MDF Rules

Comments: WHWP-00073, 20, 1; WHWP-00074, 4, 3; WHWP-00089, 6, 6; WHWP-00093, 4, 1; WHWP-00094, 4, 1; WHWP-00095, 4, 1; WHWP-00096, 4, 1; WHWP-00101, 20, 1;WHWP-00106, 12, 2; WHWP-00108, 4, 7; WHWP-00108, 5, 2; WHWP-00112, 2, 1; WHWP-00125, 3, 1; WHWP-00138, 3, 1; WHWP-00143, 1, 3; WHWP-00145, 2, 5; WHWP-00148, 6, 4; WHWP-00149, 5, 1; WHWP-00150, 11, 1; WHWP-00160, 3, 2; WHWP-00160, 7, 1; WHWP-00165, 4, 3; WHWP-00165, 6, 3; WHWP-00165, 9, 4; WHWP-00172, 41, 1; WHWP-00173, 1, 2;WHWP-00192, 6, 1; WHWP-00192, 11, 1; WHWP-00196, 4, 1; WHWP-00201, 2, 1; WHWP-00201, 15, 2; WHWP-00204, 6, 2; WHWP-00208, 1,1; WHWP-00220, 3, 3; WHWP-00239, 3, 5; WH2P-00004, 8, 1 WH2P-00004, 10, 1; WH2P-00004, 10, 7;WH2P-00004, 10, 8; WH2P-00005, 1, 2;WH2P-00005, 3, 1; WH2P-00008, 1, 2; WH2P-00010, 3, 3;WH2P-00010, 4, 7; WH2P-00012, 1, 3; WH2P-00014, 2, 2; WH2P-00016, 2, 1; WH2P-00022, 2, 4; WH2P-00022, 3, 5; WH2P-00031, 2, 6; WH2P-00031, 3, 3; WH2P-00031, 4, 4;WH2P-00033, 4, 2;; WH2P-00033, 10, 6; WH2P-00033, 12, 2; WH2P-00033, 13, 3; WH2P-00033, 14, 3; WH2P-00035, 1, 3; WH2P-00035, 6, 3; WH2P-00035, 25, 1; WH2P-00035, 28, 2; WH2P-00041, 1, 3; WH2P-00046, 3, 1; WH2P-00046, 4, 1; and WH2P-00046, 5, 5.

Comment Summary:

The Agency received comments from 42 commenters in response to both the 1995 and the 1999 HWIR proposals concerning the legality of the mixture and derived-from (MDF) rules. Of those comments, 11 were received from industry, 16 were from industry associations, 11 were from utility companies or utility company associations, two were from waste management companies, one was from a waste management association and one was from an individual commenter.

The Environmental Technology Council agreed that EPA had statutory authority under RCRA to promulgate the MDF rules in 1980, and that the agency also had ample authority to retain the basic rules now without change. The commenter, citing the court case Shell Oil Corp. v. EPA, believed that the rules were consistent with EPA's legal authority under RCRA section 3001 to determine when wastes are hazardous based on listing criteria, and under RCRA sections 3002-3004 to impose regulatory standards until wastes have ceased to pose a hazard to the public.

The rest of the commenters generally believed that EPA had overreached its statutory authority by imposing the MDF rules. These comments asserted that the mixture and derived-from (MDF) rules are illegal because (1) mixture and derived-from wastes do not meet the statutory definition of hazardous under RCRA Section 1004(5); (2) EPA has not met the requirements under section 3001, 42 U.S.C.A. Section 6921 and 40 CFR Sections 261.10 and 261.11 for designating wastes

as hazardous, thereby exceeding its authority to promulgate these rules; (3) EPA has no authority under sections 3002-3004 of RCRA to designate wastes as hazardous; (4) EPA has not met the intent of Congress to significantly revise the mixture and derived-from rules and failed to meet consent decree deadlines, therefore the interim MDF rules should be considered null and void; (and (5) EPA has failed to analyze costs and benefits of the mixture and derived-from rules, including impacts to small entities. A summary of the specific issues raised by commenters is provided below.

(1) Comment: mixture and derived-from wastes do not meet the statutory definition of hazardous under RCRA Section 1004(5)

Numerous commenters from industries, industry associations, utility companies, utility company associations and waste management companies generally believed that the mixture and derived-from rules were too broad and swept in many wastes which did not meet the statutory definition of hazardous wastes, and that the derived-from rule in particular was not supported by statutory authority. One commenter even felt that the derived-from rule was a "legal fiction" because treatment residuals must be managed as if the treatment had not occurred. Commenters noted that EPA only was authorized under the Resource Conservation and Recovery Act (RCRA) to designate as hazardous waste those solid wastes that EPA determined may (1) cause, or significantly contribute to an increase in mortality or serious illness, or (2) pose a substantial present or potential hazard to human health or the environment when improperly managed (RCRA section 1004(5), 42 U.S.C. 6903(5)). Commenters expressed the view that EPA can regulate under Subtitle C only those solid wastes that EPA determined pose substantial hazards per the language in Section 1004(5) of RCRA. Many commenters also noted that, in their view, many of these wastes pose minimal or no threat to the environment and public health. The majority of these commenters believed that EPA made no attempt to demonstrate that derived-from wastes met the statutory definition of hazardous waste. Instead, these commenters believed EPA simply drew conclusions that these materials were hazardous waste, even though many derived-from wastes had not met the statutory definition of hazardous waste. They also noted that EPA has admitted that many derived-from wastes pose little risk to human health or the environment. Therefore, they claim that the derived-from rule was not a legally valid approach to regulating materials that result from the management of hazardous waste.

EPA Response

While we agree that the mixture and derived-from rules capture some waste that may actually pose quite low hazard, we have implemented and continue to pursue approaches (such as today's revisions) to exclude such waste from full Subtitle C regulation. Nevertheless, these rules are a necessary component of cradle-to-grave waste management, to protect human health and the environment from unacceptable risks. EPA does not agree with comments that mixtures and derivatives do not meet the definition of "hazardous waste" in section 1004(5) of RCRA, nor do we agree that Congress did not intend these wastes to be regulated under Subtitle C of RCRA. The definition of hazardous waste is a broad definition which encompasses solid wastes or

combinations of solid wastes which, because of their "quantity, concentration, or physical, chemical, or infectious characteristics may . . . pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed." Because they originate from waste that has already been determined to be hazardous, EPA has a reasonable basis to conclude that mixtures and derivatives could also pose a potential or present hazard to human health or the environment if not properly managed. The original listing of the waste already establishes the reasons, i.e., the "quantity, concentration, or physical, chemical, or infectious characteristics" for having identified the listed waste as hazardous. It is reasonable to conclude, without information to the contrary, that both mixtures and derivatives of such wastes may pose a substantial potential or present hazard to human health or the environment if not properly managed, and therefore fall under the definition of hazardous waste in RCRA section 1004(5).

Nothing in the section 1004(5) definition of hazardous waste requires EPA to prove that every member of a category of waste poses a hazard. In fact, many waste listings describe categories or "classes" of hazardous wastes because they cover a range of materials that are not identical in composition.

EPA also does not agree with commenters' assertion that wastes derived from the treatment, storage, or disposal of listed hazardous wastes in particular do not meet the § 1004(5) definition. As explained in the response to comment issue MDF2, residuals from the treatment of hazardous wastes can contain higher concentrations of the chemicals that led to the hazardous waste listing in the first place, and therefore may pose a present or potential hazard to human health or the environment if improperly managed. Indeed, the objective of many forms of treatment is precisely to isolate and collect hazardous constituents, often in concentrated form, for further management. For example, de-watering of waste, e.g., to make it easier to transport, is a form of treatment that often does not significantly change the character of the waste other than to leave it in a more compact and concentrated form. At the more aggressive end of the treatment spectrum, baghouses on hazardous waste combustion devices collect hazardous constituents that would otherwise be emitted to the air from the combustion process, creating dust that predictably contains any metals that were in the original wastes as well as products of incomplete combustion. Congress specifically expressed concern in RCRA about treatment residues created by federal and state pollution control laws, RCRA 1002(b)(3). The potential for persistent hazardous constituents in treatment residues and the Congressional findings in the RCRA statute support EPA's conclusion that residuals from the treatment, storage and disposal of listed hazardous waste may pose a substantial present or potential hazard.

EPA acknowledges that not all mixtures and derivatives pose hazards to human health and the environment (see, e.g.57 FR 21451). There are mechanisms to address this fact, and we are continuing to pursue approaches to exempt low-risk wastes. First, RCRA and EPA regulations provide for the delisting of listed hazardous waste. RCRA 3001(f); 40 CFR 261.20 and 40 CFR 261.22. Since the federal delisting program took effect in 1980, EPA has excluded an estimated 45 million tons of waste, resulting in an estimated cumulative cost savings between $1.1 billion and $1.3 billion dollars (in 1999 dollars). In 2000 alone, we estimate cost savings of approximately

$105.4 million.[1] In the 1995 HWIR proposal, EPA stressed the continued need for the delisting program, although we also acknowledged that it had not provided an efficient solution to the regulation of low-risk wastes. However, as discussed in the response to comment issue MDF3, since the delisting program was delegated to the EPA Regions on October 10, 1995, a number of innovations have been adopted that have greatly improved the efficiency and effectiveness of the delisting program. EPA will continue these efforts and others in order to keep improving the delisting process.

In addition, as EPA has identified specific mixtures and derived-from wastes which no longer meet the definition of hazardous waste, and has therefore established a number of exclusions in 40 CFR 261.3. Currently, there are over a dozen types of hazardous waste mixtures and residuals excluded or conditionally exempted under section 261.3. See the "Table of Revisions to 40 CFR 261.3" in the response to comment MDF3 for a list of these exclusions. This is in addition to other exclusions and conditional exclusions set forth in 40 CFR 261.4 as well in other parts of the hazardous waste regulations.

Furthermore, EPA is continuing work to develop exit levels for listed hazardous wastes, so that listed wastes can become "delisted" automatically, under a self-implementing procedure. But that is a complex undertaking and, despite best efforts, EPA is not able at this time to propose a technically supported concentration-based exemption.[2] Also, we are also investigating and will actively pursue other specific exemption proposals.

EPA continues to believe, as it did in 1980, that it would be virtually impossible to try to identify all possible waste mixtures and treated wastes and assess their hazards individually. EPA's rule reasonably retains jurisdiction over both broad classes and places the burden of proof on the regulated community to show that a particular waste has ceased to present a hazard.

Even if all listed hazardous waste mixtures and derivatives could not be said to meet the statutory hazardous waste definition, at the very least it is reasonable and consistent with RCRA to presume that mixtures and derivatives of listed hazardous wastes remain hazardous under the definition, unless that presumption is rebutted through the delisting process. As discussed further in the next section, Congress established clear standards for hazardous waste identification, but did not speak specifically to the issue of the circumstances under which mixtures and derivatives of listed hazardous wastes should be regulated. Under these circumstances, EPA must interpret and implement the statute in a way that effectuates the statutory objectives. The mixture and derived-from rules are the only implementation approach that EPA is aware of at this time that effectuates the protective purposes of RCRA.

(2) Comment: EPA has not met the requirements under section 3001, 42 U.S.C. §6921 and 40

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[1]U.S. EPA Evaluation of Hazardous Waste Delisting Program, December 2000.

[2]Congressional report language accompanying EPA's FY 2001 appropriations act directs EPA to submit the HWIR model to an independent peer review, and respond publicly to the findings of the peer review prior to using it to establish regulatory determinations. H-Rept 106-988, October 19S.Rep. No. 106-410 at 90 (2000)). EPA is currently in the process of preparing for that peer review.

CFR §§ 261.10 and 261.11 for designating wastes as hazardous.

These commenters also disagreed with EPA's claim of authority under section 3001 (60 FR at 66348, 64 FR 63390). The commenters believed that EPA had not followed the required procedures or made the findings required by RCRA to identify "mixture and derived-from wastes" as hazardous. They noted that Sections 3001(a) and (b) outline a two-step process for classifying wastes as hazardous. EPA first must specify criteria to determine if the waste is "hazardous," 42 U.S.C. 6921(a), which is defined as presenting a substantial present or potential hazard to human health or the environment 42 U.S.C. 6904(5). Once the criteria are established -- as they have been in 40 CFR 261.10 and 261.11 -- the commenters stated that EPA must apply these criteria to identify a characteristic of hazardous waste or to list a waste as hazardous. In these commenters' view, the mixture and derived-from rules identify a broad class of wastes as hazardous without regard to the criteria established by EPA. Also, they noted that the proposal did not discuss how mixtures and derived-from wastes pose a substantial present or potential threat to human health or the environment, nor did EPA discuss concentration levels, mobility, persistence, or any other objective factors of hazardousness that are listed in the statute or the regulations.

