

US EPA ARCHIVE DOCUMENT

Appendix F: Full Text of Miscellaneous Comments on the 1995 and 1999 HWIR Proposals

The Supplemental LDR Phase VI Proposal would Modify 261.3(a)(2)(iii) to State that Nonwastewater Mixtures are Still Subject to LDRs

MISC1 - DoD, WHWP-L0004, 13,2 Federal Govt.

[...] (b) DoD wishes to call EPA's attention to the fact that EPA's supplemental proposal to proposed LDR Phase IV in 61 Fed. Reg. 2338 (Jan. 25, 1996) is inconsistent with the mixture and derived-from rules proposal which appears in the HWIR rulemaking, 60 Fed. Reg. 66348-9. The supplemental LDR Phase IV proposal would modify 40 C.F.R. Section 261.3(a)(2)(iii) to remove the provision that allows these listed nonwastewater hazardous wastes to exit subtitle C management standards. The supplemental Phase IV proposal thus conflicts with what is proposed in this HWIR rulemaking. Not only would the supplemental Phase IV proposal remove the proposed exclusion for derived-from wastes, it also would remove the current exclusion for wastes generated under the mixture rule. Therefore, the following language needs to be retained in 40 C.F.R. Section 261.3(a)(2)(iii): "unless the resultant mixture no longer exhibits any characteristic of hazardous waste identified in Subpart C of the part..."

MISC1 - DoD, WHWP-L0004, 14,1 Federal Govt.

[...] (c) DoD also wishes to alert EPA that EPA's supplemental proposal to proposed LDR Phase IV in 61 Fed. Reg. 2338 (Jan. 25, 1996) is inconsistent with the "derived-from" rule proposal which appears in the HWIR rulemaking. DoD therefore incorporates by reference the comment which appears in Specific Comments, Part I (A)(2)(b) above.

The Point at which Residues are generated should be their Point of Generation

MISC2 - CMA UIC Mgmt Task Group, WHWP-00078, 8,2 Industry Assn.

In the Third rule, EPA established the principle that the generation of a new treatability group is considered a new point of generation and thus a new point for determining whether a waste is prohibited from land disposal. In the Phase IV proposal, EPA used this principle to evaluate wastewater treatment sludges generated in Subtitle D surface impoundments. Under this principle, wastewater treatment sludges not exhibiting a characteristic were not prohibited wastes, even though the sludges may be derived from characteristically hazardous waste streams. The UIC Group has been advised in discussions with the EPA that residual solids from Class I injection well systems will also be considered to be newly-generated wastes under the "change in treatability group principle." This is a significant issue to chemical facilities which generate numerous residues, such as scrubber water, leachate, sludges, and filter media. Some of these streams are disposed of in Class I wells and some of these newly-generated streams are generated during treatment of the waste streams prior to injection. In many cases these residues carry one or more waste codes identifying that they are derived from a listed hazardous waste. In an integrated chemical facility, often times residues will be a mixture of wastes derived from listed hazardous wastes and derived from disposal of commercial chemical products produced and used at the facility. Often characteristic waste codes may be applicable to individual waste streams at the point of generation and may or may not be applicable to the combined waste stream. Since EPA has estimated that there are large numbers of facilities potentially eligible to take advantage of the proposed exit levels, EPA must intend for generators to consider the point at which residues are generated to be their point of generation. Many of these treatment residues contain hazardous constituents that are at or near exit levels. EPA should clarify that these treatment residues are eligible for the exclusion proposed, not just eligible for partial relief, because these wastes do meet the exit levels at their point of generation (newly generated).

Mixed Wastewaters Collected for Treatment at a Wastewater Treatment Facility should not be Considered Impermissible Dilution

MISC3 - CMA, WHWP-00073, 76,2 Industry Assn.

In the preamble, EPA states that "today's proposed rule specifically prohibits dilution as a means of attaining the exemption levels except as provided by the LDR program" 66385. [CMA] believes that EPA has the authority under RCRA Sections 3001 through 3004 to impose a dilution prohibition on wastes being sought to exit under this rule. Such wastes are hazardous wastes subject to Subtitle C until such time as all conditions of exit are satisfied, and a dilution prohibition can validly be such a condition. Imposition of a free-standing dilution prohibition would also avert the perceived need to apply LDRs to exiting wastes, an approach which creates more problems than it solves 1/.

While CMA agrees that dilution, by itself, may not constitute legitimate treatment, there are situations of permissible dilution that EPA should clearly recognize in this exit rulemaking, just as it did in the Third Third rule and Congress did in the recent Land Disposal Program Flexibility Act.

MISC3 - Bristol-Myers Squibb Co., WHWP-00202, 43,3 Industry

The preamble to the proposed regulation notes that "dilution is generally prohibited as a means to achieve the exemption levels under today's proposal." 60 Fed. Reg. 66,385. BMS supports the Agency's position that a generator should not be permitted to deliberately dilute a waste stream to avoid regulation. However, the regulation or the preamble should make clear that prohibited dilution does not include appropriate waste collection and manufacturing operations in which waste or process streams are combined and constituents present are "diluted" as part of an integrated treatment system. For example, a large manufacturing facility typically will have a wastewater collection system throughout the facility which receives and directs many wastewater flows to the facility's wastewater treatment system. Among the streams collected in the facility's sewer system, may be a wastewater stream regulated as listed hazardous waste under the mixture rule. BMS does not understand, and believes that the Agency does not intend, that normal collection of such waste streams is considered "prohibited dilution." Although the Agency has previously addressed this issue (see, e.g., 55 Fed. Reg. 22,520, 22,664-67 (June 1, 1990)), confusion on the proper interpretation of the hazardous waste dilution prohibition persists. Therefore, BMS recommends that the Agency clearly state again in the Federal Register preamble for the low concentration exemption, that dilution which is prohibited does not include legitimate centralized treatment of similar waste streams.

MISC4 Comments on the Contained-in Rule

MISC4 - CMA Water Additives Panel, WHWP-00074, 4,3 Industry Assn. [...] Finally, the proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. at 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful. The principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a proposed or final rule. See 5 U.S.C.A. Section 553 (West 1995). Reference: West. 1995.

MISC4 - Assn. of American Railroads, WHWP-00085, 30,3 Industry Assn. Contaminated environmental media, such as contaminated soil, which is currently regulated under the "contained in" policy, should be exempt from RCRA, Subtitle C, requirements during remedial activities. In addition, states should have the authority to establish higher exit levels for these chemicals on a site-specific basis. This process would be less burdensome than the currently required delisting process.

MISC4 - Acrylonitrile Group, Inc., WHWP-00145, 2,5 Industry Assn. [...] Finally, the proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful. The principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a final rule. See 5 U.S.C.A. Section 553 (West 1995) Reference: West. 1995.

MISC4 - Air Products & Chemicals, Inc., WHWP-00148, 6,4 Industry [...] Finally, the proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. at 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful. The principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a final rule. See 5 U.S.C.A. Section 553 (West 1995).

MISC4 - Kaiser Alumin. & Chem Corp., WHWP-00149, 7,1 Industry The proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. at 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful. The principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a final rule. See 5 U.S.C.A. Section 553 (West 1995).

MISC4 - Holnam Inc., WHWP-00150, 12,3

Waste Mgmt. Co.

The proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. at 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful. The principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a final rule. See 5 U.S.C.A. Section 553 (West 1995). References: West. 1995.

MISC4 - Hercules Inc., WHWP-00172, 45,1 Industry

[The] proposed exit levels also apply to contaminated media, which are considered hazardous via the "contained-in" principle. 60 Fed. Reg. at 66,347, 66,408. The contained-in principle is substantively unlawful for the same reasons that the mixture and derived-from rules are unlawful -- they regulate wastes that do not present a substantial hazard in many cases. Indeed, contaminated media is even less likely to present the degree of hazard that the "parent" listed process waste presented. Media rarely contain the relatively concentrated process listed waste by the time the waste is contained-in media; it is almost always at dilute levels that present little threat, particularly if it will be removed and managed in a Subtitle D unit. The contained-in principle is procedurally invalid as well since it is an attempt to impose regulatory requirements on contaminated media without going through the due process notice and comment requirements of a final rule. See 5 U.S.C.A. section 553. The contained in principle, even to this day, has not been proposed or adopted as a final rule.

MISC4 - Westinghouse Electric Corp., WHWP-00177, 2,1 Industry In [Section II.B.c.2] of the preamble, EPA discusses the proposed rule's impact on the Contained-In Policy and states, "Media that are contaminated with listed or characteristically hazardous waste must be managed as hazardous wastes until they no longer contain such wastes." For characteristic wastes, this is a significant change. In 57 FR 37221, EPA made the following statement: "Prohibited hazardous debris is intended for land disposal and exhibits a prohibited characteristic of hazardous waste or that is contaminated with a prohibited listed hazardous waste". Based on this statement, EPA has regulated differently media and debris contaminated with listed waste than media and debris that exhibits a hazardous characteristic. The latter must be managed as a hazardous waste until it no longer exhibits the prohibited characteristic. Media and debris contaminated with a listed hazardous waste must be managed as a hazardous waste until the waste no longer contains the listed waste.

Westinghouse does not believe the EPA should apply the Contained-In Policy to characteristic wastes. Media contaminated with characteristic waste should be managed as hazardous waste only if it continues to exhibit a hazardous characteristic.

MISC4 - General Electric, WHWP-00193, 23,2 Industry

EPA briefly discusses the RCRA "contained-in" policy on page 66347 of the preamble but does not give the issue sufficient attention in the rulemaking. EPA has never proposed, taken comment on, nor officially promulgated the "contained-in" policy in 40 CFR Part 261 1/, which has given rise to a wide array of interpretations of the policy on the part of EPA Regional Offices and the states. 2/ Interpretations of the policy are inconsistent with respect to the levels of contamination that bring contaminated material into Subtitle C, the levels that are needed to exit Subtitle C, and

the regulatory status of the matrix in which the contamination is found. Moreover, because it is not in the regulations, it is not clear whether it is part of state-delegated programs nor is it clear how states interpret it. As discussed in the policy section of our comments, GE believes that a broad "contained-in" rule coupled with a dilution prohibition can replace the mixture and derived-from rules by determining when a listed waste mixture or derived-from residue "contains" constituent concentrations that make it hazardous. All of the current "contained-in" interpretational issues would be resolved, since the source and method of contamination would be irrelevant. 1/ EPA has only promulgated the "contained-in" policy in 40 CFR Part 268 with respect to contaminated debris. 2/ EPA's footnote on page 66347 of the preamble makes reference to the D.C. Circuit's finding in Chemical Waste Management, Inc. v U.S. EPA, No. 869 F2d 1526 (D.C. Circuit 1989) by stating that "EPA's contained in policy was upheld as a reasonable interpretation of 40 CFR 261.3(c)(1) and (d)(2)." GE notes that this decision was made prior to the decision in Shell Oil v. EPA, 950 F. 2d 741 (D.C. Circuit 1991), vacating the mixture and derived-from rules, thus calling into question the continuing validity of the "contained-in" policy. GE also emphasizes that the language at 40 CFR 261.3(c)(1) and (d)(2) does not constitute the "contained-in" policy as it is understood today.