In addition, numerous commenters from industries, industry associations, utility companies and utility company associations disagreed with EPA identifying mixture and derived-from wastes as a "class" under 40 CFR §261.11 (60 FR at 66348, 64 FR at 66390). They believed that such identification required a finding that EPA had reason to believe that individual wastes within the class "typically or frequently are hazardous" under the definition at RCRA section 1004(5) (see 40 CFR 261.11(b)). Commenters noted that EPA's own longstanding practice was that, in a class-wide listing determination, "typically or frequently" meant that more than 50 percent of the samples taken from that class exhibited some or all of the 40 CFR 261.11(a) criteria (see, e.g., 56 FR 48020, Sept. 23, 1991 and 45 FR 33114, May 19, 1980). The commenters stated that EPA historically has required that samples of a waste class contain concentrations of toxic constituents at 100-1000 times specified health-based numbers to be considered as posing a "substantial hazard" under 40 CFR 261.11(a) (3) (see, e.g., 56 FR. 48018, Sept. 23, 1991 and 57 FR 21453, May 20, 1992). They noted that EPA generally requires that wastes typically and frequently contain toxic constituents at "many times" health-based levels and that such constituents be mobile and persistent. The current proposal made no reference to these prior practices, nor did it offer evidence that EPA collected or analyzed any samples or otherwise attempted to demonstrate that 50 percent -- or any substantial percentage -- of mixtures or treatment residues met any of the specific criteria of §261.11(a). Also, they commented that the proposal offered nothing responsive to the 100-1000 times health-based numbers requirement. In addition, they noted that the class must have "sufficient uniformity" to apply the criteria in 40 CFR §261.11 (45 FR 33114). The commenters felt that it was obvious that the class of mixture and derived-from wastes was anything but uniform, a point admitted by EPA (45 FR 33095-96, "the potential combinations of listed wastes and other wastes are infinite"). Therefore, the class did not have the requisite uniformity needed to be classified as hazardous.

EPA Response

EPA does not agree with comments that the Agency lacks statutory authority under RCRA Section 3001 for either the mixture rule or the derived-from rule. We have the statutory authority to promulgate these rules as part of the authority to "develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste." Among the criteria are the provisions of 40 CFR 261.3, which provide generally applicable criteria for the identification of hazardous waste. The mixture and derived-from rules are included in section 261.3(a)(2), which states that a solid waste is a hazardous waste if "[i]t meets any of the following criteria." These rules ensure that listed hazardous wastes that are mixed with other wastes or treated in some fashion do not escape regulation as hazardous waste until EPA has made some determination that they no longer threaten human health or the environment. This section also includes the exclusions from the definition of hazardous waste, including those promulgated today, where EPA has made specific findings on the record that the excluded wastes are no longer hazardous under the criteria set forth in the exclusions. We will continue to pursue additional approaches to exempt low-risk wastes, as appropriate.

The commenters' position rests largely on the assumption that mixtures and derivatives of wastes are entirely new and distinct substances from the originally listed waste, leading to the apparent conclusion that EPA must make a separate, record-based finding of hazardousness for each of the infinite variations of mixtures and derivatives generated from the wastes EPA has listed. EPA disagrees. In upholding the "contained-in policy," the U.S. Court of Appeals for the D.C. Circuit deferred to EPA's conclusion that a listed hazardous waste cannot be presumed to change character when it is mixed with an environmental medium. *Chemical Waste Management v. EPA,* 869 F.2d 1526, 1539 (1989). We believe that the same reasoning applies to the mixture rule. Similarly, as discussed in the response to comment issue MDF2, waste management residuals can contain constituents from the originally listed waste at even higher concentrations than the original waste and, therefore, may pose a hazard. Indeed, EPA views the mixture and derived-from rules as applications of the general principle that "a hazardous waste will remain a hazardous waste" unless it is excluded through a regulatory process. 40 CFR § 261.3(c)(1). *See Chemical Waste Management*, 869 F.2d at 1539 (upholding contained-in policy as interpretation of § 261.3(c)(1)).

EPA's approach is consistent with Congress' intention that hazardous waste be regulated for the long term under a comprehensive regulatory program. One of the findings upon which the 1976 RCRA legislation was based was that "hazardous waste presents, in addition to the problems associated with nonhazardous solid waste, special dangers to health and requires a greater degree of regulation than does nonhazardous solid waste." Public Law No. 94-580, §1002(5). With enactment of the Hazardous and Solid Waste Amendments (HSWA) in 1984, Public Law No. 98-616, Congress strengthened that provision and added three more findings: "the placement of inadequate controls on hazardous waste management will result in substantial risks to human health and the environment; if hazardous waste management is improperly performed in the first instance, corrective action is likely to be expensive, complex , and time consuming; certain classes of land disposal facilities are not capable of assuring long-term containment of certain hazardous wastes . . .". RCRA §1002(b)(5), (6), (7). Similarly, when RCRA was enacted in 1976, Congress stated one of the objectives of the Act was "regulating the treatment, storage, transportation, and disposal of hazardous wastes which have adverse effects on health and the

environment." Public Law No. 94-580, 1003(a)(4). This provision too was replaced with a stronger statement by HSWA, that an object of the statute is "assuring that hazardous waste management practices are conducted in a manner which protects human health and the environment." (Emphasis added.) RCRA 1003(a)(4). Further, HSWA added as national policy that hazardous waste "should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment." RCRA 1003(b). It is clear that Congress' principal objective under Subtitle C was protecting against threats to human health and the environment caused by hazardous waste. We acknowledge that such a goal does not imply that all mixtures and derived-from wastes must be regulated under full Subtitle C requirements, regardless of the potential risks they pose, but we believe that it is reasonable to regulate these wastes until it is shown that such wastes do not pose a hazard.

The D.C. Circuit Court of Appeals has characterized RCRA as establishing "a 'cradle-to-grave' regulatory structure overseeing the safe treatment, storage and disposal of hazardous waste." *United Technologies Corp. v. EPA*, 821 F.2d 714, 716 (D.C. Cir. 1987). The mixture and derived-from rules are a necessary part of this approach, by maintaining jurisdiction over mixtures and derivatives of already listed waste. Without these rules, as explained in the response to comment issue MDF2, the "cradle-to-grave" structure would have a major loophole, undermining the objectives of RCRA.

The delisting provision supports the mixture and derived-from rules as a means to address wastes that could pose unacceptable risks. In amending RCRA section 3001 in 1984, Congress enacted subsection (f) to require the Agency to "consider factors (including additional constituents) other than those for which the waste was listed" if the Agency "has a reasonable basis to believe that such additional factors could cause the waste to be a hazardous waste." The legislative history shows that Congress was concerned that both as generated wastes and wastes resulting from treatment were exiting the Subtitle C system while still hazardous. "The delisting process allows petitioners (usually individual hazardous waste generators or treatment facilities) the opportunity of showing that their wastes are significantly different -- because of treatment, or because they are generated in a different process -- from listed wastes of the same type. . . . Under this amendment, there would no longer be a risk that delisting a waste means releasing waste which may still be hazardous from regulation." H.R. Rep. No. 98-198 Part I (May 17, 1983). Congress made this change because it believed that under its previously existing delisting regulations, EPA allowed wastes that remained hazardous to exit the Subtitle C system. S.Rep. No. 98-284 (Oct. 28, 1983). The language and legislative history reflect Congress' assumption that treatment derivatives from listed wastes would remain subject to Subtitle C absent a delisting.

The land disposal restrictions (LDR) provisions of the statute further demonstrate that the mixture and derived-from rules are consistent with Congress' intent. The statute authorizes EPA to promulgate regulations establishing levels or methods of treatment, "if any," that substantially diminish the toxicity or mobility of the hazardous waste, and provide that the waste may thereafter be disposed of in a land disposal facility that "meets the requirements of [Subtitle C]." RCRA § 3004(m). This section demonstrates two things. (1) Congress contemplated the possibility that there may be hazardous wastes for which no form of treatment would be adequate; and (2) Congress assumed that waste that was treated according to the promulgated treatment standards would nonetheless still be disposed of in a Subtitle C (hazardous waste) facility. This provision is

at odds with the commenters' assertion that, once treated, a hazardous waste becomes a fundamentally different waste and is unregulated unless EPA undertakes a separate rulemaking to list the treated waste.

Other provisions of the 1984 amendments to RCRA relating to land disposal provide further support for the mixture and derived-from rules. *See, e.g.*, section 3004(o) (establishing minimum technological requirements for land-based hazardous waste management units); section 3004(p) (establishing groundwater monitoring requirements); section 3005(c)(3) (requiring 5-year permit reviews for land disposal facilities); section 3005(e)(2), (3) (establishing interim status termination dates for certain non-compliant land disposal facilities); section 3005(i), (j) (establishing specific additional requirements for certain land-based units); section 1002(b)(7) (finding that certain classes of land disposal facilities are not capable of assuring long-term containment). Some commenters suggest that treatment residuals from listed hazardous wastes do not remain hazardous. We believe it is unlikely Congress would have created such stringent requirements for land disposal, if it intended for treatment residuals to escape Subtitle C regulation.

Taken to the extreme, the view that mixtures containing listed wastes should not be regulated as hazardous wastes would imply that most listed hazardous wastes, even if they reached a management unit in "pure" form, would cease to be hazardous once they entered the unit, since most units contain mixtures of different wastes. However, the RCRA statute clearly assumes that units would not only receive, but continue to contain, hazardous waste. *See, e.g.* section 3005(j)(11) and (12)(A), Moreover, the comprehensive requirements mandated for hazardous waste management units, including the technical standards of section 3004 and the permitting regime of section 3005, could be undermined if facilities receiving listed hazardous wastes could argue that their management units are subject to this scheme only as long as they are receiving the waste, but that they become exempt thereafter since the units do not contain hazardous waste.

Various provisions in RCRA appear to contemplate that at least some hazardous waste mixtures and derivatives would themselves be hazardous. *See, e.g.*, section 3004(d)(2)(A), (B) (addressing liquid hazardous wastes, "including free liquids associated with any solid or sludge," suggesting that liquid derivatives of hazardous waste would themselves be hazardous). Another example is the language in section 3005(b), which requires permit applicants to provide information regarding hazardous wastes and "combinations of . . . hazardous waste and any other solid waste" to be managed at the permitted facility, as well as information regarding the site at which the "products of treatment" of hazardous waste will be managed.

Finally, the appropriations act provision that EPA is implementing with today's rule requires that the mixture and derived-from rules would continue in effect while EPA developed revisions to the regulations. Public Law No. 102-389, 106 Stat. 1571 (October 1992). That provision instructed EPA to "promulgate revisions to paragraphs (a)(2)(iv) and (c)(2)(i) of 40 CFR 261.3, as reissued on March 3, 1992 . . .". Congress expressed no intent that these rules be rescinded or replaced.

We also disagree with commenters' assertion that the mixture and derived-from rules violate the "two-step process" of section 3001(a) and (b) for hazardous waste identification. It is true that the statute requires EPA to promulgate criteria for hazardous waste identification (section

3001(a)) and, based on those criteria, to identify characteristics of hazardous waste and to list hazardous wastes (section 3001(b)). In general, EPA has done this in separate steps. See 40 CFR Part 261, Subpart B (criteria) and Subparts C and D (characteristics and lists). However, the statute does not preclude EPA from creating self-implementing criteria, as EPA has done with the mixture and derived-from rules. EPA does not interpret 3001(b) as imposing an obligation on EPA to undertake a separate waste identification rulemaking step following the development of self-implementing criteria. Alternatively, the mixture and derived-from rules could be viewed as a simultaneous exercise of EPA's 3001(a) and 3001(b) authority. Nothing in the statute prevents EPA from simultaneously, in combined regulations, establishing the criteria for waste identification, and identifying the characteristics of hazardous waste and listing waste.

We agree with commenters who point out that EPA has not used the class listing process under 40 CFR 261.11(b) to list mixtures and derived-from wastes as a class. However EPA does not agree that mixtures and derivatives must be individually listed or identified as hazardous wastes before being subject to Subtitle C jurisdiction. As previously stated, mixtures and derivatives are identified as hazardous waste by virtue of containing or coming from wastes that have been listed pursuant to the criteria in 40 CFR 261.11. EPA cannot presume that the hazardous constituents that are the basis of the original listing are always eliminated or rendered nontoxic simply because a waste is mixed with other wastes or managed in some fashion.

(3) Comment: EPA has no authority under sections 3002-3004 of RCRA to designate wastes as hazardous

Several commenters from industries, industry associations, utility companies, utility company associations and waste management companies also disagreed with EPA's claim of authority under sections 3002-3004 of RCRA. They argued that these sections of RCRA provide for hazardous waste management standards for generators, transporters, and treatment, storage and disposal facilities, not for identifying hazardous wastes. Instead, that role is unambiguously carried out by section 3001. 42 U.S.C. 6921, and in previous promulgations and in litigation, EPA relied primarily on section 3001 to justify the mixture and derived-from rules.

EPA Response

In citing sections 3002-3004 in the discussion of EPA's statutory authority, we did not intend to imply that these sections by themselves provide statutory authority for the mixture and derived-from rules. Rather, our intent was to explain that these sections inform the process of identifying hazardous waste under section 3001 because the purpose of identifying a solid waste as hazardous is to ensure that it is managed properly.

The statute directs EPA to regulate hazardous waste generators (section 3002(a)), hazardous waste transporters (section 3003(a)), and hazardous waste treatment, storage, and disposal facilities (section 3004(a)) "as necessary to protect human health and the environment." It is our view that this informs the decision of when waste should be identified as hazardous and therefore subject to the regulatory requirements of Subtitle C . In deciding whether to identify a waste as hazardous under section 3001, EPA considers whether Subtitle C controls on the waste

are necessary to protect human health and the environment. We have therefore consistently interpreted section 3001 to give us broad flexibility in fashioning criteria for hazardous wastes to enter or exit the Subtitle C regulatory system. See, *Military Toxics Project v. EPA*, 146 F.3d 948, 958 (D.C.Cir. 1998). As discussed above, this interpretation is consistent with the statutory purpose of protecting human health and environment by establishing a comprehensive hazardous waste regulatory program. (RCRA sections 1002, 1003).

In addition to providing the context in which the determination of whether a waste "should be subject to the requirements of Subtitle C," sections 3002-3004 allow us to continue to impose requirements on waste handlers until wastes have "cease[d] to pose a hazard to the public." *Shell Oil Co. v. EPA*, 959 F.2d 741, 754 (D.C.Cir. 1991). See also *Chemical Manufacturers Assoc. v. EPA*, 919 F.2d 158, 162-65 (D.C Cir. 1990) (EPA may regulate the disposal of nonhazardous wastes in a hazardous waste impoundment under section 3004) and *Chemical Waste Management, Inc. v. EPA*, 976 F.2d 2, 8, 13-14 (D.C. Cir. 1992) (EPA may require further treatment of wastes under section 3004 even though they cease to exhibit a hazardous characteristic). Without the mixture and derived-from rules, EPA could not effectively carry out its obligation under sections 3002-3004 to protect human health and the environment. Thus, in addition to the specific authority of section 3001, the mixture and derived-from rules are authorized under section 2002(a)(1), which empowers the Administrator to "prescribe. . . such regulations as are necessary to carry out his functions" under RCRA.

(4) Comment: EPA has not met the intent of Congress to significantly revise the mixture and derived-from rules and failed to meet consent decree deadlines, therefore the interim MDF rules should be considered null and void

Eli Lilly and the American Iron and Steel Institute argued that the regulated community never should have been subjected to the "unlawful" and "extremely burdensome" requirements of the MDF rules. They noted that (as of the 1995 HWIR proposal) it had been almost five years since the original rules were overturned by the D.C. Circuit and reinstated by the Agency on a temporary and emergency basis, and over a year and a half since passage of the deadline that was established by Congress for revising the MDF rules. Bethlehem Steel believed that EPA should identify the emergency that provides authority for the mixture and derived-from rules in their current, interim form. The Fertilizer Institute noted that the consent decree merely provided an extension of the deadline contained in the Chafee Amendment which extended the sunset provision to October 1, 1994 and provided that "EPA shall promulgate revisions to the MDF rules as reissued on March 3, 1992, by October 1, 1994." CMA argued that EPA had not satisfied the requirements of the fiscal year 1993 Appropriations Act that required that EPA promulgate revisions to MDF rules by October 1, 1994. The commenter noted that apart from making cross-references to the new exit subsections, the proposal made no changes to these rule, and therefore, EPA had not revised the MDF rules in any meaningful way.

Several industry commenters also believed that the current proposal broke faith with the Congressional command and the spirit of the entire HWIR endeavor. In 1992, Congress specifically directed EPA "to promulgate revisions" to the MDF rules, and now EPA only

proposed two narrow revisions to the MDF rules. The commenters believed that the Agency's approach was becoming an excuse for indefinite delay. They commented that such delay was not warranted, and the Agency could not reasonably ask the regulated community to continue complying with unlawful and onerous rules. Bethlehem Steel requested that EPA identify the emergency that it believes provided the authority for the MDF rules in their current, interim form.

Eli Lilly also cited the adoption of H.R. 2036 (104th Cong., 2nd session, 1996) as a signal of the Congress' intent to reform RCRA. They felt that based on this clear signal from Congress for common sense reform of RCRA regarding the decharacterized wastewater, the Agency should modify the derived-from rule to recognize that permitted RCRA treatment processes effectively eliminate the basis for the listing.

Response

EPA does not agree that today's rule violates either the FY 1993 Appropriations Act requirement to revise the mixture and derived-from rules or the deadlines established under the amended consent decree in *ETC. v. Browner*. EPA reinstated the rules on an interim basis in 1992 under the "good cause" exemption from the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. §553(b)(3)(B) and provided its rationale for reinstatement at that time (57 FR 7628, 7629-30, March 3, 1992).

The statutory directive to EPA in Publ L. No. 102-389, 106 Stat. 1571 provides as follows:

> Funds appropriated or transferred to EPA may be used to develop revisions to 40 CFR 261.3, as reissued on March 3, 1992, published at 57 Fed. Reg. 7628 et seq. EPA shall promulgate revisions to paragraphs (a)(2)(iv) and (c)(2)(i) of 40 CFR 261.3, as reissued on March 3, 1992, by October 1, 1994, but any revisions to such paragraphs shall not be promulgated or become effective prior to October 1, 1993. Notwithstanding paragraph (e) of 40 CFR 261.3, as reissued on March 3, 1992, paragraphs (a)(2)(iv) and (c)(2)(i) of such regulations shall not be terminated or withdrawn until revisions are promulgated and become effective in accordance with the preceding sentence. The deadline of October 1, 1994 shall be enforceable under section 7002 of the Solid Waste Disposal Act.

This statutory mandate does not direct EPA in any way with respect to what "revisions" EPA must promulgate. The only restrictions on "such revisions" concern the timing of their promulgation. Congress did not use any terms as described by the commenters, such as "meaningful, "significant," or "substantial," which, in any case, are subjective and require interpretation. Similarly, there is nothing in H.R. 2036 [Pub. L. No. 104-199] that would apply to today's rulemaking.

As stated in the preamble to the proposed rule (64 Fed. Reg. 63388) , EPA did not meet the October 1, 1994 statutory deadline, and several entities files suit in the Federal District Court

for the District of Columbia under section 7002 to enforce the deadline. The court entered a consent decree on May 3, 1995 establishing a schedule for proposing and taking final action on revisions to the mixture and derived-rom rules. *ETC v. Browner,* C.A. No. 94-2119 (TFH). On April 11, 1997, the court ordered an amendment to the consent decree which revised the schedule. EPA is in compliance with the schedule as ordered in the April 11, 1997 amendment to the consent decree.

(5) Comment: EPA has failed to analyze costs and benefits of the mixture and derived-from rules, including impacts to small entities

SOCMA and Bethlehem Steel argued that the economic and regulatory analysis failed to address the rule's impacts on any substantive level. They believed that the Agency had an obligation to fully evaluate the costs and burdens associated with the proposed retention of the MDF provisions. SOCMA believed that as a result of EPA's failure to address the costs associated with retaining the MDF rules, EPA's economic assessment was both incomplete and inconsistent with Executive Order 12866. EPA provided no basis for its failure to address the costs associated with retention of the MDF rules. SOCMA also noted that EPA's failure to assess the costs associated with the proposed retention of the MDF rules is inconsistent with the Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The commenter believed that EPA's failure to conduct a complete Regulatory Flexibility Assessment subverts the required administrative procedures of the Regulatory Flexibility Act. EPA's proposed retention of the mixture and derived from interim rules constituted a rule. The term rule means any rule for which the Agency publishes general notice of proposed rulemaking pursuant to section 553(b) of this title... for which the agency provides for notice and public comment (see 5 U.S.C. §601(2). As such, the November 19, 1999 Notice of Proposed Rulemaking met the statutory definition of a rule as defined in the Regulatory Flexibility Act. Since EPA was proposing this rule pursuant to section 553 of the Administrative Procedure Act, the Agency was required to consider the impacts of the rule on small businesses. Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule... the agency shall prepare and make available for public comment an initial regulatory flexibility analysis (see 5 U.S.C. § 603(a). Lastly, the commenter noted that because EPA's economic impact assessment failed to address the impacts of the most onerous part of the current proposal -- the retention of the MDF rules, EPA was in violation of the Regulatory Flexibility Act.

Response

EPA believes that the legally proper and factually accurate assessment of the economic impacts of today's rulemaking must begin with a baseline of costs in existence at the time the rule would become effective. The mixture and derived-from rules have essentially been in effect since 1980. Although the rules were vacated, EPA reinstated the rules without modification, at the suggestion fo the court. *Shell Oil v. EPA*, 950 F.2d 741 (D.D. Cir. 1991). EPA reinstated the

rules in accordance with the "good cause" exemption from the notice and comment requirements of the APA. 5 U.S.C. §553(b)(3)(B). Thus the baseline for evaluating the costs of today's rule must assume that mixture and derived-from rules already apply.

This cost analysis is consistent with EPA's intent when EPA reinstated the mixture and derived-from rules in 1992, (57 Fed. Reg. 7628 (March 3, 1992)). With respect to Executive Order 12291, the predecessor to Executive Order 12866, the Agency stated that "EPA does not believe an RIA [Regulatory Impact Analysis] is needed for this reinstatement given that it imposes no new costs beyond what has been in place for some time." 57 Fed. Reg.7632. The Agency also stated that it was considering modifications to the rules and therefore "determined that this interim final reinstatement should not remain in effect indefinitely." However, while establishing a sunset provision in the interim final rule, EPA also stated that the unmodified rules "will expire April 28, 1993, unless EPA, after considering comments, makes a final determination to retain these rules in their current form." 57 Fed. Reg. at 7630. With respect to the requirements for an economic analysis, the Agency stated that "EPA will complete a regulatory Impact Assessment for the modifications (emphasis added). 57 Fed. Reg.7632.

Similarly, EPA disagrees that the Regulatory Flexibility Act, 5 U.S.C §601 *et seq.*.(RFA) requires EPA to assess the costs of the mixture and derived-from rules already in existence in determining whether today's rule will have a significant economic impact on a substantial number of small entities. For proposed rules subject to the notice and comment rulemaking requirements of 5 U.S.C. §553, section 603(a) of the RFA requires the Agency to "describe the impact of the proposed rule on small entities." EPA interprets this provision as requiring the Agency to describe how the promulgation of today's rule would change the economic impact of these rules when they become effective. The changes that will occur as a result of today's rule will be to exclude certain wastes from the regulatory definition of "hazardous waste," thereby creating a cost savings to the regulated community as a whole, including small entities.

Given that the mixture and derived-from rules have been in effect for over 20 years (other than a several-month gap), EPA believes it would be artificial to view today's rule as imposing new costs. Indeed, it would be impossible to attribute costs to these rules in any meaningful way. As explained above, absent the rules, case-by-case judgments would be made, and undoubtedly litigated, regarding the extent to which waste captured by these rules would be captured in any event by the relevant listings, or by the listings combined with the provision that listed hazardous waste remains hazardous until delisted (40 CFR § 261.3(c)(1)). Moreover, because the mixture and derived-from rules have been such an integral part of the Subtitle C program since its inception, EPA does not track waste based on its mixture and derived-from status, so there would be no factual basis for the Agency to estimate what portion of waste mixtures and derivatives would be captured absent the rules, even if EPA were able to develop some principles or guidelines for making such judgments. Thus, there is no factual or legal basis to judge what portion of the presently regulated hazardous waste universe would escape regulation absent the mixture and derived-from rules.

Issue Code: MDF2: Necessity of the MDF Rules

Comments: WHWP-00035, 1, 4; WHWP-00065, 1, 1; WHWP-00078, 3, 7; WHWP-00083, 2, 1; WHWP-00099, 1, 3; WHWP-00125, 3, 1; WHWP-00139, 38,1; WHWP-00171, 4, 3; WHWP-00175, 2, 3; WHWP-00186, 2, 1; WHWP-00190, 3,3; WHWP-00193, 2, 1; WHWP-00195, 1, 2; WHWP-00197, Ltr.; WHWP-00201, 2, 1; WHWP-00224, 2,5; WHWP-00247, 2, 1; WHWP-L0004, 13, 2; WH2P-00002, 1, 3; WH2P-00004, 10,5; WH2P-00005, 1, 1; WH2P-00005, 3, 1; WH2P-00009, 1, 2; WH2P-00014, 2, 2; WH2P-00015, 5, 2; WH2P-00018, 1, 4; WH2P-00021, 4, 3; WH2P-00025, 1, 3; WH2P-00028, 1, 2; WH2P-00033, 4, 2; WH2P-00033, 7, 1; WH2P-00034, 1, 3; WH2P-00035, 1, 3; WH2P-00035, 5, 1; WH2P-00036, 1, 2; WH2P-00041, 1, 3; WH2P-00042, 1, 2; WH2P-00043, 1, 2; WH2P-00046, 1, 3; WH2P-00048, 1, 2; WH2P-00048, 3, 1; WH2P-00050, 1, 2; and WH2P-00050, 2, 5

Comment Summary:

EPA received comments from 38 commenters in response to both the 1995 and the 1999 HWIR proposals specifically concerning the necessity of the mixture and derived-from rules. Of those comments, 14 were received from industry, seven were from industry associations, eight were from State Agencies, five were from waste management companies, two were from waste management associations, one was from a Federal Agency and one was from a consultant.

The States and waste management associations supported the retention of the mixture and derived-from rules, while the industry commenters generally believed that the mixture and derived-from rules were unnecessary. A summary of the specific issues raised by commenters is provided below.

Twelve commenters explicitly supported the retention of the mixture and derived-from rules. Many of the State commenters said that the rules were necessary to capture mixtures and derivatives of listed hazardous wastes in the universe of regulated hazardous wastes in order to protect human health and the environment. The commenters noted that without these rules, it would be possible to alter a particular waste to the point that it no longer meets the listing description without detoxifying, immobilizing, or otherwise actually treating the waste. One industry association commenter also supported the retention of the mixture and derived-from rules, noting that although it is not a perfect solution, the approach has been used for the last 15 years in a generally effective manner.

One waste management association commenter also strongly supported the retention of the mixture and derived-from rules. The commenter believed the mixture and derived-from rules were necessary because they prevented many wastes that clearly were hazardous and that posed substantial threats to human health and the environment from escaping RCRA controls only because they are mixtures or derivatives that no longer fit an original listing description. The commenter noted that generators send their listed hazardous wastes to treatment facilities for initial treatment to reduce the toxicity and/or mobility of some, but not all, toxic constituents in

the waste. The commenter also agreed that EPA's experience with delisting petitions further supported the rationale for the mixture and derived-from rules.