MISC4 - Phelps Dodge Corp., WHWP-00243, 4,2 Industry Given the genesis of EPA's contained-in policy, the inapplicability of the mixture rule to environmental media, EPA's statements in the HWIR Proposal that the contained-in policy applies to environmental media contaminated with "listed or characteristically hazardous waste" is puzzling. 60 Fed. Reg. 66347. As EPA has stated, its contained-in policy: "states that environmental media . . . contaminated with a RCRA listed hazardous waste must be managed as if the media were a hazardous waste until it no longer "contains" the hazardous waste." 57 Fed. Reg. 986 (Jan. 19, 1992).

Because the contained-in policy does not apply until the environmental medium is "actively managed," 58 Fed. Reg. 25712 (Apr. 27, 1993), the contained-in policy is not needed for environmental medium which displays a characteristic of a hazardous waste because the actively managed environmental medium either is or is not characteristically hazardous. If it is not characteristically hazardous, it is not a hazardous waste and it need not be managed as a hazardous waste. Consequently, an "exit" level for determining when the medium no longer "contains" the characteristic hazardous waste is unnecessary, and whether the LDRs would apply to the medium being land disposed is an issue which it appears EPA will address in its "Requirements For Management of Hazardous Contaminated Media," to be proposed by EPA.

Under the rationale of the mixture rule, [an] environmental medium contaminated with a listed waste, if managed, remains a hazardous waste unless the listed waste is delisted [or] the medium no longer "contains" the listed waste. The HWIR Proposal's discussion of the CERCLA impacts of the HWIR reaffirms this distinction between environmental media contaminated with characteristic and listed wastes by stating that "exit levels also may be applicable to the CERCLA program where it has been documented that RCRA listed hazardous waste has been disposed of at the site." 60 Fed. Reg. 66411. Similarly, the HWIR proposal acknowledges that: "media that contain listed hazardous wastes, mixtures, or derived-from wastes with constituent concentrations below today's proposed exemption levels will be eligible for exemption under the procedures

proposed today." 60 Fed. Reg. 66408 (emphasis added).

This language confirms that the contained-in policy is applicable only to environmental media containing listed hazardous wastes.

The HWIR Proposal indicates that EPA Regions and States will retain the flexibility to determine on a case-by-case basis if a contaminated medium "contains" a listed hazardous waste, and that the proposed HWIR exit levels are not intended to be presumptive of that determination. 60 Fed. Reg. 66408. Phelps Dodge agrees with EPA that States and EPA Regions should have the flexibility to make site-specific determinations as to whether a actively managed media "contains" a hazardous waste. This procedure should not be burdened by any EPA procedural requirements. As EPA appears to acknowledge, the cleanup of contaminated media will be expedited only if EPA and the States have the option to allow site-specific, risk-based cleanups that may involve innovative technologies or remedial approaches.

MISC4 - DoD, WH2P-00017, 11,1 Federal Govt.

ISSUE 7: The Contained-in Policy With Respect to Waste Listed Solely for Ignitability Comment. DoD would like a statement on the interaction of the contained-in policy to the RCRA wastes that are listed solely for ignitability, corrosivity, and/or reactivity characteristics. Discussion. DoD supports the new language contained in proposed 261.3(g)(1). DoD believes this language is clearer than the current language in 261.3(a)(2)(iii). While the preamble and/or proposed rule language specifically mention the mixture and derived-from rules, there is not a specific reference to the applicability of the contained-in policy to these wastes. DoD believes that one ramification of the language proposed in 261.3(g)(1) would be a clarification that media that contains one of the 29 wastes listed solely for ignitability, corrosivity, and/or reactivity (ICR) and that no longer exhibits these characteristics, would not be subject to RCRA regulation, with the exception of the land disposal restrictions. Thus, in this situation, DoD would interpret the media to not contain a listed or characteristic waste. Because these 29 wastes are listed solely due to the ICR characteristics, DoD believes media containing these 29 wastes would be viewed the same as characteristic wastes and thus a "contained-in" determination would not be required if the contaminated media does not exhibit a characteristic. Recommendation. Include in the final rule a discussion or reference to the contained-in policy such that wastes listed solely for ICR, would receive similar exemption status, whether a mixture, derived-from waste, or contained in media. References. While the contained-in policy is not promulgated (with limited exceptions in 268.45, hazardous debris, and non-specific references in 261.3(c)(1), the contained-in policy is discussed in several references, for example the preamble to the LDR Phase IV rule, 63 FR 28617 (May 26, 1998), and in an October 14, 1998 EPA Memorandum "Management of Remediation Waste Under RCRA."

MISC5 Bevill Mixture Rule should be Readdressed

MISC5 - Phelps Dodge Corp., WHWP-00243, 3,2 Industry Although the intent of the Supplemental Rule was to address EPA's alleged concerns with mineral processing wastes and the Bevill mixture rule, the plain language of the changes proposed in the Supplemental Rule prohibit the mixture of non-Bevill-exempt wastes with those wastes listed solely because they exhibit one or more hazardous waste characeristics, even if the resultant mixture no longer exhibits any hazardous waste characteristics. Phelps Dodge provided comments regarding the change in its comments to the Supplemental Rules, but EPA needs to address this issue in this rulemaking as well, given its reproposal of the mixture rule, and because EPA failed to discuss the changes to (a)(2)(iii) in the Supplemental Rule preamble.

MISC6 Need to be able to Remove "Pass-through" Codes from Wastes

MISC6 - Systech Environmental, WHWP-00053, 1,4

Waste Mgmt. Co.

The proposed rule does not provide a clear ability to remove the so-called pass through codes that attach merely because a waste passes through a container or vessel that had previously contained another waste. This is especially true when for tanks since the determination of a RCRA-empty tank is not as clearly defined as for containers. Attachment of pass through codes often limits the options that are available to a generator to manage his waste in the most efficient and economical manner possible while still being protective of human health and the environment.

Epinephrine should not be Regulated as a Hazardous Waste

MISC7 & HWIR - American Society of Health-System Pharmacists, WHWP-00129, 1,2 Other ASHP supports the EPA's proposal to amend its regulations under the Resource Conservation and Recovery Act to establish exit levels for low-risk wastes under the Hazardous Waste Identification Rule. In particular, ASHP suggests the complete withdrawal of the listing of epinephrine, currently listed as [Hazardous Waste No.] P042, as a hazardous waste. Because the EPA has not provided sufficient exemption quantitation criteria (EQCs) for epinephrine, the only exit allowed for epinephrine in the proposed rule would be under the land disposal restrictions (LDRs). ASHP believes that the LDRs impose unnecessary and burdensome [SIC], and that epinephrine should be delisted for the following reasons: Epinephrine can only have physiological effect through injection of the drug; epinephrine does not pose a significant risk to human health; and because it degrades rapidly when exposed to heat, light, or air, epinephrine does not pose a significant risk to the environment.

MISC7 - Capital Returns, Inc., WHWP-00160, 2,2 Other

In light of EPA's failure to meet its burden to demonstrate that epinephrine poses risk warranting hazardous waste regulation, and in light of the fact that epinephrine simply does not pose such risks, EPA should provide an exit for it from the hazardous waste system at any and all concentrations. Under HWIR, however, EPA has proposed to allow epinephrine to exit the hazardous waste regulatory system only after it meets the applicable land disposal restriction requirements. Because those requirements specify that epinephrine must be destroyed through incineration or certain other means, no meaningful relief is provided from the RCRA hazardous waste regime. Under EPA's proposal, epinephrine still will have to meet the hazardous waste manifesting, storage, transportation and other requirements until destroyed. This result is unnecessary and inappropriate. EPA should instead provide a full exit for epinephrine from the hazardous waste system.

MISC7 - Capital Returns, Inc., WHWP-00160, 8,1 Other

Epinephrine is one of the materials for which an appropriate exit from the RCRA Subtitle C program is necessary and appropriate. Epinephrine is an important medical product. Its regulation as listed hazardous waste P042, when discarded under RCRA's commercial chemical product provisions, imposes significant, unduly burdensome, and wholly unwarranted requirements on pharmacies, hospitals and others who use or handle it. This regulation is inappropriate, as EPA simply does not have information to support regulating epinephrine as a hazardous waste and, indeed, epinephrine does not pose a substantial threat to human health or the environment. 1. The Regulation of Epinephrine as Listed Waste P042 Imposes a Significant and Undue Regulatory Burden on Pharmacies, Hospitals and Others Who Use or Otherwise Handle It Epinephrine is a hormone, adrenalin, that is generated naturally in the human body. In addition, it serves an important medical function as a manufactured drug product, in a wide variety of clinical uses in medicine and surgery. For example, epinephrine commonly is injected into the body to relieve respiratory distress and to restore cardiac rhythm in cardiac arrest. See Goodman & Gilman, The Pharmacological Basis of Therapeutics 209 (9th ed. 1996) (included in Attachment 2.] Letter from

Thomas Rudy, Ph.D (Professor of Pharmacology, University of Wisconsin, Madison) to Charlotte A. Smith (President, Capital Returns, Inc.), at 1 (April 16, 1996) (included in Attachment 3 to these comments). [Note: See hardcopy of WHWP-00160 to review Attachment 3.] It may also be inhaled through pressure for relief of asthma or applied directly to mucous membranes or other tissues to aid in controlling bleeding. Id. These and other medical uses make epinephrine an essential drug product. As such, it is fully regulated as a drug by the Food and Drug Administration. When epinephrine drug products become outdated or otherwise unusable by pharmacies and hospitals, those entities typically either return the products to the manufacturer or a returns intermediary, or discard the products. In the case of a return to a manufacturer, such as Abbott, the manufacturer determines whether the material may be reclaimed or whether it must be discarded. In the case of a return through a returns intermediary, such as Capital Returns, the material will be returned to the manufacturer for possible reclamation or, if ineligible for return, will be discarded. If discarded, the manufacturer or returns intermediary becomes the generator of hazardous waste P042 and must handle the material as hazardous waste and comply with all applicable provisions of Subtitle C.1/In the case where the pharmacy or hospital discards the epinephrine, the pharmacy or hospital becomes the generator. Unless they manage only small amounts of hazardous waste and otherwise meet the requirements to be deemed conditionally exempt small quantity generators, the pharmacies and hospitals become fully subject to Subtitle C requirements. In many cases, the non-empty vials, unused syringes or other containers in which epinephrine products are contained may also be considered hazardous waste P042 and have to be managed as such. See 40 C.F.R. section 261.33(c). The Subtitle C requirements, as EPA is well aware, impose significant duties on those who are subject to them. The manifesting, storage, transportation and treatment requirements can be difficult to comply with, particularly for pharmacies and hospitals that may not be as familiar with them. The requirements are extremely costly for all. At a time when health care costs are of great concern, it is especially important to focus financial and labor resources where they are particularly needed. Such resources should not have to be expended for handling discarded epinephrine as hazardous waste, because, as discussed below, EPA has not shown that epinephrine is "hazardous" within the meaning of RCRA and, in fact, it is not. Thus, the real-world, burdensome and expensive consequences of Subtitle C regulation on epinephrine are not warranted and relief from them should and, indeed, must, be provided. 2. EPA Does Not Have Any Basis to Support Regulating Epinephrine as a Hazardous Waste and No Such Basis Exists EPA does not appear to have any basis for regulating epinephrine at any level as a hazardous waste, although EPA listed epinephrine as hazardous in 1980 and since then has maintained that mixtures and treatment residuals from epinephrine are hazardous. Capital Returns and Abbott have scoured EPA's 1980 listing background materials to determine why epinephrine was listed as a hazardous waste and have found nothing to support that listing. Specifically, Capital Returns and Abbott have reviewed the preambles to the regulations in which epinephrine was listed as a hazardous waste and have found no information to support a finding that epinephrine is "hazardous." See 45 Fed. Reg. 33,084, 33,115-16 (May 19, 1980) (final rule); 44 Fed. Reg. 49,402 (Aug. 22, 1979) (supplemental proposed rule); 43 Fed. Reg. 58,946, 58,957-66 (proposed rule). Moreover, the background document used to support the commercial chemical products listings, while enumerating epinephrine on a chart that purports to identify the basis on which the wastes were listed, provides no information regarding epinephrine other than to identify it as a product on the Toxic Substances Control Act Chemical Substances Inventory ("TSCA Inventory"). See U.S. EPA, RCRA Subtitle C, Hazardous Waste Management Section