Twenty-six commenters did not support the retention of the mixture and derived-from rules. Some asserted that eliminating the derived-from rule would be a common sense reform of RCRA to reduce unnecessary over-regulation of many wastes. Many industry commenters and industry associations commented that the mixture and derived-from rules unnecessarily continue to regulate low-risk material resulting in significant waste management costs with no associated environmental benefit, thus also affecting the credibility of EPA. Several of the comments cited EPA's 1992 HWIR proposal, saying that "millions of tons of mixtures and derived-from residuals that must be managed as hazardous waste . . . may actually pose quite low hazards." (57 FR 21451, May 20, 1992). The Department of Defense acknowledged the need to retain the mixture and derived-from rules; however, the commenter noted that the mixture and derived-from rules have been a source of over-regulation for low-risk wastes.

Several commenters asserted that the mixture and derived-from rules have no continued viability, particularly in light of the technological advances that have developed since the rules were first promulgated in 1980. They noted that since 1980, the regulated community has made considerable improvements in the treatment, storage, and disposal of hazardous waste. In their view, the result is that the risks that formerly may have been associated with the management of hazardous waste have been reduced significantly or eliminated, such that the universe of waste that may have warranted Subtitle C regulation in 1980 has been reduced significantly. Six commenters agreed with the U.S. Court of Appeals observation in *Shell Oil Co. v. EPA,* 590 F.2d 741, 752 (D.C. Cir. 1991) that, "the derived-from rule becomes counterintuitive as applied to processes designed to render wastes nonhazardous. Rather than presuming that these processes will achieve their goals, the derived-from rule assumes their failure." Commenters also noted that the hazardous waste characteristics, particularly the Toxicity Characteristic, would continue to ensure proper management of high risk wastes under RCRA.

Several commenters stated that when compared to established standards, a waste material is either hazardous or it is not and it is not necessary to consider the origin of the material. The consultant noted that the mixture rule is completely unnecessary and isn't scientifically appropriate because if the compound or element in the waste needs to be controlled in a certain environment, it doesn't matter what the source is. Therefore, a regulation should set the limit for that environment for that compound or element and the mixture and derived-from rules should be eliminated. One commenter believed that the continued inflexible application of the mixture and derived-from rules has served only to bring to light the self-defeating complexity of the program.

Agency Response:

EPA acknowledges that the mixture and derived-from rules apply regardless of the concentrations and mobilities of hazardous constituents in the waste. We have implemented and will continue to pursue actions to reduce any overregulation of low-risk wastes arising from the mixture and derived-from rules. Nevertheless, EPA believes that retention of the mixture and derived-from rules are necessary to ensure protection of human health and the environment. When EPA determines that a waste should be listed as hazardous, we consider several different

factors, including the toxicity of the chemicals in the waste, the persistence of those toxic chemicals, and the degree to which the chemicals bioaccumulate in the environment. As discussed below, the act of mixing a hazardous waste with another waste, or storing, treating, and disposing of that waste does not necessarily remove the hazard posed by these toxic chemicals. Under RCRA, EPA has an obligation to ensure that the risk posed by a hazardous waste is controlled from the cradle to the grave. Both the mixture and derived-from rules are needed to make sure that this obligation is carried out.

Concerns About Deliberate Evasion

When EPA originally promulgated the mixture and derived-from rules in 1980, one of our main concerns was that, without these rules, generators could deliberately evade regulation by taking advantage of a "loophole" in the hazardous waste identification process. (45 FR 33084, 33095 (May 19, 1980)). Specifically, we believed that without the mixture and derived-from rules, generators could potentially alter their waste so that it no longer meets the listing description without detoxifying, immobilizing, or otherwise effectively treating the waste.

Despite the progress that has been made in environmental compliance in the past twenty years, this concern remains, and the comments of EPA's co-regulators, the State governments, echo this continuing concern. EPA agrees with those industry comments that claim many companies are more environmentally aware and responsible than they were in the past. However, there will always be some entities who might try and exploit gaps in the regulatory system. Absent the mixture and derived-from rules, there would be a potentially significant gap in the coverage of the hazardous waste listings.

For example, without a "mixture" rule, generators of hazardous wastes could potentially evade regulatory requirements by mixing listed hazardous wastes with other hazardous wastes or nonhazardous solid wastes to create a "new" waste that arguably no longer meets the listing description, but continues to pose a serious hazard. Similarly, without a "derived-from" rule, hazardous waste generators and hazardous waste treatment, storage, and disposal facilities (TSDFs) could potentially evade regulation by minimally processing or managing a hazardous waste and claiming that the resulting residue is no longer the listed waste, despite the continued hazards that could be posed by the residue even though it does not exhibit a characteristic. A hazardous waste regulatory system under which it could be argued that hazardous waste could leave the system as soon as it was modified to any degree by being mixed or marginally treated would be ineffective and unworkable. Such a system could act as a disincentive to adequately treat, store and dispose of listed hazardous waste.

In addition, as explained below, even if generators or TSDFs do not deliberately try to evade hazardous waste regulations, certain waste mixtures and derived-from wastes could pose substantial present or potential hazards if mismanaged. We, therefore, continue to believe that the mixture and derived-from rules are necessary to capture wastes that would pose unacceptable risks to human health and the environment.

Regulating Hazardous Waste Mixtures

Mixing hazardous waste with another waste may dilute, and sometimes mask, the concentrations of toxic constituents in the listed waste, but does not necessarily address the hazards posed by these constituents. Some of the comments focused on diluted wastewaters as an example of mixtures that are potentially "low risk." Of the "millions of tons" of waste that EPA

estimated would be exempted under the 1995 HWIR proposal because they may pose low risks, 99% of the waste by volume is wastewater (60 FR 66415, December 21, 1995). Wastewaters are generally disposed either in an underground injection control well regulated under the Safe Drinking Water Act (SDWA)or to the environment under the Clean Water Act (CWA). Because discharged hazardous wastewaters must meet CWA standards, some commenters believe that these wastewater mixtures should be excluded from hazardous waste regulation prior to their discharge.

We have several concerns with this argument. The management of wastewater mixtures is already largely exempt from most RCRA requirements. The two main requirements that remain under RCRA are that the wastewaters must be managed in tanks, and the treatment sludge must be managed as a hazardous waste once removed from the tank. Continued management of these wastewaters in tanks is usually needed to avoid infiltration to groundwater of concentrations of toxic constituents that pose unacceptable risks. Even when they meet their CWA discharge limits, mismanaged wastes could pose unacceptable risks through the groundwater pathway, which is not addressed by the CWA. Sludges from wastewater treatment need to be managed as hazardous waste, because they can contain the same persistent and toxic chemicals (e.g., heavy metals) that originated in the wastewaters. Each of these points is discussed in more detail below.

RCRA section 1004(27) already excludes industrial wastewater discharges subject to CWA section 402 regulation from the definition of "solid waste" under RCRA. See also, 40 CFR 261.4(a)(2). In addition, wastewater treatment units, as defined in 40 CFR 260.10 (i.e., tanks), are excluded from almost all RCRA regulation (see 40 CFR 264.1(g)(6); 265.1(c)(10); and 270.1(c)(2)(v)). RCRA has historically deferred to the Clean Water Act and its oversight in properly regulating hazardous wastewaters discharged by CWA wastewater treatment systems or other point sources subject to CWA discharge requirements, including storage in wastewater treatment units prior to discharge. However, with the exception of sewage sludge, the CWA does not apply to sludges which are a byproduct of wastewater treatment. To the extent treatment of listed hazardous wastewaters generates sludges, those sludges are considered hazardous by the derived-from rule (as discussed below).

Furthermore, to the extent that additional hazards may be associated with wastewaters managed in such systems (including risks via inhalation pathway and risks via groundwater ingestion when treatment takes place in surface impoundments)[3], the Agency considers such wastes as hazardous and within RCRA jurisdiction until discharged. While wastewaters must meet CWA requirements at the point of discharge, they can still have high concentrations of constituents during the management of the waste.

Even after hazardous wastewaters have been treated to meet CWA standards, they could still have the potential to pose unacceptable risks to human health and the environment when managed in surface impoundments or other retention ponds (or otherwise managed on the land, i.e., during a spill) prior to discharge to the receiving water body. Both surface impoundments

[3] The Revised Air Characteristic Study (EPA 530-R-99-019a) published August 1999 suggests that potential risks to airemanating from wastewaters managed in wastewater treatment tanks may be of regulatory concern and may represent a regulatory gap because of the existing exclusions for wastewater treatment units from certain RCRAcontrol requirements.

and retention ponds can have high potential for discharge of the wastewaters they contain to underlying groundwater (see RCRA sections 1002(b)(7) and 3005(j)). Discharge treatment requirements based on State water quality standards are calculated by taking the nature of the effluent and the receiving water body into account. An effluent treated to meet water quality standards for a surface water body could leach into groundwater, depending on the hydrogeology of the site, if subsequently held in a surface impoundment or retention pond prior to discharge. This leachate could undergo a lesser degree of dilution in groundwater than in the intended surface water body, potentially posing unacceptable risks to groundwater users through a drinking water well. This risk is not accounted for under the current federal CWA standards.[4] Therefore, EPA continues to believe that retaining jurisdiction over hazardous wastewaters under RCRA prior to their NPDES-permitted discharge is necessary to ensure protection of human health and the environment.

Another reason why these wastewaters should not be categorically designated as non-hazardous prior to discharge is because that would effectively exclude their treatment sludges as well (by avoiding the application of the derived-from rule).[5] As explained below in more detail, treatment sludges from these dilute wastes cannot be assumed to be low risk. In fact, treatment sludges can contain high levels of the very chemicals (e.g., heavy metals) that caused the original waste to be listed. In these cases, the hazard that was identified as the original basis of listing has not been removed; it has merely been transferred to another type of waste matrix (i.e., from a water to a solid).

In sum, EPA has excluded (through the wastewater treatment unit exclusions) hazardous wastewaters from regulation where we believe there is a reasonable basis to do so, grounded in the protection of human health and the environment, and the statute excludes from RCRA jurisdiction industrial wastewater discharges subject to CWA discharge permits. But based on the available data, EPA believes that a blanket wastewater exclusion from regulation is not warranted. Instead, EPA will continue to develop approaches (e.g., targeted exemptions and HWIR exemption levels) to address wastewaters that are be considered low risk.

Regulating Derived-From Wastes

As explained in 40 CFR 261.3(c)(2)(i), any solid waste derived from the treatment, storage, or disposal of a hazardous waste is also considered a hazardous waste. Specific examples

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[4]The current federal National Pollution Discharge Elimination System (NPDES) program under the CWA does not require permitting authorities to issue permits for discharges of wastewater to groundwater (See 40 CFR 122.1 and 122.2). The exception is those instances in which a discharge to surface water may occur via a hydrologic connection between a groundwater and surface water. In addition, some states have chosen to exceed federal program requirements and do issue such permits. see also U.S. EPA NDPES Permit Writers' Manual, United States Environmental Protection Agency, Office of Water, December 1996. EPA-833-B-96-003

[5]These wastes would still be subject to the hazardous waste characteristics of 40 CFR Part 261, Subpart C, but, as explained later in this section, such coverage would not address all the unacceptable risks potentially posed by the chemicals in these wastes.

of these derived-from wastes include sludges, spill residues, ash, emission control dust, and leachate. For derived-from wastes that change location but are otherwise unmodified, the question of their continued regulation is more straightforward. Because such waste would have the same levels of toxic constituents and presumably the same potential exposure patterns as the waste that was evaluated for the original hazardous listing determination, it would pose the same unacceptable risk as the original waste.

Other types of derived-from wastes may have a different physical form than the original waste, but still present the same chemical hazard. Leachate derived from the disposal of hazardous waste, for example, can contain the same chemicals as found in the original waste. When EPA analyzed leachate for purposes of promulgating effluent guidelines for landfill leachate (65 FR 3007, January 19, 2000), we found that wastewater generated as a result of a particular industrial operation can have a similar pollutant profile to leachate generated by a landfill receiving the bulk of their waste from that same operation (65 FR 3008, 3012, January 19, 2000). During treatment, chemicals in hazardous wastewater are transferred to the sludge, which is disposed of in the captive landfill. Once the sludge is disposed in a landfill, persistent chemicals in this sludge can then transfer to the leachate, which, when managed in a wastewater treatment unit, transfers them once more to sludge. Although changed in form, the treatment sludge (and leachate) could still pose similar unacceptable risks as the originally listed waste, depending on actual concentrations and exposure patterns.

We also found considerable differences between the leachate samples from hazardous and those from non-hazardous waste landfills in both numbers of constituents of concern and their concentrations. Hazardous waste landfill leachate contained a greater number of constituents than non-hazardous waste landfill leachate, and constituents found in both hazardous and non-hazardous waste landfill leachate were generally present in hazardous waste landfill leachate at concentrations an order of magnitude higher than those found in non-hazardous waste landfill leachate.[6] Absent a risk assessment, it is not possible to determine whether the levels of these constituents pose unacceptable risk. However, the presence of such constituents creates a continuing concern regarding leachate derived from hazardous waste.

The other broad category of derived-from waste are treatment residues. At least six commenters cited the D.C. Circuit Court of Appeals observation in *Shell Oil Co. v. EPA*, 590 F.2d at 752 that "the derived-from rule becomes counterintuitive as applied to processes designed to render wastes nonhazardous." However, the presumption that treatment always renders hazardous waste nonhazardous is overly simplistic. This presumption does not take into account all products of treatment. Even treatment that operates properly is often designed to isolate a hazardous residual. For example, wastewater treatment designed to produce a sufficiently clean effluent for discharge is also designed to move the hazardous constituents from the wastewater into the sludge. The resulting de-watered sludge, while much lower in volume than the original hazardous wastewater, has the potential to have much greater concentrations of hazardous chemicals. As explained above, once the sludge is disposed in a landfill, persistent chemicals in this sludge can then transfer to the leachate, which, when managed in a wastewater treatment unit,

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[6]Development Document for Final Effluent Limitations Guidelines and Standards for the Landfills Point Source Category, EPA-821-R-99-019, U.S. EPA, January 2000.

transfers them once more to sludge.

The derived-from rule thus ensures that the chemicals in the originally listed waste that are transferred to another matrix when the waste is managed remain under RCRA Subtitle C control. Without the derived-from rule, a hazardous wastewater could be treated so that hazardous constituents are moved to the sludge. If the generator could claim that the resulting sludge, regardless of chemical concentration, no longer meets the listing description, then that sludge could be handled as non-hazardous waste, and placed in an unlined industrial landfill, or sent to a land application unit[7]. The resulting leachate would not necessarily be collected. Instead, those chemicals that first caused the waste to be listed could potentially now enter the environment and, depending on the actual chemical concentrations and exposure patterns, could pose unacceptable risks.

Other types of treatment, which result in combining wastes with different chemical concentrations, can result in dilution of those chemicals, but may not adequately address the hazard they could pose. As mentioned earlier in the discussion on regulating mixtures, combining wastewaters for centralized treatment is often a legitimate treatment practice, but the diluting effect of such treatment does not address the transfer of persistent chemicals to the sludge.

Finally, treatment that reduces the amount of organic chemicals in a waste does not typically address the risk from metals in the waste. For example, biological treatment and incineration, which are among the most aggressive forms of treatment, are designed to reduce or destroy organic chemicals. However, these types of treatment do not address heavy metals and may form chemical by-products (e.g., dioxins) that could pose unacceptable risks, if not managed properly. For example, baghouses on combustion devices serve to collect hazardous constituents that would otherwise be emitted to the air from the combustion process, and the dust that is removed from the baghouses predictably contains metals that were in the original waste. In response to industry comments, EPA will explore specific approaches for dealing with biological treatment residues and has already begun considering an alternative approach to address combustion residues. EPA will also continue to develop approaches (e.g., targeted exemptions and HWIR exemption levels) to exempt other waste streams that are currently captured by the derived-from rules but pose low risks.

Historic Information on Mixture and Derived-From Wastes

As we discussed in the 1999 proposal, EPA's experience with the delisting program further supports retaining the mixture and derived-from rules as a necessary part of hazardous waste identification. Generators can petition EPA under 40 CFR 260.22 to exclude a waste produced at a particular facility from the definition of hazardous waste. Such petitions must demonstrate that the waste does not meet any of the criteria for which it was listed nor has other attributes that might result in the waste being hazardous.

Over the 20-year period from 1980 through 1999, EPA reviewed over 900 petitions to delist wastes, and granted delistings to 136 waste streams generated at 115 separate facilities. Most of the

[7]These wastes would still be subject to the hazardous waste characteristics of 40 CFR Part 261, Subpart C, but, as explained later in this section, such coverage would not address all the unacceptable risks potentially posed by the chemicals in these wastes.

petitions (i.e., more than 600) were withdrawn or mooted before the review was complete; 108 were denied. Most of these denials were based on lack of information. In at least 13 of the 36 cases where enough information is available in the source documentation to determine whether a waste was a mixture or derivative, we denied delisting petitions for mixtures or residuals of listed waste because risk analyses indicated that the toxicity and leaching potential of hazardous chemicals in those wastes posed unacceptable risk to human health. These mixture and derived-from wastes had potentially hazardous levels of a wide range of chemicals including barium, cadmium, chromium, lead, mercury, nickel, benzene, benzo(a)pyrene, cyanide, chloroform, 1,1-dichloroethane, 1,1-dichloroethylene, 2,4-dinitrotoluene, methylene chloride, trichloroethylene, and vinyl chloride.[8]

We have also identified possible damage cases associated with mixture and derived-from wastes. For example, there are Superfund sites that contain mixture and derived-from wastes (See 50 FR 658). We have identified at least twenty sites that may have involved the mismanagement of mixture and derived-from wastes.[9] The sites identified include cases of extensive contamination of soils and groundwater with metals (e.g., arsenic, lead, mercury), cyanide, and organics (e.g., benzene, toluene, and xylenes). It is very difficult to identify the full range of damage cases that specifically involve waste mixtures or derivatives since neither EPA nor other parties track or categorize waste based on its status under the mixture or derived from rules.

The legislative history of RCRA also provides examples of damage cases caused from disposal of mixture and derived-from hazardous wastes. In introducing the purpose of Subtitle C, the House Committee on Interstate and Foreign Commerce cited seven pages of damage cases, stating, "The most effective way of illustrating the dangers of improper hazardous waste disposal is perhaps to cite actual instances of damage caused by current hazardous waste disposal practices. The following section is merely illustrative of the problem. Far more cases could be cited, even more have gone unreported." H.R. Rep. No. 94-1491 (94th Cong. 2d Sess. 1976) 17-23. Of the 59 instances described in the House Committee Report, at least 40 involved spills, leachate or runoff from landfills, lagoons or waste storage facilities. Leachate and run-off are derived-from wastes, as are spills from storage and disposal facilities, and some of the sources contained mixtures of hazardous and non-hazardous solid wastes.

Intrinsic chemical properties of RCRA hazardous waste "mixtures" and "derived-from" wastes

We also analyzed the information in EPA's National Hazardous Waste Constituent Survey (NHWCS) Database to assess the intrinsic physical and chemical properties of RCRA hazardous waste "mixtures" and "derived-from" wastes. The purpose of the NHWC Survey was to collect descriptive information about the identity and measured concentrations of chemical constituents contained in RCRA hazardous wastes. The NHWCS was a one-time, voluntary participation mail survey we administered in 1996, providing a single-year "snapshot" of the intrinsic physical and chemical properties of RCRA hazardous wastes. It is EPA's most comprehensive and current database about hazardous waste constituents. We benchmarked the 1996 survey to data already collected in our 1993 Biennial Reporting System (BRS) database -- which contains data provided by the 1993 universe of RCRA hazardous waste large quantity generators -- by pre-loading

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[8]U.S. EPA Evaluation of Hazardous Waste Delisting Program, December 2000; and Analysis of the Delisting Petition Data Management System, U.S. EPA, September 1998). EPA Docket 99-WH2P-FFFFF.

[9]EPA 2000. Releases of Hazardous Constituents Associated with Mixture and Derived-from Wastes (An Update) U.S. EPA, April 2000.

survey questionnaires with the known 1993 BRS data for the NHWC survey facilities, and asking facilities to verify the known BRS data, as well as to provide new data about the known chemical constituents in the RCRA hazardous wastes they managed (constituent data are not contained in the BRS database). This analysis is presented as a technical supplement to this rulemaking for purpose of public understanding of the intrinsic nature of these two groups of wastes, which we currently regulate as RCRA hazardous. This supplemental analysis corroborates the substance of our proposed rule (64 FR 63382-63461, Nov. 19, 1999).

Although the survey results apply to a subset of the total universe of waste and should not be extrapolated to the larger universe of RCRA hazardous waste generators, the information provides valuable insight into the types and levels of chemicals that could be present in such wastes. A large number of waste streams captured in the NHWCS were identified by their generators as mixtures of solid waste and hazardous waste or derived-from hazardous wastes. The analysis revealed that potentially hazardous chemical constituents, have been and can be present in wastes mixed with or derived-from, RCRA hazardous wastes. Although this analysis is not a quantitative risk assessment, this conclusion is supported by the presence of persistent, bioaccumulative, and toxic (PBT) chemicals in these two waste groups, some of which are at relatively high concentrations. Consequently, we continue to be concerned about the potential risks posed by the mismanagement of RCRA hazardous waste "mixtures" and "derived-from" wastes.

For more information about this analysis, please see the background document Analysis of RCRA "Mixtures and Derived-from" Hazardous Waste Constituent Data, which is available to the public from the RCRA Docket. The NHWCS database is available to the public via the Internet at http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/economic.htm.

Regulatory coverage by the Toxicity Characteristic

EPA also does not agree with comments that the mixture and derived-from rules are not necessary because the Toxicity Characteristic (TC) provides regulatory coverage of these wastes. The TC currently sets regulatory levels for only 40 chemicals. (see 40 CFR 261.24). On the other hand, the hazardous waste listings are based on hundreds of different chemicals. (see Appendix VII to 40 CFR Part 261). In addition, the TC levels are the result of laboratory analyses to predict whether a waste is likely to leach chemicals into groundwater at hazardous levels, not the result of a comprehensive risk assessment. Depending on the actual constituents in a waste and their concentrations, wastes with constituents that fall below TC levels can still pose unacceptable risks to human health and the environment if mismanaged. (55 FR 11799). EPA has listed wastes based on the presence of constituents below the TC levels. For example, in the final listing decision for spent hydrotreating and hydrorefining catalysts from refinery operations, we analyzed the potential risk from arsenic and benzene using input leachate concentrations capped at TC regulatory levels. The results of this analysis suggested unacceptable risks posed by these wastestreams from concentrations below the TC regulatory levels (63 FR 42154). The mixture and derived-from rules are necessary for capturing such wastes that could pose unacceptable risks from chemicals without TC levels and for risks not addressed by the TC approach.

Conclusion

When EPA determines that a waste is capable of posing a hazard to human health or the environment when improperly managed, that determination is based on consideration of several different factors, including the toxicity, persistence, degradability in nature, the potential of chemicals to bioaccumulate in tissue, flammability, corrosiveness, and other hazardous characteristics and related factors. The act of mixing, storing, disposing or even treating the waste does not guarantee removal of the hazard posed by these chemicals, nor does it remove

EPA's obligation to ensure that the hazards presented by the waste continue to be controlled from the cradle to the grave, even when it is transferred to another waste matrix. Nevertheless, EPA will continue to develop approaches to exempt low-risk wastes from full Subtitle C regulation, as appropriate. Since the original promulgation of the mixture and derived-from rules, we have invited suggestions as to better ways of handling the difficult issues associated with the mixing, treating, storing, disposing, and otherwise managing waste following its generation. See 45 Fed. Reg. 33095 (May, 19, 1980). We have considered and are continuing to pursue suggestions for targeted exemptions as well as a risk-based exit level approach to identifying low-risk wastes.

Issue Code: MDF3: Regulatory Cost of the MDF Rules
Comments: WHWP-00162, 8, 1; WHWP-00185, 9, 1; WHWP-00201, 2, 1; WHWP-00219, 1, 1; WH2P-00035, 7, 2; and WH2P-00035, 10, 1

Comment Summary:

EPA received comments from five commenters in response to both the 1995 and the 1999 HWIR proposals concerning the regulatory cost of the mixture and derived-from rules. Of those comments, four were received from industries, and one was from an industry association. The commenters generally argued that the rules constituted over-regulation of low-risk wastes causing high costs and heavy burdens with little benefit to human health and the environment. A summary of the specific issues raised by commenters is provided below.

One industry commenter argued that the rules have added significant costs to the operation of manufacturing facilities throughout the nation, while providing insignificant benefits to human health and the environment. The commenter noted that the generation of large quantities of hazardous wastewaters based solely on the practice of efficient, centralized wastewater treatment has led the company to evaluate the segregation of hazardous and non-hazardous wastewaters, to prevent the attachment of a "hazardous" label to those non-hazardous wastewaters. Such a segregation would require a second treatment facility and much re-piping, with the net result that millions of dollars would be expended and there would be no improvement in the wastewaters ultimately discharged to the environment through two, rather than one, discharge points. All that would be achieved is an apparent reduction in hazardous waste generation which does not, in reality, represent a decrease in waste generation, treatment or discharge, but rather a reporting game and artificial waste minimization driven by EPA requirements. It is this kind of "game" that compromises the credibility of both EPA and the regulated community and imposes a significant burden on the regulated community.

Another industry commenter noted that managing the residuals as if they were listed hazardous waste was significantly more expensive than managing the waste in accordance with solid waste regulations. For example, in 1995 transportation and disposal of ash from a hazardous solids incinerator cost approximately $185,000. In comparison, the ash could be managed in a state permitted Subtitle D landfill as non-hazardous waste for about $25,000. Another industry stated that these rules have resulted in significant expense that has diverted resources away from greater environmental opportunities.

One association commenter stated that the rules frequently cause waste codes to be carried through and applied to wastes that are fundamentally different from the original waste considered in the development of the listing classification. The commenter noted that there are many instances in which the risk associated with the original listed waste simply does not carry through in the same way, and that the composition and nature of any risk posed by these materials often bears little or no relationship to the original listed waste. Specific examples cited include (1) wastewaters where most of the arsenic has been precipitated and removed, (2) debris from hazardous waste refractories undergoing repair, and (3) wastewaters that had received ethylene oxide as part of an emergency incident. The costs and impacts of this automatic waste-code carry-through are quite significant. Much of the industry operates through smaller “batch” processes, while the regulations are crafted for a continuous manufacturing process. And, in many operations, delisting the mixture is not an option, as the facility can only store the mixture on-site for 90 days, which is not enough time for a delisting.