3001, Identification and Listing of Hazardous Waste; Section 261.33, Hazardous Waste from Discarding of Commercial Chemical Products and the Containers and Spill Residues Thereof: Background Document, 64 (April 1981).2/ The TSCA Inventory does not provide any information upon which a hazardous waste listing could be based, however, as it is merely a listing of chemical substances. Indeed, substances are listed on the inventory without regard to whether they pose a hazard, and the list itself does not provide any information regarding hazards. See 15 U.S.C. section 2607(b). Capital Returns and Abbott also contacted an official in EPA's Hazardous Waste Identification Division, telephoned the RCRA/Superfund Hotline, and checked the RCRA docket for the commercial chemical products listings. None of these sources yielded any information regarding why epinephrine was listed as a hazardous waste. Also, as discussed in detail below, by failing to undertake a risk assessment for epinephrine under HWIR, EPA has failed in the context of the HWIR proposal to demonstrate that epinephrine poses a substantial risk. Indeed, in HWIR EPA effectively opened the question of whether and, if so, at what level epinephrine poses a substantial risk and failed to answer either question. Capital Returns and Abbott believe that there is no information to support a finding that epinephrine poses a substantial threat to human health or the environment, even assuming epinephrine were mismanaged in the ways that EPA has evaluated in HWIR. With respect to human health, epinephrine has physiological effects on the human body only when it is directly injected, forced into the lungs through inhalation, or applied directly to mucous membranes. See American Hospital Formulary Drug Information, 877 (1996) (included in Attachment 4 to these comments); see also Letter from Thomas Rudy, Ph.D. to Charlotte Smith, at 1. Given that the route of exposure must generally be direct and specifically applied, it is virtually impossible, if not impossible altogether, for a human to be exposed in the environment to a dose of epinephrine that would pose any harm. See generally id. Although epinephrine clearly does pose a potential medical risk (as well as potential medical benefit) when injected, inhaled through pressure or applied directly to mucous membranes, the Food and Drug Administration regulates epinephrine as a useful product when applied in these ways. In any event, it is not reasonable or even plausible to assume that upon discard epinephrine will be injected, inhaled through forced delivery or directly applied to mucous membranes. These are not exposure routes of concern under RCRA nor are they routes addressed in HWIR. Moreover, epinephrine rapidly breaks down (i.e., undergoes oxidation) when exposed to light or air. See American Hospital Formulary Drug Information, at 876. The resulting oxidation product is adrenochrome. Adrenochrome does not pose a significant risk to human health or the environment. Thus, there is no reasonable basis to expect that epinephrine would persist in the environment such that it could pose a substantial risk to human health or the environment. In sum, epinephrine simply does not pose a substantial risk to human health or the environment. Accordingly, Subtitle C regulation of epinephrine is not warranted. 1/ This discussion assumes that the epinephrine meets the requirements for being considered a commercial chemical product subject to the hazardous waste listing, i.e., that the epinephrine be unused and of pure or technical grade or in a formulation that contains epinephrine as the sole active ingredient. See 40 C.F.R. section 261.33(d) (comment). 2/ Notably, other entries on the chart provide specific reasons for listing, such as oral, inhalation, dermal or explosive risks. See id. at 33 (key to chart entitled "Basis for Inclusion on section 261.33(e)").

MISC7 - Capital Returns, Inc., WHWP-00160, 13,2 Other [...] Epinephrine is one of the constituents for which EPA did not undertake a risk assessment. Instead, the Agency merely extrapolated potential exit levels for wastewater and non-wastewater forms of epinephrine from the corresponding exit levels for other constituents that EPA deems to be "of concern" under the HWIR proposal. See generally 60 Fed. Reg. at 66,376, 66,435, Table C-2. As discussed below, the extrapolation approach that EPA took and, hence, the extrapolated numbers it derived for epinephrine are fatally flawed.

Although the Agency ultimately declined to propose these extrapolated numbers as exit levels for epinephrine, it did so not in recognition that the numbers are insupportable, but because the Agency concluded that it was unable to develop an exemption quantitation criteria ("EQC") concentration, or quantitation limit, for epinephrine. Id. at 66,378-79. Instead, EPA proposed that epinephrine, along with other constituents for which EPA did not develop an EQC, be allowed to exit the RCRA Subtitle C system "by complying fully with [land disposal restrictions or] LDR treatment standards applicable to the waste." Id. at 66,379. While Capital Returns and Abbott support EPA's recognition that an exit is necessary and appropriate for epinephrine, EPA's proposal to use the LDR standards to provide that exit is inappropriate as a legal matter and insufficient as a practical one.

MISC7 - Capital Returns, Inc., WHWP-00160, 21,1 Other

EPA's proposal to allow epinephrine to exit the Subtitle C system only upon satisfaction of the LDRs is unlawful and insufficient as a practical matter. Because EPA did not develop an EQC limit (i.e., quantitation limit) for epinephrine, the Agency is allowing exit only upon satisfaction of the LDRs.1/ See 60 Fed. Reg. at 66,378-79. This approach is inappropriate and unlawful. If it is impossible to determine whether a waste contains any allegedly "hazardous" constituents, such as epinephrine, in concentrations that are above risk-based levels, it is impossible to make a determination that the waste poses a substantial threat to human health or the environment. Because such a determination is a statutory prerequisite to classifying a waste as hazardous, EPA should delete from the HWIR list of constituents of concern epinephrine and any other constituents for which EQCs cannot be developed, and allow wastes to exit Subtitle C regardless of whether they contain such constituents.

Moreover, requiring compliance with the LDR treatment standards for epinephrine to exit Subtitle C would be especially inappropriate because the LDR standards are based on technological considerations that have nothing to do with risk, even though risk is the only relevant consideration in determining whether a waste should be classified as hazardous. In addition, satisfaction of the LDRs before exit imposes needless, burdensome hazardous waste regulation on epinephrine. Under EPA's proposal, epinephrine presumably would have to be handled as a hazardous waste until it meets the applicable LDR treatment standard. See 60 Fed. Reg. at 66,379. The treatment standard for epinephrine is expressed as a specified treatment technology, e.g., incineration for non-wastewater forms of it. See 40 C.F.R. section 268.40, Table. Thus, almost no relief would be provided from Subtitle C, as epinephrine would have to be handled as hazardous until it is destroyed. Further, this effectively would foreclose other safe and potentially desirable waste management options. Accordingly, EPA's proposed HWIR exit for epinephrine does not provide the relief from Subtitle C that is needed and warranted.

1/ As a threshold matter, Capital Returns and Abbott question EPA's efforts to develop an EQC for epinephrine. EPA has acknowledged that the Food and Drug Administration has a test method for epinephrine. See U.S. EPA, Background Document to Support the Selection of Analytical Methods and Determination of EQCs under the Hazardous Waste Identification Rule, at 8, 9 (Nov. 1995). However, the Agency has not specified why it was unable to develop an EQC from this method for epinephrine. Moreover, given the Food and Drug Administration method, and the requirement that drug manufacturers quantify the level of constituents such as epinephrine in their products, there are levels at which EPA could have identified and assessed the risks posed by epinephrine. Based on the information discussed above, see Section II.B.2, had EPA undertaken this course, Capital Returns and Abbott do not believe that epinephrine would have or could have been shown to pose a substantial risk to human health or the environment.

MISC7 - Capital Returns, Inc., WHWP-00160, 22,2 Other

EPA must provide an exit from the hazardous waste regulatory system for epinephrine at any and at all concentration levels. Given that EPA has not supported and cannot support a finding that epinephrine poses a substantial risk to human health or the environment, EPA should provide an exit from Subtitle C for epinephrine at any concentration level. As discussed above, this result is mandated by RCRA. In addition, it is fully supported by HWIR. In developing the HWIR proposal, EPA identified five management scenarios and numerous exposure pathways from which it determined whether the various constituents posed substantial risks when mismanaged under worst-case conditions. See 60 Fed. Reg. at 66,357-76. Had EPA undertaken the necessary risk assessment for epinephrine, EPA would have found that epinephrine does not pose a substantial risk under any of these mismanagement scenarios.1/

Indeed the exposure pathways would have to include injection, forced pressure inhalation, or direct application to mucous membranes to have any human health effect. See Section II.B.2. None of these exposure pathways was considered by EPA. The reason is simple: these are exposures of concern to the Food and Drug Administration in its regulation of drug products like epinephrine, not to EPA in its regulation of wastes. Further, given the rapid degradation of epinephrine when exposed to light and air, it does not pose a substantial risk to the environment, even under EPA's mismanagement scenarios. Id. Accordingly, EPA should provide an exit from the Subtitle C system under HWIR for epinephrine at any concentration level.

1/ Although Capital Returns and Abbott do not believe that epinephrine could be demonstrated to pose a substantial risk even under EPA's "mismanagement" scenarios, Capital Returns and Abbott note that these scenarios are inappropriate in the first place. The mismanagement units were chosen by EPA to be "worst-case" examples of their type, assuming absolutely no legal controls (e.g., limitations on site access or design and operating standards) on those units. 60 Fed. Reg. at 66,356-58. The Agency stated that these management scenarios "were selected to reflect those that might be commonly associated with the management of exited hazardous wastes." Id. at 66,356. The assumption that there will be no legal control upon exit from the Subtitle C system is totally unreasonable, however, as it fails to take into account the existence of solid and industrial waste programs at the state level. EPA has acknowledged that it is appropriate to eliminate management scenarios from consideration if there are regulatory or practical controls in place that prevent those scenarios from being actualized. See 59 Fed. Reg. 66,072, 66,075 (Dec. 22, 1994).

MISC7 - Capital Returns, WHWP-00160, 24,1 Other

Not only is a HWIR exit at any level warranted, but to best address the problems with the hazardous waste listing for epinephrine, that listing should be withdrawn. To the extent that an exit from Subtitle C is warranted for epinephrine at an concentration level, rather than merely relying on the HWIR exit, EPA simply should withdraw the hazardous waste listing for epinephrine altogether. EPA has decided in the context of the HWIR proposal to address overbroad listings. In the case of epinephrine, the Agency should extend this effort to not only provide an exit, but to eliminate the unnecessary and inappropriate listing. Of course, the hazardous characteristics provisions would still apply, so that if any waste containing epinephrine were truly "hazardous" by virtue of its own characteristics, it would have to be handled as hazardous waste under Subtitle C. Accordingly, elimination of the listing would provide much-needed and warranted relief, and no substantial hazard to human health or the environment would result.

MISC7 - National Wholesale Druggists Assn., WHWP-00188, 1,1 Other These comments are being submitted to EPA to recommend that epinephrine, a P-listed hazardous waste subject to regulation under EPA's proposed Hazardous Waste Identification rule, be removed from this list. This product, sold by many drug wholesalers to retail outlets, hospitals and clinics is a low risk waste that should not be regulated as hazardous.

Epinephrine is used in medicine and surgery in a number of ways. The most common use is to relieve respiratory distress and hypersensivity reactions and prolong the action of anesthetics. Epinephrine is also used for the relief of asthma via inhalation and, otherwise, is injected or applied topically to control bleeding. Epinephrine is a naturally-occurring hormone that rapidly degrades when exposed to heat, light or air. In addition, the only way that epinephrine can have a physiological effect is by injection. There is no significant risk upon exposure to either the environment or human health.

It is not logical to require that epinephrine be listed as an acute hazardous waste when discarded and thereby subject to the same reporting and disposal requirements as high level wastes under the proposed regulation. The inclusion of epinephrine on the P list imposes an extreme burden not only on drug wholesalers disposing of expired epinephrine but also upon the health care industry as a whole. NWDA supports EPA efforts to encourage pollution prevention and waste minimization but it is impractical and burdensome to enforce stringent regulations on a substance that cannot contribute to these problems.

Totals LDR Standard for Arsenic in K088 cannot be met in Treated Waste, even when the Untreated Waste did meet the Standard

MISC8 - Waste Management, WH2P-00006, 3,3 Waste Mgmt. Co.

As a separate issue, EPA's establishment of a standard for arsenic as a totals concentration for K088 has caused subsequent management problems due to the mixture rule and derived from rule. At 63 FR 51253, EPA established standards for aluminum production potliner wastes, or K088, and included an arsenic standard of total arsenic. At the time, WM commented that establishing a totals standard rather than a standard based on the Toxicity Characteristic Leachate Protocol (TCLP) would likely lead to significant logistical problems if, on rare occasions, a waste stream carried total arsenic above the standard. EPA has recently become aware that such a problem is arising where incinerator ash from the treatment of mixtures of waste containing K088 are not meeting the total arsenic standard despite the fact that the untreated K088 did meet the standard. As a result, these derived from wastes cannot be land disposed without undertaking a length process for a treatability variance. WM recently submitted information to EPA describing its recent experience with this problem and made a number of recommendations to EPA on how the dilemma can be resolved. In the context of this proposal, WM also recommends that, as another possible solution, EPA consider amending the mixture rule and derived from rules so that an LDR based on total concentrations is not carried through to a treatment residual if the original waste met the LDR standard.

MISC8 - Onyx Env. Services, WH2P-00015, 3,1 Waste Mgmt. Co.

This approach also provides a sensible means of dealing with the K088 issues OES and other combustion operators have brought to the Agency. Specifically, hazardous wastes that carry numerous listed codes and also carry the K088 code due to the mixture rule (e.g., wastewater treatment sludges) must meet the K088 treatment standard for total arsenic of 26.1 mg/l. OES is aware of wastes that meet the K088 total arsenic standard prior to combustion; however, because these wastes are combusted with other wastes which contain arsenic subject to a TCLP standard, the resultant ash may exceed the total arsenic standard in some cases. OES believes that this approach would address this issue by allowing the residue to meet the TCLP arsenic standard.

MISC9 EPA Should Develop Risk-based LDRs

MISC9 - DOE, WH2P-00007, 6,2 Federal Govt.

While DOE recognizes that LDR treatment standards would continue to apply to decharacterized mixtures and residuals as described in the preceding paragraph, DOE believes that, as long as LDR treatment standards remain technology-based rather than risk-based, requiring decharacterized mixtures and residuals to meet LDR treatment standards could force treatment that is not necessary to minimize threats to human health or the environment. Hence, DOE urges EPA to move forward with development of risk-based LDR treatment standards as expeditiously as possible.

MISC9 - Heritage Environmental Services, WHWP-00017, 2,3 Waste Mgmt Co. Heritage supports the EPA's proposal to replace technology-driven land disposal restrictions (LDR) treatment standards with risk-based "minimize threat" levels. This approach only makes sense as EPA continues to develop better, more sophisticated methods of estimating risk. Development of more reasonable risk-based LDR treatment standards to replace the technologyderived treatment standards will allow industry to concentrate its compliance resources on more cost-effective means of protecting the environment. Heritage encourages EPA to develop risk-based "minimize threat" levels for all of the constituents in the universal treatment standards list.

MISC9 - National Assn. of Metal Finishers, WHWP-00141, 5,3 Industry Assn. We support EPA's move toward risk-based land disposal restrictions (LDRs). The metal finishing industry does not favor rigid, technology-based standards. This discussion, however, is meaningless in light of the exit criteria proposed by EPA. While we would like to see the entire LDR program move to a risk-based approach, the unduly low exit levels make the current technology-based disposal requirements preferable at this time.

MISC9 & HWIR - Shell Chemical Co., WHWP-00191, 16,2 Industry Shell supports the use of risk-based LDR treatment levels only where those levels are achievable through available technology.

A. The proposal that all listed wastes which "as generated" contain constituents exceeding exit levels must meet LDRs even if the waste subsequently becomes exempt from hazardous waste regulations because the waste is subsequently brought below the exit level is the continuation of an unwarranted regulatory interpretation.

1. This proposal exceeds the purpose of the law which was designed to protect human health and the environment.

a. RCRA Sec. 1003. (b) "NATIONAL POLICY -- The Congress hereby declares it to be the national policy of the United States that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible. Waste that is nevertheless generated

should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment." Emphasis added.

2. There is no incentive to treat a waste to a "risk based" exit level, if after treatment, it must be further treated to meet a "technology based" level.

a. Because a risk based level may be relatively easy to reach (vs. a technology level) the additional time and effort are not productive or necessary.

3. This is treatment for treatment's sake. This is not a common sense approach to a problem which can be defined by risk (exposure and toxicity).

B. Risk Based Standards, in Limited Situations, Can Serve as Land Disposal Restriction Levels

Our support for the use of such standards, at this time, is very qualified. Because of the ultra conservative nature of the multi-pathway model only those levels that are greater than technology standards should be considered for use as a land disposal restriction level.

1. The current multi-pathway model is not ready for any use other than potentially delisting already listed hazardous waste. In fact, the model will not allow realistic delisting now but if limited to that use, or to uses where its overly conservative assumptions will not penalize the regulated community, it can possibly be utilized.

Note: As we have indicted in prior comment sections, Shell suggests that either the multi-media model should either not be promulgated as proposed at this time, or should only be promulgated after (1) eliminating the un-validated environmental impact aspects, (2) simplifying it, and (3) strictly limiting its use to delisting

MISC9 - Shell Chemical Co., WHWP-00191, 18,2 Industry Shell supports the use of risk-based LDR treatment levels only where those levels are achievable through available technology.

A. Risk Based Levels Should be Utilized Where They are Greater Than Technology Based Standards

1. Risk based levels should be utilized when there is a human health exposure pathway.

Note: If the exposure pathway can be eliminated the risk-based level should not apply. Without exposure there is no risk.

2. LDR requirements, which are based on technology, are appropriate when they are higher than risk-based levels.

B. The Use of Risk Based Exits Levels are Generally Preferred

Shell has long supported the use of risk based data to set decision levels under RCRA. The proposal to use such risk levels instead of technology based UTS levels is a welcome approach.

1. The situation where the Risk Based Exit Level is greater than the UTS is the obvious situation where the risk level should be utilized.

2. It does not make any technical sense to treat a waste to below its risk based exit level prior to land disposal. To do so would be an example of technology for technology's sake.

C. The Use of a Risk Based Exit Level Should Not be Used If Less Than a UTS

The risk base level could not substitute for the UTS where that number is less than the UTS.

1. Because of the ultra conservative nature of the multi-pathway model only those levels that are greater than technology standards should be considered for use as an exit level

The Proposal does not Create any Incentives for Recycling

MISC10 - National Oil Recyclers Coalition, WH2P-00023, 2, 2 Industry Assn. NORA's second concern is the failure of the proposal to create any incentives for recycling. NORA believes that virtually all proposals under Subtitles C and D of the Resource Conservation And Recovery Act should advance the objectives of legitimate resource conservation and recovery (i.e. recycling.) Legitimate recycling by its nature preserves natural resources and often saves vast quantities of energy. Incentives to exit the hazardous waste regulatory program that promote legitimate recycling should always be considered when EPA undertakes rulemaking under RCRA.

EPA Should Renounce its Position on the Application of the Mixture Rule to the K170 Listing

Industry Assn.

MISC11- API, WH2P-00031, 2,6

[...] That intention is reflected in the position recently taken by EPA in litigation (API v. EPA. No. 94-1683, et al.) challenging the scope of the 1998 hazardous waste listing rule for petroleum refinery Clarified Slurry Oil Storage Tank Sediment (K170). In that rulemaking and litigation, EPA has claimed that the mixture rule allows it to classify as a listed hazardous waste residues from the lawful mixing of products if one of those products is a precursor to a listed waste, despite the fact that the mixture rule is expressly limited to mixtures of solid wastes and listed hazardous wastes. See 63 Fed. Reg. 42153 (Aug. 6, 1998); EPA Brief in No. 94- 1683, at 74. EPA has no justification for its position, other than its apparent speculation that some generators might attempt to evade an eventual listing by blending products prior to the generation of any wastes. In any event, this unprecedented interpretation could vastly increase the potential scope of the already overbroad mixture rule, and could extend the Subtitle C program far upstream in the production process to regulate materials that have not even become solid wastes, let alone hazardous wastes under RCRA. API urges EPA in this rulemaking to renounce this untenable assertion. API will comment on the concentration-based HWIR exemption option discussed in the November 19 notice, including the risk assessment model, by the May 17, 2000 deadline.

MISC12 EPA Should Revise the Test Method for Cyanide

MISC12 - National Coil Coaters Assn., WHWP-00192, 9,1 Industry Assn. [...] 2/ In some cases, however, even when cyanide is not used anywhere in a particular coil coaters' process, the test method for cyanide results in "false positives" for cyanide. EPA should revise the test method for cyanide to eliminate this problem.

MISC13 EPA Should Modify the Rules to Make Their Intent Clear

MISC13 - Caufield Enterprises, WHWP-00035, 2,3 Consultant [We] also find that your proposal is very difficult to comment upon for many small businesses and the public. EPA needs to make clear specific questions with identification numbers for the public and businesses to use in their response. This rule should be reissued for comment with specific questions identified. General comments should also be allowed.

MISC13 - Caufield Enterprises, WHWP-00035, A2,2 Consultant EPA should modify the rules to make their intent clear and not depend on policy memorandums and other policy directives. Regulated businesses don't have the staff, time or means to research every issue for all the policies, many of which may not even be readily available. The rule needs to make clear what is necessary for compliance at minimum cost, all in one place! We have actually had EPA staff refer us to a rule preamble more than 20 years old. Fortunately, we were able to find the Federal Register in the McGeorge School of Law Repository. This type of information isn't readily available to the public, yet they need to use it for compliance.