An industry association also stated that the costs imposed by the rules from a number of member companies are easy to identify: on-site storage costs, paperwork and administrative costs, higher shipping and transportation costs, and higher treatment, storage and disposal costs. And, these are the same types of costs analyzed and tallied by EPA in documenting the cost savings it

attributes to the modified exemption for hazardous wastes listed solely for a characteristic of ignitability, corrosivity and/or reactivity. The commenter also stated that another significant cost of the current regulatory regime was the extra time and effort required to evaluate and apply the rules in the real world. Even after 20 years, facilities still have difficulty evaluating when, whether and why certain waste streams must be managed as Subtitle C hazardous wastes under this approach.

Agency Response:

We agree that the mixture and derived-from rules have captured wastes that could safely be managed outside of RCRA Subtitle C regulation. As explained below, we have addressed specific cases of such over-regulation through targeted rulemaking in the past, and we will continue to explore options for exempting wastes that do not warrant Subtitle C regulation. However, we do not agree that hazardous waste regulation of mixture and derived-from waste provides no additional protection of human health and the environment. For example, as we discuss in the response to comment issue code MDF2, wastewaters prior to discharge may contain constituents at levels that could pose unacceptable risks if they are mismanaged. Furthermore, the mixture and derived-from rules address cross-media transfer of persistent hazardous chemicals from the wastewater to the treatment sludge.

One way of reducing the regulatory burden available to individual waste generators is the delisting process. Generators have the option of petitioning the Agency under 40 CFR 260.20 and 40 CFR 260.22 to exclude their wastes from the lists of hazardous wastes in subpart D of part 261 if they believe those wastes no longer pose risk to human health and the environment. Since the delisting program was delegated to the EPA Regions on October 10, 1995, a number of innovations have been adopted that have greatly improved the efficiency and effectiveness of the delisting program. In particular, EPA Region VI's award-winning program has created a process that produces a decision within an average of 180 days, provides a streamlined application checklist, proactively coordinates with State personnel, and includes a user-friendly, stand-alone software program that produces an updated, state-of-the art assessment of risks associated with delisting a petitioned waste. In addition, EPA and the applicant now work together to develop an initial application that can be approved without the need for major revisions, which is a major factor in reducing the processing time. EPA will continue these efforts and others in order to keep improving the delisting process. Since 1980, EPA has excluded an estimated 45 million tons of waste, resulting in an estimated cumulative cost savings between $1.1 billion and $1.3 billion (in 1999 dollars). In 2000 alone, we estimate cost savings of approximately $105.4 million.[10]

In addition, EPA has taken steps since the mixture and derived-from rules were promulgated in 1980 to further reduce the scope, and therefore the cost, of these rules when appropriate. As one commenter to the 1999 proposal pointed out, eighteen months after the original mixture and derived from rules, EPA promulgated the first of several exclusions for low-risk waste from the definition of hazardous waste. Over the past twenty years, EPA has developed exclusions and/or tailored regulations to reduce the regulatory cost for more than a dozen types of hazardous waste mixtures and residuals. (see table below)

Revisions to 40 CFR 261.3 That Have Reduced the Regulatory Cost of the Mixture and Derived-from Rules

[10]U.S. EPA Evaluation of Hazardous Waste Delisting Program, December 2000.

CFR Citation	Hazardous Waste(s) Affected	Year Promulgated (FR Citation)
40 CFR 261.3(a)(2)(iv)(A) and (B)	certain solvents managed in wastewater treatment systems	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(C)	certain petroleum wastes discharged to the refinery oil recovery sewer	1981 (46 FR 56582) Additional wastes added in 1998 (63 FR 42184)
40 CFR 261.3(a)(2)(iv)(D)	de minimis losses of commercial chemical product	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(E)	certain laboratory wastewaters	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(F) and (G)	certain carbamate wastewaters	1995 (60 FR 7848)
40 CFR 261.3(a)(2)(v)	used oil	1992 (57 FR 41611)
40 CFR 261.3(c)(2)(ii)(A)	certain waste pickle liquor sludges	1984 (49 FR 23284)
40 CFR 261.3(c)(2)(ii)(B)	wastes derived from burning certain oil-bearing wastes as fuel	1987 (52 FR 11819)
40 CFR 261.3(c)(2)(ii)(C)	wastes derived from high temperature metals recovery of certain hazardous wastes	1992 (57 FR 37263)
40 CFR 261.3(c)(2)(ii)(D)	certain types of biological treatment sludge	1995 (60 FR 7848)
40 CFR 261.3(c)(2)(ii)(E)	certain types of catalyst inert support media	1998 (63 FR 42184)
40 CFR 261.3(f)	certain types of debris contaminated with a hazardous waste	1992 (57 FR 37264)

In each of these revisions to 40 CFR 261.3, EPA considered the case-specific circumstances of the waste affected and, through the formal rulemaking process, determined that these wastes merited special consideration under the hazardous waste identification rules. In many cases, these wastes still warranted enough concern to impose specific management and other implementation requirements. For example, the solvent exclusions in 40 CFR 261.3(a)(2)(iv)(A) and (B) require that (1) these wastes are managed in a system the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act,

and (2) the total weekly usage of these solvents divided by the average weekly flow of the wastewater into the treatment works would not exceed a specific regulatory level (either 1ppm or 25 ppm).

Under today's final rule, EPA has continued the effort to reduce the burden from the mixture and derived-from rules where appropriate by excluding wastes listed solely for ignitability, corrosivity, and/or reactivity, once the waste no longer exhibits any of the hazardous waste characteristics (40 CFR 261.3(g)). We are also finalizing a conditional exemption for mixed waste from the mixture and derived-from rules, provided the mixed waste is handled in accordance with 40 CFR Part 266, Subpart N. (40 CFR 261.3(h))

Finally, over the past twenty years EPA has promulgated numerous rules establishing exclusions or conditional exemptions from the solid and hazardous waste definitions, and from regulatory requirements for particular wastes and management practices. These exemptions are part of EPA's overall effort to avoid unnecessary regulation of waste.

EPA plans to continue work on other types of hazardous waste exemptions, including the additional targeted exemptions for certain categories of wastes and management practices, and the concentration-based exemptions (HWIR exemption) discussed in the November 19, 1999 proposal. We also plan to continue on-going efforts to streamline the existing delisting program.

In regard to the specific examples of over-regulation claimed by one commenter (see comment # WH2P-00035, page 10), it is difficult for EPA to fully evaluate these cases without more specific data. For example, in the case of wastewaters where most of the arsenic has been precipitated and removed, it is not clear whether there are any other hazardous constituents of concern in the treatment sludge, and whether the residual arsenic might still pose a risk (depending on waste volume and management method). In the case of contaminated bricks from hazardous waste refractories undergoing repair, it would appear that the exclusion for debris [40 CFR 261.3(f)] could address this concern. Finally, for wastewaters that had received ethylene oxide as part of an emergency incident, while it is true that ethylene oxide eventually breaks down to ethylene glycol, this reaction is not instantaneous. When released into water, ethylene oxide will primarily be lost by three processes: volatilization, hydrolysis and biodegradation. The half-lives of these reactions range from a few hours to up to 20 days.[11] Ethylene oxide itself is toxic, and if these wastewaters were automatically considered non-hazardous, they could present a substantial risk, depending on actual concentrations and exposure patterns. Both low level chronic exposure and acute high levels of ethylene oxide can lead to a broad spectrum of neurological effects. Also, inhalation studies have shown that exposure to ethylene oxide can result in a wide range of carcinogenic effects, and NIOSH considers ethylene oxide to be a potential occupational carcinogen.[12] Therefore, EPA does not agree that such a mixture should be automatically excluded from hazardous waste regulation. More importantly, since the purpose of this rulemaking is not to evaluate individual wastestreams, EPA does not believe this example demonstrates that the mixture and derived-from rules themselves are unnecessary as a general matter.

EPA understands that the RCRA regulations, in particular the waste identification

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[11]Agency for Toxic Substances and Disease Registry. (1990). Draft Toxicological Profile for Ethylene Oxide.

[12]National Institute for Occupational Safety and Health. (1989). Ethylene Oxide Sterilizers in Health Care Facilities, Engineering Controls and Work Place Practices. DHHS (NIOSH) No. 89-115.

regulations, can be difficult to understand. We have attempted to use plain language in drafting today's revised regulatory language, and will continue to make regulatory language more accessible to readers in the future. In addition, we believe that the mixture and derived-from rules are more straightforward than the alternative of having to evaluate each combination and permutation of listed waste on a case-by-case basis. We believe this alternative would create uncertainty for the regulated community, state agencies, the public, and the courts, as various stakeholders press conflicting views as to whether a particular waste does or does not continue to meet the listing description.

Issue Code: MDF4: Unintended Consequences of the MDF Rules
Comments: WHWP-00165, 27, 2; WHWP-00174, 9,2 WH2P-00004, 1, 3; and WH2P-00004, 8, 1

Comment Summary:

The Agency received comments from three commenters in response to both the 1995 and the 1999 HWIR proposals concerning the unintended consequences of the mixture and derived-from (MDF) rules. Of those comments, one was received from an industry, one was from a private citizen, and one was from an industry association. The commenters generally argued that the Agency must consider the consequences of the MDF rules. A summary of the specific issues raised by commenters is provided below.

Bethlehem Steel, AISI and M. Shere argued that EPA has ignored the risks that are likely to be created by continued classification of waste mixtures and derivatives as hazardous wastes (e.g., the risks of longer-range waste transport and the risks to waste management personnel), even though such risks are almost certain to be greater than the risks considered by the Agency (i.e., the risks avoided by classification of waste mixtures and derivatives as hazardous wastes). M. Shere and AISI noted that EPA performed only half of a risk assessment, and probably the less significant half (see Cf. Corrosion Proof Fittings, 947 F.2d at 1224 - requiring EPA to consider the risks caused by a regulation, as well as the risks avoided by the regulation).

Bethlehem Steel stated that EPA needed to consider the potential that its classification criteria will create unintended consequences that might increase risks. The commenter noted that the 1997 report of the Presidential/Congressional Commission on Risk Assessment and Risk Management concluded that tradeoffs among different risks must be identified and considered in conducting a risk analysis, and the analysis must consider whether an option may cause any adverse consequences. The commenter noted this also is necessary because in its March 1999 Residual Risk Report to Congress under the Clean Air Act, EPA explained: the Agency will consider significant negative health and environmental consequences and the risk-risk tradeoffs associated with any future standards (p. 102). It also was noted that recent court decisions have emphasized that rational rulemaking requires consideration of unintended consequences, and none of the Agency's analysis considers the potential for the proposal to have unintended consequences. A simple analysis shows that the classification criteria that EPA proposed in the HWIR are too restrictive. Bethlehem Steel and M. Shere noted that these criteria will cause unintended transportation risks that are worse than the chemical risks EPA seeks to prevent. Lastly, if the Agency conducts this analysis, it also should include an evaluation of increased risks to workers who operate heavy equipment to excavate wastes or to construct landfill-style caps to comply with hazardous waste requirements.

Agency Response:

EPA does not agree with the comments. First, the Agency has information that suggests the majority of the RCRA hazardous waste generated in the United States today is managed (i.e. recycled, treated, stored and/or disposed) on-site at the same facility which generates it. For example, the 1995 "National Biennial RCRA Hazardous Waste Report" (EPA-530-R-97-022c, August 1997), indicates that only 5% (five percent) of hazardous waste generated by RCRA large quantity generators is shipped off-site (i.e. 10.7 million tons shipped off-site, out of 214.1 million tons generated in 1995). Those generators who generate large quantities of hazardous waste have apparently found it economically more efficient to build and maintain their own hazardous waste

facilities on-site.

Furthermore, a large portion of the volume of RCRA hazardous waste managed on-site would likely be considered mixture and derived-from hazardous wastes. According to data contained in the EPA Office of Solid Waste's "National Hazardous Waste Constituent Survey" database (which is available to the public from the RCRA Docket and from EPA's website http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/economic.htm), about 90% (ninety percent) of wastes that are identified by the generating facilities as mixture or derived-from wastes remain on-site at the same facility after generated. If the RCRA mixture and derived-from rule were eliminated, it is possible that some of these waste generators would conserve their Subtitle C management capacity and send their waste off-site. In this case, retaining the mixture and derived-from rule might act to help avoid increasing any transportation related risks to human health, safety and the environment.

In addition, commercial landfills typically also provide on-site waste treatment services. Many of the hazardous wastes which are transported off-site, particularly hazardous waste solids, are transported to commercial waste management facilities "as generated", i.e. without being mixture and derived-from hazardous wastes. These wastes are then treated on-site at the commercial waste management facility, to meet EPA's RCRA land disposal restriction (LDR) requirements, at which time, derived-from treatment residual wastes are generated. The derived-from residuals generated by the commercial waste management facility are then placed in an on-site Subtitle C landfill cell. Here again the RCRA mixture and derived-from rule would certainly not increase transportation and occupational risks, but instead, elimination of this rule may increase such risks, by encouraging the Subtitle C operator to ship the hazardous derived-from waste off-site to a nonhazardous waste landfill.

Issue Code: MDF5: Pollution Prevention and Treatment Technology under the MDF Rules
Comments: WHWP-00160, 3, 2; WHWP-00160, 5, 2; WHWP-00165, 4, 3; WHWP-00192, 9, 1; WHWP-00192, 6, 1; and WHWP-00215, 1, 1

Comment Summary:
The Agency received comments from five commenters in response to the 1995 HWIR proposal concerning pollution prevention and treatment technology under the mixture and derived-from (MDF) rules. Of those comments, two were received from industry associations, one was from an industry and one was from another commenter. A summary of the specific issues raised by commenters is provided below.

The commenters argued that the MDF rules may be counterproductive from an environmental perspective because facilities have little incentive to reduce their generation of truly "hazardous" wastes when the wastes remain classified as hazardous wastes regardless of the concentrations of hazardous constituents that they contain. Capital Returns argued that the automatic application of the hazardous waste listings, as with the automatic application of the MDF rules, and attendant Subtitle C duties serve as a disincentive for facilities to take advantage of different raw materials or to alter their processes to reduce the use of hazardous constituents.

The National Coil Coaters Association added that F019 was listed as a hazardous waste due to the expected presence of hexavalent chromium and cyanide. In virtually all cases, cyanide has now been eliminated from coil coaters' processes. Similarly, some aluminum conversion coating processes are now conducted with non-chrome materials or, where chrome is used, with trivalent rather than hexavalent chrome materials unless a specific chrome or hexavalent application is requested by the customer. Nonetheless, coil coaters have not received any regulatory relief from these environmentally beneficial changes; the F019 listing and mixture and derived-from rules automatically apply to all sludges from the conversion coating of aluminum regardless of whether they contain cyanide or hexavalent chromium or any chromium at all. Many of the commenters argued that if all waste meeting a broad listing description (i.e., MDF waste) are deemed hazardous and have to be managed as such regardless of their own characteristics, a facility is unlikely to invest in changes that will make no regulatory difference, particularly where such changes may have at least some adverse cost and product quality consequences.

Nucor noted that the strict MDFs frequently have rendered promising technologies economically impracticable due to the high cost of process residual treatment and disposition. One industry commenter argued that the derived-from rule misdirects expenditures that should be channeled toward environmentally beneficial projects and activities.

Agency Response:

EPA acknowledges that the mixture and derived-from rules, of themselves, provide no direct incentive for pollution prevention or innovative treatment technologies. However, other aspects of the RCRA hazardous waste program, such at the Universal Treatment Standards (UTS) under the land disposal restriction program, do continue to provide such an incentive. By setting maximum chemical concentrations for waste destined for land disposal without requiring a specific treatment technology, the UTS encourage the generator to look at different alternatives for reducing the chemical concentrations in the waste. In addition, the delisting process under 40 CFR 260.20 and 40 CFR 260.22 allows generators who have successfully reduced the

concentration of hazardous chemicals in their waste to permanently exclude them from hazardous waste regulation. F019 that has had all hazardous constituents removed is eligible for such a process. Similarly, as EPA develops the concentration-based HWIR exemption, generators will have an additional incentive to reduce the concentration of chemicals in their waste in order to exit the hazardous waste system.

Issue Code: MDF6: Mixture Rules Should be Replaced by a General Dilution Prohibition
Comments: WHWP-00124, 3, 4; WHWP-00193, iii, 1; WHWP-00193, 2, 1; WHWP-00194, 2, 3; and WHWP-00197, Ltr.; WH2P-00004, 8, 1;

Comment Summary:

The Agency received comments from four commenters in response to both the 1995 and the 1999 HWIR proposals concerning the mixture rules and a general dilution prohibition. Of those comments, three were received from industries and one was from an industry association. The commenters generally argued that the mixture and derived-from (MDF) rules should be replaced with a dilution prohibition. A summary of the specific issues raised by commenters is provided below.

Safety-Kleen noted that the MDF rules were no longer necessary because they have been made obsolete by more recent regulations, including the dilution prohibition and the LDR regulations which provide adequate assurance that a listed waste will not be able to escape the RCRA system without significant and legitimate treatment. The American Auto Manufacturing Association believed that EPA should address the issue by moving the dilution prohibition into Part 261 so that intentional dilution could not occur. Safety-Kleen believed that the dilution prohibition found in 40 CFR 268.3 already prohibits a generator or treater from removing a characteristic from a hazardous waste simply because he had diluted that waste with some other material (unless dilution occurs as a result of legitimate treatment), or from removing a listing because the mixed material no longer meets the description of the listing. GE stated that the MDFs, originally put in place to ensure that inappropriate mixing and sham treatment did not occur, should be replaced with a general program-wide prohibition on dilution. This program could be accomplished by expanding the LDR prohibition to apply to circumstances beyond land management, clarifying that the dilution prohibition also applies to mixing of hazardous waste with non-waste materials such as media and debris, and clarifying that aggregation of similar wastes (e.g., high Btu organic wastes or metal bearing wastewaters) which are routinely combined for the purposes of treatment is not considered dilution.

Agency Response:

EPA agrees that the primary purpose of the mixture rule is to prevent a generator from evading regulation by diluting a waste without addressing the hazardous chemicals contained in the waste. The mixture rule is therefore already *de facto* a prohibition on dilution for the purposes of changing the regulatory status of a waste. EPA does not agree that the existing dilution prohibition in 40 CFR 268.3 is an adequate protection against risks posed by hazardous waste mixtures because the current prohibition does not apply to wastes that are not managed on the land, such as wastewaters managed in tanks, and subsequently discharged under the Clean Water Act. As discussed in EPA's response to issue MDF2, these wastewaters are, by volume, the primary mixtures of concern.

However, EPA also believes that a strict prohibition on dilution of these wastewaters would be inappropriate. Combining wastewaters for treatment purposes before discharge under the Clean Water Act is often the most efficient and effective way of treating them. Prohibiting such an aggregation would be counter-productive.

Therefore EPA continues to support the current structure of the mixture rule. Generators are allowed to combine hazardous wastewaters for the purpose of treatment. These mixtures are

largely exempt from RCRA requirements when managed in tanks and discharged under the CWA (see 40 CFR 264.1(g)(6); 265.1(c)(10); and 270.1(c)(2)(v)), but the sludges generated from these wastes continue to be regulated as hazardous.

Issue Code: MDF7: MDF Wastes Should be Regulated in the Same Way Non-hazardous Solid Wastes are Regulated (Characteristics, Supplemented by Waste-specific Listings, as Warranted)

Comments: WHWP-00088, 2, 3; WHWP-00089, 6, 6; WHWP-00099, 1, 3; WHWP-00108, 5, 2;WHWP-00125, 3, 1; WHWP-00165, 6, 3; WHWP-00165, 4, 3; WHWP-00193, 2, 1; WHWP-00201, 12, 2; and WHWP-00201, 2, 1

Comment Summary:

The Agency received eight comments in response to the 1995 HWIR proposal concerning the manner in which mixture and derived-from (MDF) wastes are regulated. Of those comments, five were received from industry, two were from utility companies or associations, and one was from an industry association.

The commenters generally argued that MDF wastes should be evaluated against the same criteria as all other solid wastes, i.e., hazardous characteristics. A summary of the specific issues raised by commenters is provided below.

Eli Lilly and AISI argued that residuals from hazardous waste treatment processes should be evaluated in the same manner as other solid wastes. The commenters noted that this approach is warranted especially in the case of treatment residuals because hazardous waste treatment processes generally are regulated highly (under 40 C.F.R. Parts 264, 265, and 270) and must meet stringent standards of performance (under the land disposal restrictions program of Part 268). In addition, treatment residuals frequently bear little resemblance to the listed wastes from which they are derived. Several commenters went further in stating that rather than trying to prove a negative (i.e., that a certain class of wastes clearly is not hazardous), EPA should be trying to identify a class of wastes that can be demonstrated to pose a substantial threat to human health or the environment.

Eli Lilly also noted that by issuing land disposal minimum technology standards on a waste constituent basis, the lack of waste-specific treatment standards is no longer a rational basis for the derived-from rule. The existence of the LDR standards creates a significantly different regulatory environment today than was present in 1980 when the derived-from rule was issued originally. They commenter added that if residuals from treatment of hazardous waste were not regulated under the derived-from rule as listed hazardous waste, the residuals would continue to be subject not only to the requirements for characteristic waste, but to the LDR standards. In addition, several commenters noted that, since 1980, EPA also has had the authority to adopt more or broader hazardous waste listings to capture distinct categories of MDF wastes (i.e., those categories that "typically and frequently" test hazardous).

GE believed that EPA should develop a comprehensive set of hazardous characteristics to replace listings. GE and Cyprus Amax Mineral Co. stated that the MDF rules should be addressed through appropriate revision or expansion of the hazardous characteristics, and Pennzoil noted that replacing these rules with a hazardous waste determination utilizing concentration limits and physical properties based solely on risk to human health and the environment would have made the much of HWIR unnecessary. USWAG and Pacifi Corp. noted that EPA also has the authority to adopt more or broader hazardous waste listings to capture distinct categories of MDF wastes that truly warrant hazardous waste regulation.

Agency Response:

EPA agrees that since 1980, the development of the land disposal restriction program has resulted in more and better treatment of hazardous wastes. However, EPA does not agree that the residuals from these waste treatment processes should automatically be considered non-hazardous. LDR standards are technology-based, not risk-based. As explained in response to comment issue MDF2, residuals from treatment can be expected to contain the chemicals that caused the waste to be listed in the first place, in some cases at even higher levels than the parent waste. Therefore EPA does not agree that the hazardous waste listing should not apply to the treatment residual.

In addition, as is also explained in response to MDF2, EPA disagrees with the suggestion that the hazardous waste characteristics provide an adequate protection against toxicity risks posed by these treatment residuals. The toxicity characteristic (TC) was set to ensure that wastes that contain chemicals exceeding those levels are clearly hazardous. However, wastes with chemicals below those levels can pose a risk to human health and the environment. (55 FR 11799). Thus, even with the promulgation of the TC, the mixture and derived-from rules are still necessary to protect against risk posed by non-TC chemicals, and risk present below the TC levels in wastes that have been listed as hazardous.

The idea of replacing the current listing program with an expanded set of hazardous characteristics may be a possible long-term goal of the RCRA program, but there would be many technical and administrative issues that would need to be addressed. Given the current state of the science, this approach is impractical under our current court-ordered timeframe.

Issue Code: MDF8: EPA should Implement the MDF Rules through Directives to the States
Comment: WHWP-00017, 8, 2
Comment Summary:
The Agency received one comment from Heritage Environmental Services in response to the 1995 HWIR proposal suggesting that EPA should implement the mixture and derived-from (MDF) rules through directives to the States. Heritage believes that much of what EPA hopes to accomplish with the HWIR can be readily achieved without promulgating new rules by: 1) more reasonable application of the mixture and derived-from rules, perhaps by developing explicit directives to the regions and the states, using many of the concepts in the HWIR (similar to the contained-in policy case-by-case determinations); 2) an expedited system for evaluation of delisting petitions, with an emphasis on upfront delistings; and 3) issuing site-specific treatability variances to non-superfund remediation projects with the same speed and criteria as is used for Superfund Guidance 6A and 6B. At a minimum, Heritage especially encourages EPA to develop criteria for the consistent and reasonable implementation of the delisting program by the regions.

Agency Response:

EPA disagrees that issuing directives to the States is the most appropriate method for implementing the mixture and derived-from rule revisions. The rulemaking process, although time consuming, allows the Agency to receive and evaluate input from all stakeholders, and creates a more transparent process in general.

EPA does support an expedited system for evaluating delisting petitions. As explained in more detail in response to issue MDF10, EPA recognized that the delisting process was slow in the past, therefore, delegated its delisting authority to all ten EPA Regions in October 1995. This delegation enabled each Region to more quickly review the delisting petitions received from facilities in their jurisdictions. Since the delegations, all EPA Regional offices have been making a strong effort to revamp the process by which delisting petitions are reviewed and considered.

[The issue of site-specific treatability variances to non-superfund remediation projects is beyond the scope of the hazardous waste identification rules].