MISC13 - Systech Environmental, WHWP-00053, 2,1 Waste Mgmt. Co. There are some inconsistencies in the language of the rule. In some instances, the rule refers to land application and in other instances the rules reference land treatment units. The context would appear to mean the same in both instances but the terminology is different. Thus, EPA needs to be careful in its selection of terminology.

MISC13 - American Institute of Chem Engineers, WHWP-00084, 5,3 Industry Assn. Clear and Concise Language: The HWIR regulation, although addressing a technically complex subject, should be written to describe the requirements for compliance in [a] manner that can be readily understood by the entities to whom it is directed.

MISC14 PCBs Should be Regulated Exclusively Within the TSCA Program

MISC14 - Pacifi Corp., WHWP-00108, 23,3 Utility Co./Assn. The regulation of the management and disposal of PCBs should remain exclusively within the TSCA program, and should not be subject to regulation under RCRA.

MISC14 - CMA PCB Panel, WHWP-00079, 2,2 Industry Assn. The PCB Consensus Group opposes the inclusion of PCBs as a constituent in the

The PCB Consensus Group opposes the inclusion of PCBs as a constituent in the HWIR proposal, which would subject the disposal of PCBs to regulation under RCRA. For nearly twenty years, the TSCA PCB program has developed and set standards for the disposal of PCBs. During this process, EPA has studied PCBs extensively, and has reached its regulatory determinations based upon these studies. While the PCB Consensus Group continues to take issue with certain aspects of EPA's regulations based upon recent studies that support a less stringent approach for PCBs, the Consensus Group is convinced that the basic approach to the management and disposal of PCB waste established under TSCA is fully protective of human health and the environment.

Moreover, strong agreement exists within the regulated community for maintaining the regulation of PCBs under TSCA. The TSCA PCB program is working to eliminate PCBs from the environment, and much effort has been invested in the development of amended requirements to improve and refine the PCB regulations. As an example, EPA has recently requested and received extensive comments on amendments to the PCB program under the "mega" disposal rule proposal. See 59 Fed. Reg. 62788 (Dec. 6, 1994). Both the Agency and the regulated community have spent and continue to spend significant resources on the development of this proposal and in the implementation of rational and cost-effective PCB regulations. Therefore, EPA should maintain its support of the TSCA system and refrain from disrupting it with unnecessary RCRA regulations.

MISC14 - CMA PCB Panel, WHWP-00079, 3,2

Industry Assn.

Since Congress passed TSCA in 1976 and EPA first promulgated disposal regulations in 1978, the disposal of PCBs has been governed by TSCA rules codified at 40 C.F.R. Part 761. This regulatory scheme is unique in that it governs the disposal of a chemical whose manufacture has been banned, in contrast to waste materials that are regulated under RCRA. The basic disposal issue to be addressed is thus not how to manage a stream of continuously generated hazardous waste as is the case for RCRA-regulated materials, but rather how to regulate final disposal of a chemical that is no longer commercially produced. Since the amount of PCBs to be disposed is continually declining, new or modified controls on PCB disposal should be structured to expedite rather than impede disposal in an environmentally sound manner.

Industry has worked cooperatively for many years with EPA, the states, and environmental groups to achieve agreement on the details of the TSCA disposal rules. By now, these rules are well established; and industry is familiar with the regulatory requirements, technologies and procedures needed to implement the TSCA regulations.

This is not to say that elements of the RCRA program are irrelevant to PCB disposal. To the

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contrary, over the years, a number of elements from the RCRA regulatory scheme already have been adopted for use in the TSCA program. For example, EPA now requires RCRA-type financial responsibility and closure planning in TSCA approvals issued to PCB treatment and disposal facilities. Additional elements of the RCRA program have been added to enhance the TSCA program, such as monitoring and tracking of PCB wastes through a manifest system. See 40 C.F.R. Section 761 Subpart K.

However, after a careful multi-stakeholder review of the benefit of using TSCA or RCRA authority to regulate the disposal of PCBs, accommodation of perceived gaps in the TSCA rules have been achieved through targeted revisions of the TSCA rules -- rather than through a wholesale shift of the PCB regulations into the RCRA program. Although we do not always agree on the appropriateness or cost-effectiveness of the TSCA rules, industry, EPA, and other interest groups have worked together and invested significant time and resources in revising aspects of the TSCA program when necessary. It would be administratively difficult and extremely expensive to integrate the PCB disposal regulation into RCRA while retaining the most effective aspects of each program.

EPA historically has supported regulation of PCBs under TSCA, rather than RCRA. In 1987, Congress briefly considered the idea of moving PCB disposal regulations into RCRA. At that time, EPA opposed such a movement and instead promulgated rules to improve the TSCA PCB disposal regulations.1/

EPA has acknowledged in several RCRA rulemakings the comprehensive PCB disposal regulatory framework provided under TSCA. For example, in 1990, the Agency agreed that "if PCBs wastes were to be regulated now under RCRA as well as under TSCA, serious legal, practical and administrative complications could result."2/ The Agency has identified the "significant potential negative impact of dual regulation" of PCBs to be "the unique scope and timing of PCB disposal," and has stated that it is best not to disrupt TSCA's "specifically tailored [program] to deal with the problem of widely dispersed waste generation." Id. The Agency also has concluded that the TSCA program is adequate to protect human health and the environment Id. Certainly there is no reason for wastes whose sole criterion for hazardous treatment is PCB content to be included in the RCRA System.3/ Therefore, the PCB Consensus Group urges EPA to recognize once again the utility of regulating PCBs under TSCA and refrain from including them in this RCRA rule.

1/ EPA, Final Rule, Polychlorinated Biphenyls; Notification and Manifesting for PCB Waste Activities, 54 Fed. Reg. 52718 (Dec. 21, 1989).

2/ EPA, Final Rule, Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revisions, 55 Fed. Reg. 11798, 11841 (Mar. 29, 1990).

3/ Indeed, we believe that where waste containing PCBs is regulated under TSCA, the management options are sufficiently protective even where RCRA-regulated material is mixed with it and the single set of TSCA requirements should apply. See e.g., 40 C.F.R. Section 261.8.

MISC14 & HWIR- USWAG, WHWP-00089, 58,1 Utility Co./Assn.

USWAG fully supports and endorses the comments filed today by the PCB Consensus Group 1/ regarding the effects of the HWIR proposal on the regulation of polychlorinated biphenyls ("PCBs"). The primary comments made by the PCB Consensus Group include the following:

The regulation of the management and disposal of PCBs should remain exclusively within the TSCA program, and should not be subject to regulation under RCRA.

The establishment of any risk-based exit levels for PCBs should be based on EPA's most recent cancer slope estimates.

The dilution attenuation factors for PCBs that are used in calculating proposed exit levels are overly conservative and fail to consider the most recent available information on the environmental fate and transport of PCBs.

EPA should take into consideration the biodegradation of PCBs in determining appropriate exit levels.

1/ The PCB Consensus Group is composed of USWAG, the Chemical Manufacturers Association PCB Panel, and the National Electrical Manufacturers Association.

MISC14 - General Electric, WHWP-00193, 24,3 Industry

GE has two main objections to EPA's establishment of exit levels for PCBs in this rulemaking. First, PCBs are already heavily regulated under the Toxic Substances Control Act (TSCA) and, therefore, should not be the subject of dual regulation under RCRA. GE agrees with comments filed by the Utility Solid Waste Activities Group, Chemical Manufacturers Association PCB Panel, and National Electrical Manufacturers Association (the "PCB Consensus Group"), which detail the comprehensive regulatory framework that exists under TSCA for controlling the manufacture, use, distribution and disposal of PCBs. Given that TSCA already governs the disposal of PCBs, EPA should not create undue confusion and inconsistency by setting exit levels under RCRA. [...]

MISC14 - Aluminum Company of America, WHWP-00199, 3,4 Industry The disposal of PCBs are already regulated by EPA under TSCA and RCRA used oil regulations. The exit levels for PCBs, established at the EQC, essentially further regulate the disposal of PCB wastes by preventing any waste stream with a measurable concentration of PCBs to exit RCRA regulation.Setting the exit level for PCBs at the EQC is inconsistent with current EPA requirements that regulate PCBs for disposal at concentrations of 50 ppm or greater and specify technology requirement for only a single type of waste management (the burning of used oil containing 2 - 49 ppm of PCBs).

The proposed rule would require that a waste with otherwise unregulated low levels of PCBs (.0005 - 0.25 ppm depending on the bench mark option and type of waste), which could otherwise exit Subtitle C, to be managed and disposed of as a hazardous waste. In contrast, a waste which originally was considered non-hazardous and that contains 49 ppm of PCBs has no prescribed

management requirements. Soils containing 10 ppm of PCBs are acceptable under EPA PCB Spill clean-up policy for residential and commercial areas.

Management of RCRA waste as hazardous simply because it has detectable levels of PCB is inappropriate. EPA already has an effective mechanism for regulating PCB wastes. Subtitle C requirements should not be imposed for wastes containing PCBs that otherwise meet exit criteria.

MISC14 - Jersey Central P&L Co., WHWP-00220, 7,1 Utility Co./Assn. PCBs, which are regulated as part of the Toxic Substances Control Act ("TSCA"), should not also be included as a constituent of concern in the HWIR rule.

MISC14 - General Public Utilities, WHWP-00239, 9,2 Utility Co./Assn. PCBs, which are regulated under the Toxic Substances Control Act ("TSCA"), should not be included as a constituent of concern in the HWIR rule.

EPA Should Promulgate Conditional Exclusions for Recyclable Materials

HWIR and MISC15- State of Missouri DNR WHWP-00034, 3,6 State Govt. Regarding XIV.D.1., we are concerned that the proposed rule could eliminate incentives for environmentally protective recycling. However, if recycling is addressed as a contingent management option under a state program approach as discussed in the comments above, this could be a means of encouraging recycling while still providing a mechanism for effective risk management in the review process. It would help if EPA stated this explicitly and got behind the idea more.

MISC15 - SOCMA, WH2P-00035, 21,1 Industry Assn.

SOCMA Recommends that EPA Pursue Contingent Management Options That Promote Qualified Recycling Activities SOCMA recommends that EPA also pursue development of contingent management options that exempt wastes from the automatic application of waste listing classifications where those classifications preclude effective use of wastes that otherwise could be reused or recycled. SOCMA recognizes that a relatively smaller percentage of recycling and reused scenarios may involve waste streams that are classified solely as a result of the mixture and derived-from rules. Nonetheless, since EPA has faced significant challenges in effectively narrowing the reach of the hazardous waste classification scheme, SOCMA urges EPA to focus also on establishing exemptions geared to the waste classification part of the equation. The following example from a SOCMA member illustrates the difficulty that companies have engaging in productive recycling activities under the current regulatory scheme. In this instance, the continuing difficulty that both the regulated community and regulators face in interpreting the hazardous waste classification provisions is readily apparent. In this instance, the company makes a product, which it manufactures by distilling a raw material purchased from a supplier. In order to verify that the product meets specifications, the company takes a sample of the product, dissolves it in a solvent and performs a test in the laboratory. Note that the solvent used is a chemical which is also present in the purchased raw material from which the product is manufactured. The solvent, if disposed, would fall within one of the spent solvent listings under RCRA. The company desired to recycle the solvent-dissolved product back into the raw material tank where it could then be reprocessed (distilled) into a useable product again, rather than being disposed of by being sent off-site as a hazardous waste. The company was of the view that this practice would meet one or more of the exclusions from the definition of solid waste provided in 40 C.F.R. § 261.2(e)(1). Under this provision, as in effect at that time, materials are not solid wastes when they can be shown to be recycled by being: (I) used or reused as ingredients in an industrial process to make products, provided the materials are not being reclaimed; (ii) used or reused as effective substitutes for commercial products; or (iii) returned to the original process from which they are generated without first being reclaimed, in which case the material must be returned as a substitute for raw material feedstock, and the process must use raw materials as principal feedstocks. Placing this material back into raw material tank would have allowed the company to maintain control of the material on-site and avoid the risks associated with the packaging, transportation and disposal of the material at an off-site location. The solvent-dissolved product would have been made into a useful product by direct insertion into the process from which it originally came, and the solvent/chemical itself would the packaging, transportation and disposal of the material at an

off-site location. The solvent-dissolved product would have been made into a useful product by direct insertion into the process from which it originally came, and the solvent/chemical itself would have been incorporated into another product (co-product) of the distillation which is also incorporates the same solvent/chemical which is present in the purchased raw material. The Agency took the position that by application of the mixture rule solvent-dissolved product was a listed spent solvent that must be managed as a hazardous waste. The Agency further maintained that none of the exceptions from the definition of solid waste would apply in this situation and that introduction of the solvent-dissolved material into the raw material tank would be interpreted as management of a listed hazardous waste. Furthermore, the tank of raw material would also become a listed hazardous waste by the mixture rule and subject to all RCRA requirements for storage and treatment. In this instance, both a product and a solvent could have been safely and productively reused with lower environmental risk than would be associated with off-site management of the materials. Given the need for the company to meet specifications for both production activities, there was no identifiable risk of inappropriate placement of materials into a production process. SOCMA encourages EPA to develop a contingent management mechanism that can facilitate flexibility that promotes greater reuse and recycling of valuable material that presently is precluded from recycling due to the structure of the hazardous waste regulations.

MISC15 - Molten Metal Technology, Inc., WHWP-00120, 10,1 Waste Mgmt Co. EPA should establish conditional recycling exemption options in HWIR.

EPA's authority to establish conditional exemption options under RCRA is well established. See e.g. the Petroleum Refining Process Waste proposals 1/ and the Supplemental Proposal to LDR Phase IV.2/ In view of the intense and widespread criticism and controversy over the multipathway model and the proposed exit levels, the Agency should further evaluate alternatives for conditional exemption options, especially options to encourage waste minimization. Specifically, MMT urges EPA to take this opportunity to establish conditional exemptions from the Definition of Solid Waste (DSW) for recyclable materials that are managed and recycled in accordance with specified conditions. In the final HWIR, EPA should include, and find ways to establish a preference for, non-risk based conditional exemptions for recycling efforts, while at the same time avoiding the many difficulties that seem to be associated with the current state of the science of risk assessment. In fact, a contingent management approach for encouraging recycling under RCRA could probably be implemented in a way that eliminated all important risk pathways, thereby eliminating the need for reliance on a multipathway risk analysis.

EPA should use its authority to establish conditional recycling exemptions to promote the Pollution Prevention Act waste management hierarchy which favors prevention and recycling over treatment and disposal. The proposed conditional disposal exemptions (and the lack of conditional recycling exemptions) would skew the exiting of wastes towards Subtitle D disposal facilities and not towards environmentally sound recycling. Resolving this imbalance, EPA's inclusion of conditional recycling exemptions would support the waste management hierarchy, provide direct incentives to send wastes to recycling facilities and result in maximum overall reductions of discharges to all media. Shifting HWIR's focus to potential conditional recycling exemptions would harmonize HWIR's goals with the Agency's other on-going efforts and policies to increase recycling practices.

MMT is aware of other EPA initiatives to encourage recycling, including the ongoing project by the Office of Solid Waste (OSW) on the Definition of Solid Waste (DSW), addressing jurisdictional and other recycling issues. In other recent policy-making proposals, specifically the Petroleum Refining Process Waste proposal3/ and the Supplemental Proposal to LDR Phase IV concerning mineral processing waste.4/ EPA incorporated waste minimization and recycling, including specified non-risk based exemptions for recycling. To consistently promote environmentally sound waste management, EPA at a minimum should address waste minimization and recycling in a similarly coherent and comprehensive fashion in the final HWIR.

The Agency has begun to address similar waste minimization and DSW recycling issues and their relation to conditional exemption scenarios in the Petroleum Refining Process Waste proposal5/ and the Supplemental Proposal to LDR Phase IV.6/ In the petroleum proposal, EPA acknowledges its waste minimization goals and notes its continued work with the petroleum refining industry and others for a number of years to explore pollution prevention efforts related to changes proposed in the rule.7/ In the rule, the Agency proposes to broaden the existing exemption in 40 CFR 261.4 (a)(12) for oil-bearing residuals from specified petroleum industry sources that are re-inserted (recycled), in the refining process (including the petroleum coker).8/ Specifically, the RCRA "exclusion would cover oil-bearing secondary materials that are generated on-site at refineries, transported intra-company from off-site, or received from any off-site facilities (inter-company transfers)" within certain SIC codes.9/ In effect, this rule-making for the petroleum industry proposes potential precedent-setting changes to the DSW for other industries, depending on how the materials are managed.

In addition to the non-risk based exemptions for recycled wastes, the petroleum proposal contains options for non-risked based conditional exemptions based on the management of wastes for disposal. Acknowledging the disincentives that disposal exemptions provide for recycling and waste minimization, EPA states:

One of the drawbacks of contingent management listings that link regulatory status to particular management practices is that contingent regulation may reduce the incentive for generators to explore pollution prevention opportunities. Thus, allowing disposal in Subtitle D landfill may result in more waste being placed in Subtitle D landfills, because it is less expensive than Subtitle C management or recycling, and easier than implementing process changes that would result in reduced or eliminated waste volumes. However, EPA is also proposing ... to allow generators to reinsert oil-bearing wastes...back into the refining process. Thus, generators will still have an incentive to deoil or reuse these residuals, if possible, thereby resulting in increased recycling.10/

Thus, in the petroleum proposal, EPA concedes the perverse incentives for disposal created by contingent management options and attempts to address and offset them with recycling incentives, including policies to support the Pollution Prevention Act's waste management hierarchy that prefers recycling over disposal. EPA's enlightened approach to contingent management options in the petroleum rule contrasts sharply with the HWIR contingent management options, which would virtually compel generators to dispose of exited waste in Subtitle D

disposal facilities. The latter approach is entirely at odds with the Pollution Prevention Act, EPA policies and pronouncements, and sound principles of environmental management.

Similar to the petroleum proposal, the Supplemental Proposal to LDR Phase IV concerning mineral processing wastes also includes non-risk based recycling exemptions. In that rule, EPA proposes that "mineral processing secondary materials would not be classified as solid wastes when recycled legitimately within the mineral processing industry," allowing for the recycling of wastes based on the management of the materials.11/ Explaining the general principles for redefining solid waste within the mineral processing sector, EPA said:

At least for this industry, distinctions among secondary material types are not especially meaningful. The critical factor ... does not relate to the type of metal-bearing materials being recovered but to the type of unit involved in the recycling activity What matters is how that secondary material is managed, so that the chief focus of the definition can be on the types of units receiving the material. Focusing on the types of management units involved in the recycling activity coincides with a critical feature of the test enunciated repeatedly by the courts: whether the materials have become part of the waste disposal problem.12/

In the rule, EPA also requests comments on a proposal by the iron and steel industry that "calls for flexible minimum management standards to be met which conditionally exclude recyclable materials from the definition of solid wastes" (emphasis added).13/ Both the petroleum and the mineral processing rules address the "question of whether recoverable secondary materials generated by and recycled within a single industry need be classified as solid (and potentially hazardous) waste.14/ We believe that a similar approach and principles with consideration to recycling issues should be examined in HWIR. Of particular note, because contingent management recycling exemptions would not necessarily be based on risk, the inherent problems of the multipathway risk analysis could be avoided.

MMT recognizes that certain conditions or restrictions -- some industry specific - may be required to ensure legitimate recycling. For example, particular attention should be paid to sham recycling issues, management standards, storage issues, and toxics along for the ride (TARs). EPA might consider including such conditions as: no land storage of recyclable materials; formal, written demonstration to the appropriate regulatory authority that legitimate recycling occurs; demonstration that products meet standard specifications and contain no TARS; and specific demonstrations that the recyclable materials contain appropriate quantities of recoverable constituents. For example, in the petroleum proposal, the recycling exemption would be valid "if these materials are not stored in a manner involving placement on the land, or accumulated speculatively before being so recycled, and if the resulting coke product does not exhibit one or more of the characteristics of the hazardous waste.15/ Conditions to ensure legitimate recycling for the mineral processing proposal include stipulations for certain concentrations of recoverable minerals and acids, constraints on nonrecoverable hazardous constituents, no speculative accumulation and certain ground water protection standards.16/ Thus, EPA, with consideration to the industries most-impacted by HWIR, can and should develop conditional exemptions to

encourage legitimate recycling.

MMT believes the Agency should (indeed, must under the Pollution Prevention Act and waste minimization policy) include waste minimization and recycling incentives in HWIR. The DSW project and the conditional recycling exemption proposals put forth in the Petroleum Refining Process Waste proposal and the Supplemental Proposal to LDR Phase IV, demonstrate the Agency's belief that there is a rational basis and foundation for the encouragement of waste minimization in Agency rulemaking activities. Essentially, to achieve its overarching waste minimization goals, the Agency must take a holistic, integrated policy approach, using its rulemaking and other policy-making efforts to support the Pollution Prevention Act waste management hierarchy. EPA simply can not "defer" waste minimization policies to more convenient rulemakings, but must effectively incorporate them into HWIR. Otherwise, HWIR's incentives for disposal would effectively undermine waste minimization (and EPA's other initiatives to implement pollution prevention), diverting resources from recycling.

MISC15 - Safety-Kleen Corp., WHWP-00124, 3,2 Waste Mgmt Co.

Safety-Kleen believes that, before incorporating contingent management into the HWIR Process Waste exits, the EPA should first address "contingent management" at "entry" by promulgating conditional exclusions from the definition of solid waste for materials that are clearly not managed as wastes (e.g., recycled materials).

Safety-Kleen believes that the simplest and most straightforward approach that the EPA could take to incorporate regulatory encouragement for recycling would be to provide conditional exclusions to the definition of solid waste in 40 CFR 261 (40 CFR 261.6 and 261.4(a)) for those materials destined for recycling. We understand that such an approach is being evaluated by the EPA for an upcoming proposed rulemaking (the Definition of Solid waste rulemaking scheduled for proposal in October, 1966). Safety-Kleen believes that, prior to creating a contingent management alternative for the HWIR Process Waste regulation, it is imperative that the EPA first develop entry criteria that will allow conditional exit from Subtitle C for wastes that are destined for legitimate recycling. This will significantly reduce the complexity from that required for a contingent management approach for exit. Specifying that a material is outside the definition of solid waste when it is properly recycled will create incentives for generators to recycle their wastes. On the other hand, by keeping these wastes in the system, failing to consider recycling as a method which qualifies for contingent management, and requiring constituent-by-constituent analysis, the EPA would be creating disincentives for recycling.