Issue Code: MDF9: Relationship of a Concentration-based HWIR Exemption to the MDF Rules

Comments: WHWP-00125, 2, 3; WHWP-00125, 3, 1; WHWP-00148, 6, 4; WHWP-00149, 5, 1; WHWP-00074, 4, 3; WHWP-00150, 10, 3; WHWP-00150, 11, 1; WHWP-00172, 41, 1; WHWP-00145, 2, 5; WHWP-00106, 12, 2; WHWP-00138, 3, 1; WHWP-00192, 6, 1; WHWP-00160, 3, 2; WHWP-00196, 4, 1; WH2P-00035, 1, 3; WHWP-00160, 5, 2; WHWP-00173, 1, 2; WHWP-00089, 72, 1; WHWP-00208, 1, 2; WHWP-00220, 3, 4; WHWP-00239, 3, 6; WHWP-00099, 1, 3; WHWP-00083, 2, 1; WHWP-00193, 2,1; WHWP-00073, 11, 2; WHWP-00100, 38, 1; WHWP-00162, 12, 4; WHWP-00065, 1, 1; WHWP-00162, 8, 1; WHWP-00078, 3, 7; WHWP-00114, 1, 1; WHWP-00122, 1, 2; WHWP-00193, iii, 1; WHWP-00034, 1, 3; WHWP-00158, 1, 1; WHWP-00238, 17, 1 WHWP-00037, Cvr. Ltr.; WHWP-00037, Cvr. Ltr.; WHWP-00160, 3, 1; WHWP-00160, 1, 4; WHWP-00130, 1, 1; WHWP-00119, 1, 1; WHWP-00196, 2, 1; WHWP-00248, 2, 5; WHWP-00095, 17,3; WHWP-00096, 17,2; WHWP-00093, 18,3; WHWP-00094, 15,4; WHWP-00197, Ltr.; WHWP-00099, 3,2; WHWP-000140, 1,1; WHWP-00250, 1,2; WHWP-00185, 1, 3; WHWP00083, 18,2; WHWP-00182, 1,1; WHWP-00075, 1,3; WHWP-00056, 1,1; WHWP-00205, 1,4; WHWP-00117, 1,2; WHWP-00155, 1,2; WHWP-00165, 13,2; WHWP-L0005, 1,2; WHWP-00136, 2,1; WHWP-00135, 2,1; WHWP-L0004, 4,5; WHWP-00139, 38,3; WHWP-00167, 3,4; WHWP-00035, 1,3; WHWP-00072, 18,3; WHWP-00138, 6,5; WHWP-00208, 4,3; WHWP-00167, 3,4; and WHWP-00250, 1,2

Comment Summary:

The Agency received comments from 58 commenters in response to both the 1995 and the 1999 HWIR proposals concerning the relationship of a concentration-based HWIR exemption to the mixture and derived-from (MDF) rules. Of those comments, 16 were received from industry, 24 were from industry associations, five were from utility companies, three were from waste management companies, five were from State Agencies, one was from a waste management association, two were from Federal Agencies, one was from a consultant, one was from a private citizen. A summary of the specific issues raised by commenters is provided below.

While many commenters believed that the MDF rules inappropriately regulate many low-risk wastes, they did support EPA's approach of providing a risk-based exit system. Several commenters supported relief from the MDF rules, however, they believed that the proposed exit levels were set so low that very few wastes would qualify for exit and many companies would not be able to support the cost of the exit demonstrations.

The majority of commenters generally believed that the proposed exit levels do not correct the overbroad classification and MDF wastes will continue to be classified as hazardous when they do not pose a substantial hazard. Several commenters also argued that the HWIR proposal failed because the MDF rules were not altered by this proposal and the exit levels are too conservative to allow many low-risks wastes to exit the system. Several commenters also noted that the proposal was too complex, expensive and inflexible for many businesses. Cyprus Amax Minerals

Company noted that the Agency offered no evidence to support the broad-based and arbitrary assumption that all wastes containing constituents at levels exceeding the HWIR exit levels pose a threat to human health and the environment. Instead of making such unfounded blanket determinations, EPA must carefully reevaluate the MDF rules and develop a less conservative structure for allowing more low-risk wastes to exit the RCRA Subtitle C system. Cyprus Amax also believed that the HWIR rule should focus on following the Shell Oil mandate and that the exit levels be used solely to replace the vacated MDF rules.

Agency Response:

As EPA continues to develop an HWIR exemption, we will address both the technical and administrative issues surrounding such an exemption. However, to the extent that these comments reflect on the mixture and derived-from rules, EPA disagrees with the comments that state these rules inappropriately regulate wastes. As explained in response to issue MDF2, the mixture and derived-from rules are crucial in ensuring continued protection of human health and the environment. EPA continues to support development of risk-based HWIR exemption levels, but does not believe that there is any pre-determined amount of waste that should be exempted based on these levels.

Issue Code: MDF10: Relationship of Delistings to the MDF Rules
Comments: WHWP-00122, 1,2; WHWP-00160, 3, 2; WHWP-00160, 5, 2; WHWP-00182, 4, 2; WHWP-00192, 6, 1; WHWP-00201, 2, 1; WHWP-00237, 1,1; WHWP-00237, 3,3; WH2P-00015, 6, 1; WH2P-00020, 1,2; WH2P-00035, 1, 3; WH2P-00035, 5, 1; and WH2P-00035, 7, 2;

Comment Summary:
The Agency received comments from nine commenters in response to both the 1995 and the 1999 HWIR proposals concerning the relationship of delistings to the mixture and derived-from (MDF) rules. Of those comments, five were received from industry associations, two were from industry, one was from a waste management company and one was from a State. A summary of the specific issues raised by commenters is provided below.

The commenters argued that the delisting mechanism does not cure the overbreadth of the MDF rules, as agencies cannot exercise powers denied them by Congress by using a variance mechanism to bring the regulations back within statutory boundaries. Several commenters also noted that the only current mechanism for obtaining relief from the MDF rules is a delisting petition. However, they argued that this *delisting* program is slow, lacking in agency resources, unduly onerous and virtually unavailable in most cases. In addition, SOCMA noted that delisting petitions are ill suited to the typical batch or custom chemical manufacturing operation. one commenter noted that the delisting program largely has been inapplicable to wastes with organic constituents due to the unreasonably rigid delisting levels. Lastly, the Methacrylate Producers Association urged EPA to ensure that existing delisting petitions are considered promptly in the order in which they are submitted.

Agency Response:

The purpose of delisting is to ease the regulatory burden on handlers of listed wastes improperly captured by the broad listing definitions and/or the mixture and derived from rules. A delisting decision, specific to a waste generated at a particular facility, is made based upon a thorough review of waste process information and data related to that particular waste stream. The review process is inherently time consuming and resources intensive. EPA recognized that the delisting process was slow in the past, therefore, delegated its delisting authority to all ten EPA Regions in October 1995. This delegation was shortly before the 1995 HWIR proposal, so commenters to that proposal might not know, or might not have data showing the impact of that delegations. The delegation enabled each Region to more quickly review the delisting petitions received from facilities in their jurisdictions.

Since the delisting program was delegated to the EPA Regions, a number of innovations have been adopted that have greatly improved the efficiency and effectiveness of the delisting program. In particular, EPA Region VI's award-winning program has created a process that produces a decision within an average of 180 days, provides a streamlined application checklist, proactively coordinates with State personnel, and includes a user-friendly, stand-alone software program that produces an updated, state-of-the art assessment of risks associated with delisting a petitioned waste. In addition, EPA and the applicant now work together to develop an initial application that can be approved without the need for major revisions, which is a major factor in reducing the

processing time.

The statute requires the Agency to publish a proposal to grant or deny a complete petition within 24 months after a petition is received, and EPA has generally met that deadline in recent years. Over the period of 1995-2000, the Regions combined have issued 16 proposed and 15 final delisting decisions, and 1 repeal. There are 8 petitions currently in different stages of review and concurrence. The average processing time (from receipt of the petition through publication of the proposed rule in the Federal Register) was 18 months to 2 years (approximately 20 months).

One commenter suggested that delisting was "virtually unavailable in most cases." EPA notes that delistings are available in all ten EPA Regions and in States that are authorized to administer their own delisting programs, as long as the delisting criteria are met. One commenter stated that delisting was ill-suited to custom chemical manufacturing operations. EPA disagrees with this comment, noting the difficulty of certifying that a highly variable waste stream does not pose a significant risk to human health or the environment. A facility that generates wastes from batch operations, or accepts and treats wastes from diverse sources, would typically have a testing program to ensure their wastes consistently meet delisting criteria. The testing requirements for some initial period might be extensive, but the subsequent testings would normally be reduced.

One commenter stated that the delisting program largely had been inapplicable to wastes with organic constituents due to the unreasonably rigid delisting levels. We note that delisting levels are typically set based on the characteristics of a petitioned waste and its plausible management scenario. Most of the delisting petitions that we granted were for metal bearing wastes managed in nonhazardous Subtitle D landfills. Therefore, the delisting levels for organic constituents were not to be exceeded in landfill leachates. The calculated delisting levels for organic constituents tend to be much higher than their LDRs.

Once EPA completes work on the HWIR exemption, there will be a self-implementing alternative to delistings for those wastes that can meet the exemption criteria. Because HWIR would not require a formal rulemaking, EPA expects HWIR exemptions will be a faster alternative to delistings.

Issue Code: MDF11: If MDF Rules are Finalized, EPA Should Identify When Any Petitions Seeking Judicial Review May be Filed

Comments: WH2P-00004, 10, 3

Comment Summary:

The Agency received one comment from Bethlehem Steel in response to the 1999 HWIR proposal stating that if EPA does issue the mixture and derived-from rules as final regulations, it should identify specifically when it believes that any petitions seeking judicial review of these rules may be filed. At this point, it is unclear whether the agency proposes these rules to become final independent of promulgation of the rest of the HWIR proposal.

Agency Response:

Judicial review of the final regulations is governed by section 7006 of RCRA, 42 U.S.C. 6976.

Issue Code: MDF12: MDF Rules Should have a Sunset Provision of One Year while being Revised

Comments: WHWP-00101, 17, 1

Comment Summary:

The Agency received one comment from the Fertilizer Institute in response to the 1995 HWIR proposal concerning a sunset provision while revising the mixture and derived from (MDF) rules. The commenter stated that EPA's only option is to utilize the comments received in response to the December 21, 1995 Proposal to develop a new proposal. EPA is left with few options as it seeks to comply with the consent decree deadline. If it goes forward with a final rule based on this administrative record, it almost certainly will be challenged successfully and the rule will be vacated. If it does not promulgate a new rule, the legal effect of the MDF rules will lapse. To address this dilemma, the commenter suggests that EPA repromulgate the mixture and derived-from rules, as they currently exist, with a sunset provision of one year. With the additional time, EPA should undertake an additional round of information gathering and publish another proposed rule. In that way, EPA can develop an appropriate administrative record and properly respond to comments received on its revised proposal.

Agency Response:

Rather than follow the commenter's suggestion, the consent decree was amended on April 11, 1997, establishing a deadline of October 31, 1999 for a proposal, and a deadline of April 30, 2001 to take final action. EPA is in compliance with the revised consent decree deadlines.

Issue Code: MDF13: Exemptions are Consistent with the RCRA Statutory Language and General Principles of Administrative Law
Comments: WH2P-00021, 4, 3
Comment Summary:
The Agency received one comment from the Basic Acrylic Monomer Manufacturers (BAMM) in response to the 1999 HWIR proposal concerning RCRA statutory language and general principles of administrative law for exemptions from the mixture and derived-from (MDF) rules. A summary of the specific issues raised by commenter is provided below.

BAMM stated that under the specific statutory requirements of RCRA and general principles of administrative law, EPA is not only authorized, but is obligated to exempt from regulation those wastes that present an insignificant risk to human health or the environment. In 1996 comments, the commenter noted that EPA had adequate statutory and case law authority to proceed with eliminating unnecessary and burdensome waste handling requirements. The commenter added that in a variety of regulatory contexts, courts have held that Agencies are precluded from regulating insignificant risks unless Congress expressly directs otherwise. The specific statutory language of RCRA is consistent with the general principle of administrative law that an agency should only regulate significant risks. Section 1004(5) of RCRA defines hazardous waste as a solid waste that may significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, injury or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

Agency Response:

As explained the response to comments concerning EPA's legal authority under RCRA for the mixture and derived-from rules, mixtures and derivatives "may pose a substantial present or potential hazard to human health or the environment" and therefore meet the definition of "hazardous waste" in section 1004(5). EPA agrees that we have the authority to exempt waste from regulation when we determine that it does not pose risk to human health and the environment. We also agree that the mixture and derived-from rules may capture some waste that may actually pose quite low hazard, and we have implemented and continue to pursue approaches to exclude such waste from full Subtitle C regulation. The revisions to the mixture and derived-from rules promulgated today are an examples of such approaches, as is the ongoing effort to develop a constituent-based HWIR exemption.. However, EPA has limited resources and is not able to make risk determinations on all possible permutations of waste.

Issue Code: MDF14: LDR Treatment Should be Required of Mixture-rule Process Wastes
Comments: WHWP-00167, 3,4
Comment Summary:
The Agency received one comment from the Pennsylvania DEP in response to the 1995 HWIR proposal concerning LDR standards of mixture-rule process wastes. Pennsylvania believed that LDR treatment should be required of mixture-rule process wastes.

Agency Response:

EPA agrees with this comment. Wastes that result from the mixture of hazardous wastes and other wastes are required to meet LDR treatment standards.

Issue Code: MDF15: EPA Should Ensure that the Federal Revisions are Applicable in Authorized States
Comments: WHWP-00139, 50,2
Comment Summary:
The Agency received one comment from Browning-Ferris Industries in response to the 1995 HWIR proposal concerning State authorization. The comment is provided below.

By next November, the "mixture and derived from" rules will be revised by the HWIR rule. A number of states which "adopted" such rules did so by reference to the Federal requirements. The only logical approach to the question of modification of the RCRA rules governing the identification of hazardous waste is to provide that the Federal revisions are, pursuant to Section 3006 and the Agency's regulations, applicable in authorized states. [...]

Agency Response:

EPA has revised the mixture and derived-from rules under the authority of sections 3001(a), 3002(a), and 3004(a) of RCRA. These revisions do not go into effect in authorized States until they adopt the revisions and receive authorization from EPA for the revision to their regulations. Authorized States are not required to modify their programs when EPA promulgates changes to Federal requirements that are less stringent than, or that narrow the scope of, existing Federal requirements. This is because RCRA section 3009 allows the States to impose (or retain) standards that are more stringent than those in the Federal program. (See also 40 CFR 271.1(i)). Therefore, because the revisions to the mixture and derived-from rules are not more stringent or broaden the scope of the existing Federal requirements, States are not be required to adopt the revisions to the mixture and derived-from rules in today's rule, although EPA will strongly encourage their adoption.