Recycling of spent and discarded materials generally poses less environmental hazard than land-based disposal of the same material. In fact, recycling of a spent material not only keeps that material out of land disposal, but also reduces dependency upon raw materials. The Agency's own wastes management hierarchy places recycling much higher than land disposal on the pyramid of waste management strategies. Furthermore, in several recent rulemaking pertaining to the definition of solid waste, the Agency has acknowledged the desirability of recycling (e.g., the recovered oil exclusion discussed in the petroleum refinery waste listings; the mineral processing waste exclusion discussed in the supplemental Phase IV LDR regulation, etc.). Clearly, the EPA views recycling as a preferred management alternative that poses significantly less human health and ecological risk than land-based alternatives. Therefore, Safety-Kleen believes that the Agency is justified in providing conditional exclusions from Subtitle C for wastes destined for legitimate recycling.

MISC16 EPA Should Use of the Higher of the Two Numerical LDR Values

MISC16 - CMA, WHWP-00073, 101,4 Industry Assn.

EPA has, with a few exceptions, revised the LDR program so that all constituents, regardless of waste code, have the same treatment levels. The larger problem is that different waste matrices have different treatability capabilities either in actuality, due to chemical complexing, or empirically, due to analytical problems. In the case where the same constituent occurs in two different waste codes, thereby giving two different treatment levels, EPA should allow the use of the higher of the two numerical values, since these numbers are based on minimize threat levels.

MISC17 EPA Should Exclude Distilled Spirits from RCRA Regulation

MISC17 - Distilled Spirits Council, WHWP-00016, 1,2 Industry Assn. We understand that the primary purpose of the proposals in this rulemaking is to address possible exit criteria for listed wastes. DISCUS submits that unlisted characteristic waste streams also should benefit from the same public policy considerations expressed in these proposals. Therefore, we recommend that EPA expressly exclude distilled spirits from RCRA regulation.

Distilled spirits are a food under the Food, Drug, and Cosmetic Act. Pursuant to applicable RCRA regulations, however, certain distilled spirits exhibit the characteristic of ignitability because of the presence of ethanol in these products. As a result and nothwithstanding the fact that distilled spirits are intended for human consumption, they require management as a hazardous waste when discarded.

In addition to their unique status of being both fit for human consumption and deemed a "hazardous waste," distilled spirits also are extensively regulated by the Bureau of Alcohol, Tobacco and Firearms (BATF) pursuant to Subtitle E of the Internal Revenue Code, 26 U.S.C. Section 5001 et seq., and the Federal Alcohol Administration Act, 27 U.S.C. Section 201 et seq. Producers of distilled spirits may operate only under permits issued in accordance with the Federal Alcohol Administration Act. Careful production records also must be kept pursuant to the requirements of Title 27 of the Code of Federal Regulations, including records of breakage, loss and disposal, because of federal tax implications. See, e.g., 27 C.F.R. Part 19.

Distilled spirits products may need to be disposed of due to, for example, mislabeling, discontinuation of a product line, or excessive age. In each instance, the discarded product still is potable and dispsoal records are maintained to satisfy BATF requirements. Further, ethanol is totally miscible in water and disperses rapidly. Ethanol, diluted, rapidly biodegrades to carbon dioxide and water.

The potential ignitability of discarded distilled spirits results from the presence of ethyl alcohol. Distilled spirits are not a listed hazardous waste, and they have no underlying hazardous constituents. As stated above, the ignitability characteristic is effectively and efficiently deactivated through dilution because ethanol is totally miscible with water. In addition, ethanol aqueous solutions of an alcohol content below 24% alcohol by volume are not regulated under RCRA. (40 C.F.R. Section 261.21(a)(1).)

EPA's position in this rulemaking represents sound public policy to reduce or eliminate unnecessary or duplicative regulatory requirements. In determining whether a need exists for RCRA regulation, DISCUS supports EPA's concept of contingent management that considers the presence of alternative controls and procedures that are protective of public health and the environment which are used to manage particular waste streams for reasons other than RCRA regulation. We submit that the extensive controls maintained by BATF already provide commensurate protection for public health and the environment against mismanagement of discarded distilled spirits and against any fire hazard. Thus, additional regulation of distilled spirits under RCRA is both unnecessary and duplicative.

In the era where each federal agency is revisiting its regulatory scheme to ensure it meets its intended purpose, we appreciate that EPA is reviewing the scope of RCRA regulations to that end. For the reasons proffered, we urge the Agency to exclude distilled spirits as a "hazardous waste." Distilled spirits are unique in that they are the only product that can be ingested yet are deemed a "hazardous waste" when discarded. Both common sense and fundamental facts dictate the exclusion of distilled spirits from the RCRA scheme.

MISC18

Biological Toxins May or May not be Medical Wastes if they Occur Naturally

MISC18 - M. Lewis, WHWP-00054, Cvr. LTR. Citizen

Toxic wastes, not specifically identified, present horrendous hazards. Hunta, Ebola, botulism toxin all present unaddressed dangers. Biological toxins may or may not be medical wastes if they occur naturally.

MISC19

EPA should Exempt Wipers Containing De Minimis Amounts of Listed Solvents from the Subtitle C Regulatory System

MISC19 - Kimberly-Clark Corp., WHWP-00012, 1,5 Industry

On behalf of its small business and other customers, Kimberly-Clark Corporation ("Kimberly-Clark") is writing to urge that the United States Environmental Protection Agency ("EPA") take immediate action to include wipers, both disposable and reusable, which are contaminated with de minimis amounts of commonly used, listed solvents, in the Resource Conservation and Recovery Act ("RCRA") Hazardous Waste Identification Rule ("HWIR") signed on November 13, 1995. To that end, we request that in promulgating the HWIR, the Agency address this issue explicitly. The issue of the regulatory status of wipers contaminated with de minimis amounts of listed solvents has been in front of the Agency for more than ten years, with substantive agreement from all sides that such wipers pose no appreciable threat when disposed of as part of the nonhazardous waste stream. Because the proposed HWIR is intended to address the general issue of exempting low-risk listed wastes from the full range of Subtitle C requirements, it is appropriate to deal with this issue now within the context of the HWIR rulemaking.

Directly addressing this issue as part of the HWIR is consistent with protection of human health and the environment. It is a logical outgrowth of the present HWIR proposal and the 1992 HWIR proposal. It is also consonant with the Administration's efforts to "reinvent" government and your concern with preservation and strengthening of environmental protection while encouraging common sense, innovation and flexibility in how that protection is achieved.

In the period before the November 13th proposed rule was signed, Kimberly-Clark recommended to EPA's Office of Solid Waste staff that the wiper issue be addressed promptly and directly. It appears that it was not included in the HWIR proposal because data provided some years ago included information on 1,1,1-trichloroethane ("TCA"), which indicated that that solvent would not pass proposed HWIR exit criteria. This is a red herring. As of January 1, 1996 the use of 1,1,1-TCA was virtually banned. It is no longer a common solvent. Had this issue been addressed with us by the Agency prior to the November 13th proposal and had we been afforded the opportunity to discuss our data in the context of the HWIR exit criteria, we are confident that the issue of solvent contaminated wipers would have been addressed in the November 13th proposal as it was in the 1992 proposal.

I. The Issue

Industrial wipers and rags, both disposable and reusable, are used by a large number of businesses to wipe up small amounts of solvents. Many solvents are classified as "listed" hazardous wastes under RCRA. Under EPA's existing "mixture" and "debris" rules, when wipers which have a "listed" solvent on them are disposed of, they are treated as hazardous waste, and if they are laundered, RCRA's treatment regulations may also be applicable. This result is reached without consideration of the de minimis nature of the solvents in such wipers.

US EPA ARCHIVE DOCUMENT

The basis for addressing wipers explicitly in the HWIR rule is threefold. First, the listed solvents most commonly used (i.e., acetone, xylene, methyl ethyl ketone ("MEK") and toluene) are highly volatile and evaporate off the wipers in a matter of hours; in fact, most solvents evaporate more rapidly. Consequently, there is in fact virtually no listed solvent on the wipers when they are subjected to treatment or disposal. Second, as noted by EPA in the 1992 HWIR proposal, the total volume of solvent in wipers under the most conservative assumptions is truly de minimis. Third, wipers are a high-volume, low-risk waste. Indeed, wipers are used in a wide array of service and industrial operations throughout the United States, such as small automobile shops, electronics assembly plants and printing facilities. The truly de minimis quantity of solvents involved at the time of disposal assures that disposal in secure, solid waste landfills will provide a sufficient and appropriate level of protection for human health and the environment.

In addition, states and EPA Regional Offices vary significantly in the interpretation and application of existing regulations regarding wipers containing de minimis amounts of solvents. As a consequence, there has not been uniform interpretation or implementation of the regulations, resulting in considerable confusion within the regulated community. For instance, in determining whether wipers must be managed as hazardous waste, some Regions distinguish between putting solvents on a wiper before wiping versus wiping solvents directly off machinery. This ad hoc approach has produced illogical results, has resulted in inequities within the regulated community, lacks any sound environmental basis and does not contribute to the prudent use of enforcement resources. This problem can be resolved by addressing the status of wipers in the current HWIR proposal.

II. The History of the Issue

In March 1985, Kimberly-Clark first raised this issue with EPA, filing a petition with the Agency to exempt solvent-contaminated wipers from regulation under Subtitle C. The Agency has taken no action on the petition.

In April 1992, Kimberly-Clark again filed comments on the need for an exemption from Subtitle C for solvent-contaminated disposable wipers.

In May of 1992, EPA, as part of the initial HWIR proposal, formally proposed a conditional exemption from Subtitle C for solvent-contaminated wipers. Under the Agency's proposal, wipers which did not contain free liquids when disposed of would be exempt from Subtitle C regulation. Comments on this issue were overwhelmingly favorable. Kimberly-Clark filed comments, providing data to the Agency showing that, under EPA's Toxicity Characteristics Leaching Procedure ("TCLP"), wipers contaminated with de minimis amounts of listed solvents would not be hazardous. Scott Paper Company also filed comments and provided the Agency with data confirming Kimberly-Clark's findings. Approximately 47 parties, including 2 states, the U.S. Department of the Army and the U.S. Department of Energy, filed comments supporting an exemption. For unrelated reasons, EPA withdrew its initial HWIR proposal in the fall of 1992.

In April, 1993, as part of EPA's efforts to redefine the RCRA definition of "solid waste," EPA requested comment on the propriety of promulgating, on a fast-track, a conditional exemption from

the RCRA Subtitle C program for solvent-contaminated wipers. Although no action was taken on that proposal, Kimberly-Clark filed comments supporting the action, as did approximately 41 other parties, including 5 states and the U.S. Department of Energy.

In July, 1994, the Industrial Wiper Management Coalition, composed of a number of trade associations 1/, many representing small businesses, again wrote to you, requesting that the Agency take action on the Agency's Definition of Solid Waste Task Force 1994 proposal to exempt wipers containing de minimis amounts of solvents from the Subtitle C system if specific management standards were met. Again, the Agency failed to act on this proposal.

Over the past ten years, no substantive disagreement to the proposal to exempt wipers containing de minimis amounts of listed solvents from the Subtitle C program has been raised. This is explained by the fact that these wipers are not hazardous in fact when disposed of in landfills. Indeed, the only opposition has been from commercial treatment, storage or disposal facilities ("TSDFs"), who have a financial interest in maintaining the current scheme, and one environmental lobbyist, who recommended that this issue not be divorced from the larger HWIR rulemaking effort.

Thus, an exemption for wipers containing de minimis amounts of listed solvents from the Subtitle C regulatory system is not controversial and is long overdue.

III. The Final HWIR Rule

]We request that the Agency make the following changes to the proposed HWIR. These proposed changes are straightforward, easily implemented, and recognize that the predominant generators of contaminated wipers are small businesses with limited resources. Simply put, the HWIR exit criteria should apply to solvent-contaminated wipers, but the proposed testing and notification provisions serve no useful purpose with regard to wipers and should not be applied.

A. Definition

The Agency should add a definition of "wipers" to 40 C.F.R. Part 261. That definition should describe "wipers" as disposable or reusable tissue-type wipers, cotton swabs, absorbent towels or rags.

B. Generic Exit Levels

Kimberly-Clark does not object to the nonwastewater 2/ generic exit levels established by EPA as part of the recent HWIR proposal. Data previously provided to the Agency indicate that wipers containing de minimis amounts of commonly used, F-listed solvents in the service and industrial sectors (i.e., acetone, xylene, MEK and toluene) satisfy proposed HWIR exit levels. These data support the development of a list of designated "commonly used" solvents for which no testing to demonstrate compliance with HWIR exit level would be required. See infra. The list of "commonly used" solvents should also be readily expanded whenever data on an F-listed solvent shows that the concentration on wipers which do not contain free liquid solvents is below the

generic exit levels in the rule.

C. Categorization of Wipers

Wipers containing commonly used listed solvents (F001 to F005) should be categorized into two groups: (1) those that are visibly contaminated and (2) those that are not visibly contaminated. This categorization should be made by the generator as wipers are sent for disposal, incineration or laundering, using a simple wringing test to determine whether a wiper contains free liquid solvents.

Wipers which are "visibly contaminated," i.e., contain free liquid solvents, and wipers which are not "visibly contaminated" but which contain solvents which have not been designated as "commonly used" would exit the Subtitle C system only by the mechanisms available under delisting or the generally applicable terms of the final HWIR. In contrast, wipers which are not "visibly contaminated" and which contain only designated "commonly used" solvents would exit the Subtitle C system under the proposed HWIR standards subject to modified implementation requirements. See infra.

Consistent with the terms of the HWIR, all generators of wipers containing any listed solvents, including those designated as "commonly used," should determine whether the wipers exhibit a characteristic either through testing or knowledge of the waste, as presently set out in 40 C.F.R. Section 262.11(c), prior to handling the waste as nonhazardous.

D. Implementation Requirements

The proposed HWIR establishes detailed and complex implementation requirements for parties who wish to claim an exemption. For the many small businesses using wipers with de minimis amounts of solvents, these requirements are unduly costly and burdensome. The practical application of the rule would allow large companies which generate large quantities of exempt wastes to take advantage of the exemption, while forcing small companies which generate small quantities of exempt waste to remain within the Subtitle C system because of the financial hardship created by the implementation requirements. This result defies "common sense" and is inimical to the purposes for which the HWIR was proposed -- to exempt truly low-risk wastes from Subtitle C regulation. Equally important, repeated testing designed to demonstrate that volatile solvents volatilize is wasteful and pointless. It is well established and undisputed that the listed solvents volatilize off wipers. Demonstrating that fact over and over serves no useful purpose. Accordingly, we request that the Agency propose the following exceptions to the implementation requirements.

1. Testing

Testing should not be required for those wipers which contain only designated "commonly used" listed solvents not present as free liquids for which EPA has data from Kimberly-Clark or other sources indicating that such wipers fall below applicable exit levels under the proposed HWIR exit levels. 3/ Generators should be able to use knowledge that their wastes fall below exit levels

based on data provided to EPA by others so long as the wipers contain no free liquids (as determined by a simple manual wringing test) at the time they are sent for disposal. Testing would be required only in those instances where the wipers contain free liquids or listed solvents for which no data has been provided to EPA.

2. Notification Requirements

The proposed notification requirements should be revised to exempt the generators of wipers contaminated with de minimis amounts of designated "commonly used" solvents (as identified above) from placing a notice of the claimed exemption in a major newspaper of general circulation. Further, where testing is not required of the generator, the proposed certification should request only that the generator claiming the exemption verify (1) that the wipers contain only designated "commonly used" listed solvents and (2) that such solvents are not present as free liquids at the time of disposal.

IV. Conclusion

We believe these modest changes are consistent with the goals of the Agency and the intent of the proposed HWIR. Furthermore, the changes represent a pragmatic solution to a widespread, recurring problem with which EPA has failed to deal effectively for more than ten years. The time to act is now. We look forward to your early and positive reply.

1/ Members of the Coalition included the American Furniture Manufacturers Association, Automotive Service Industry Association, Chemical Specialties Manufacturers Association, National Association of Metal Finishers, National Tooling and Machining Association, Printing Industries of America, Screen Printing Association International and Secondary Materials and Recycle Textiles Association.

2/ Consistent with the preamble to the proposed HWIR, Kimberly-Clark considers contaminated wipers to be a "nonwastewater" waste.

3/ We do not consider 1,1-trichloroethane to be a commonly used solvent. As of January 1, 1996, its use was virgually banned under the Stratospheric Ozone provisions of the Clean Air Act and the Montreal Protocol. See 60 Fed. Reg. 24970 (May 10, 1995).

MISC19 - Electronic Industries Assn., WHWP-00114, 4,2 Industry Assn. Many EIA members are concerned about the application of HWIR to rags and wipes. As EPA has acknowledged in other contexts, rags and wipes pose minimal risk to the environment. See Office of Solid Waste, "Reengineering RCRA for Recycling, Definition of Solid Waste Task Force: Report and Recommendations" at 6-5 to 6-6 (Sept. 19, 1994). Moreover, these wastes are routinely managed in an environmentally safe manner, including such measures as the covering of containers during accumulation, compliance with regulatory requirements during laundering, and the cleansing of reusable textiles before they are discarded. Id. Although these materials pose little risk to the environment, it will be difficult as a practical matter to ensure that rags and wipes can be covered under the rule. Rags and wipes used to clean solvents from machinery or to clean up minor spills are generated at a wide range of locations in a facility. It would be infeasible, however, to sample and test these wastes at each of the multiple points of generation. Accordingly, we suggest that the Agency expand the definition of "point of generation" to include the "area of accumulation" for rags and wipes, and other appropriate actions to ensure that rags and wipes may be realistically covered by the rule.

MISC20 EPA Should Exempt Printed Wiring Board Wastewater Sludge

MISC20 - IPC, WHWP-00083, 5,1 Industry Assn.

It is IPC's position that the wastewater sludge that results from the manufacture of [printed wiring boards (PWBs)], which is currently classified by EPA as an F006 hazardous waste, is not waste. Rather, IPC contends that this material is a valuable by-product of the manufacturing process, which can be recycled into copper as well as other metals. As a result, IPC believes that this material should not even be subject to EPA's regulatory authority. Nevertheless, for purposes of the general HWIR, IPC is submitting these comments as the proposed rule could apply to the PWB wastewater sludge which EPA currently classifies as F006.

MISC21 EPA Should Exempt Spill-related Wastes from Train Derailments

MISC21 - Assn. of American Railroads, WHWP-00085, 30,4 Industry Assn. [AAR] recommends that wastes generated on a one-time basis, such as spill-related wastes or wastes from remediation of a train derailment, be exempt from all RCRA requirements for listed hazardous wastes.

MISC22 Remediation Wastes Should Not Be Treated the Same as Process Wastes

MISC22 - American Institute of Chemical Engrs., WHWP-00084, 5,5 Industry Assn. Remediation Wastes Should Not Be Treated the Same as Process Wastes

Subtitle C was largely developed with the intention of controlling process wastes. Remediation wastes are unlike process wastes. Remediation often involves the management of a wide range of contaminated materials, including groundwater, soil, sediments, debris, urban fill (e.g., ash, cinders), sludges, slags, and various mixtures of these materials. Any of these materials may contain or may have been historically mixed with wastes that exhibit characteristics or are considered hazardous by regulations. In terms of volumes, generally these wastes contain a much larger fraction of non-hazardous wastes than hazardous wastes.

Remediation activity typically takes place in two phases. The intense initial phase includes the removal, treatment, and disposal of contaminated impounded liquids and solids, including soil, sludge, and debris, over a one- to three-year period. This is followed by an extended phase of groundwater recovery and treatment that may last for 20 years.

Despite critical and fundamental differences in the nature of the wastes as well as the character of waste management needed to handle remediation wastes, the current RCRA Subtitle C regulatory framework demands the same management practice for remediation wastes as it does for process wastes. Under RCRA's land disposal restriction (LDR) program, even very low-risk listed wastes must often be treated to constituent levels known as "universal treatment standards" (UTS). The UTS are not risk-based standards - they are based on what the "best demonstrated available technology" (BDAT) can achieve -and thus often necessitate treatment to levels far below what is necessary to protect human health. These provisions, as well as other elements of RCRA developed to promote waste minimization or to ensure protective management of process wastes, have proven to be serious impediments to remediation efforts.

A unitary program, where all remediation wastes managed under a Remediation Action Plan (RAP) would be exempted from Subtitle C, would be simple and would provide States the maximum flexibility in implementing and enforcing remediations. We believe that remediation wastes should be removed from Subtitle C if they are managed under an enforceable EPA or state order and EPA or the state determines that the cleanup will be protective of human health and the environment. Such an approach would, abandon the current "one-size-fits-all" approach and allow EPA to address the most serious risks by focusing on the risks of various wastes and cleanup methods and prioritizing actions. It would rely on States' abilities to ensure that remediation wastes will not be mismanaged, thereby eliminating the need to identify those wastes as hazardous. Historically, the States have routinely made sensible and site-specific decisions regarding the management of non-hazardous remediation wastes; it should be noted that these non-hazardous remediation wastes. Under this approach, remediation waste would be defined broadly to encompass those materials typically encountered in various remediation actions. An agency could

apply the requirements considered appropriate in any given situation, including substantive elements of Subtitle C, by making them a part of the RAP. These requirements could include treatment and disposal methods, as appropriate.

MISC23 EPA Should Address Mercury Contaminated Soil

MISC23 - Chlorine Institute, WHWP-00224, 2,5 Industry Assn.

[T]he Institute is disappointed that EPA has not yet specifically addressed mercury contaminated soils in any of the proposed regulations to date. Even though contaminated media is discussed in the proposed rule, mercury contaminated soil is not currently addressed. The Institute encourages EPA to address this issue in the upcoming HWIR for contaminated media.

MISC24

EPA Should Develop Exclusions Based on Risk for Characteristic Wastes

MISC24 - Coastal Corp. WHWP-00030, 2,3 Industry

[Coastal] believes that similar exclusions based on risk could be allowed for characteristic wastes. The opportunity to exclude characteristic wastes treated on-site appears to be available in this rulemaking. Yet, listed hazardous wastes that exhibit any of the characteristics are excluded. If the EPA's intent is to truly exclude wastes being sent to landfills and yet offer protection to public health and the environment, it seems reasonable from a risk standpoint that proper on-site treatment of these characteristic wastes is less of a risk than transporting these wastes' long distances to landfills that later could become a CERCLA site.