



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[EPA-HQ-RCRA-2016-0040; FRL9944-67-OLEM]

Hazardous Waste Management System; Tentative Denial of Petition to Revise the RCRA Corrosivity Hazardous Characteristic

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of tentative denial of petition for rulemaking.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is responding to a rulemaking petition (“the petition”) requesting revision of the Resource Conservation and Recovery Act (RCRA) corrosivity hazardous waste characteristic regulation. The petition requests that the Agency make two changes to the current corrosivity characteristic regulation: revise the regulatory value for defining waste as corrosive from the current value of pH 12.5, to pH 11.5; and expand the scope of the RCRA corrosivity definition to include nonaqueous wastes in addition to the aqueous wastes currently regulated. After careful consideration, the Agency is tentatively denying the petition, since the materials submitted in support of the petition fail to demonstrate that the requested regulatory revisions are warranted, as further explained in this document. The Agency’s review of additional materials it identified as relevant to the petition similarly did not demonstrate that any change to the corrosivity characteristic regulation is warranted at this time.

The Agency is also soliciting public comment on this tentative denial and the questions raised in this action.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2016-0040, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Gregory Helms, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery, (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: 703-308-8855; email address: corrosivitypetition@epa.gov.

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I. Executive Summary

This action responds to a rulemaking petition requesting revision of the Resource Conservation and Recovery Act (RCRA) corrosivity hazardous waste characteristic regulation (see 40 CFR 261.22). The petition requests that the Agency make two changes to the current corrosivity characteristic regulation: 1) revise the regulatory value for defining waste as corrosive from the current value of pH 12.5, to pH 11.5; and 2) expand the scope of the RCRA corrosivity definition to include nonaqueous wastes in addition to the aqueous wastes currently regulated. The petition argues that the regulatory pH value should be revised to pH 11.5 because information supporting this value was, in the petitioners' view, inadequately considered in developing the regulation and because petitioners allege that this value is widely used as a threshold for identifying corrosive materials. The petition further argues that corrosive properties of inhaled dust caused injury to first responders and others at the World Trade Center (WTC) disaster of September 11, 2001, and that such dusts should be regulated as corrosive hazardous waste under RCRA.

After careful consideration, and as described in greater detail below, the Agency is tentatively denying the petition, since the materials submitted in support of the petition fail to demonstrate that the requested regulatory revisions are warranted. Where used in other regulatory frameworks, the pH 11.5 value is either optional or a presumption that may be rebutted by other data, a use very different than the way pH is used in the RCRA corrosivity regulation.

Moreover, the dust to which 9/11 first responders and others were exposed was a complex mixture of pulverized concrete, gypsum, metals, organic and inorganic fibers, volatile organic compounds, and smoke from the fires at the site. No single property of the dust can be

reliably identified as the cause of the adverse health effects in those exposed to the WTC dust. In addition, the injuries that were suffered by those exposed to the WTC dust did not appear to include corrosive injuries – i.e., the serious destruction of human skin or other tissues at the point of contact. Persons exposed to simpler dusts of concern to the petition (Cement Kiln Dust and concrete dust) similarly did not appear to experience corrosive injuries. Finally, the petition does not show that waste management activities resulted in the exposures of concern, nor does it identify how the proposed regulatory changes would address these exposures. The Agency's evaluation of additional materials it identified as relevant to the petition similarly did not demonstrate that any change to the corrosivity characteristic regulation is warranted at this time. The Agency is therefore tentatively denying the petition, and is also soliciting public comment on this tentative denial and the questions raised in this action.

II. General Information

A. Does this action apply to me?

The Agency is not proposing any regulatory changes at this time. Persons that may be interested in this tentative denial of the rulemaking petition include any facility that manufactures, uses, or generates as waste, any materials (either aqueous or nonaqueous) with a pH 11.5 or greater, or 2 or lower.

B. What action is EPA taking?

Under Subtitle C of RCRA, the EPA has developed regulations to identify solid wastes that must then be classified as hazardous waste. Corrosivity is one of four characteristics of wastes that may cause them to be classified as RCRA hazardous. The Agency defines which wastes are hazardous because of their corrosive properties at 40 CFR 261.22. On September 8, 2011, the non-governmental organization (NGO) Public Employees for Environmental

Responsibility (PEER) and Cate Jenkins, Ph.D¹, submitted a rulemaking petition to the EPA seeking changes to the current regulatory definition of corrosive hazardous wastes under RCRA. The petitioners express concerns about potentially dangerous exposures to workers and the general public from dusts that may potentially be corrosive. In particular, the petition is concerned about inhalation exposures, primarily to concrete or cement dust, which may occur in the course of manufacturing or handling of cement, and during building demolitions. To address these concerns, the petition urges the Agency to make two changes to the current regulatory definition of corrosive hazardous waste: 1) revise the pH regulatory value for defining waste as corrosive from the current value of pH 12.5, to pH 11.5; and 2) expand the scope of the RCRA corrosivity definition to include nonaqueous wastes in addition to the aqueous wastes currently regulated.

With this action, the Agency is responding to requests in the petition by publishing its evaluation of the petition and supporting materials, and by requesting public comment on the topics raised by the petition. A detailed discussion of the petition and the issues identified by the Agency on which we are soliciting public input are discussed later in this document. The Agency is soliciting information and other input on issues related to the scope of the changes proposed in the petition. This may include information on the adverse health effects, if any, that may be avoided if the Agency were to grant the requested regulatory changes. It may also include information on changes in the universe of waste (including type of waste and volume) that may become regulated as corrosive hazardous waste if the Agency were to make the requested changes, including potentially affected industries and the possible impact of such regulatory changes.

C. What is EPA's authority for taking this action?

¹ Dr. Jenkins is an EPA employee.

The corrosivity hazardous waste characteristic regulation was promulgated under the authority of Sections 1004 and 3001 of the RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6903 and 6921. The Agency is responding to this petition for rulemaking pursuant to 42 U.S.C. 6903, 6921 and 6974, and implementing regulations 40 CFR parts 260 and 261.

D. What are the incremental costs and benefits of this action?

As this action proposes no regulatory changes, this action will have neither incremental costs nor benefits.

III. Background

A. Who submitted a petition to the EPA and what do they seek?

On September 8, 2011, petitioners PEER and Cate Jenkins, Ph.D, sent the EPA a rulemaking petition seeking revisions to the RCRA hazardous waste corrosivity characteristic definition (see 40 CFR 261.22). On September 9, 2014, the petitioners filed a petition for Writ of Mandamus, arguing that the Agency had unduly delayed in responding to the 2011 petition, and asking the Court to compel the Agency to respond to the petition within 90 days. The Court granted the parties' joint request for a stay of all proceedings until March 31, 2016.

The petition seeks two specific changes to the 40 CFR 261.22(a) definition of a corrosive hazardous waste:

1. Reduction of the pH regulatory value for alkaline corrosive hazardous wastes from the current standard of pH 12.5 to pH 11.5; and
2. Expansion of the scope of the RCRA hazardous waste corrosivity definition to include nonaqueous wastes, as well as currently regulated aqueous wastes.

The Agency is responding to this RCRA rulemaking petition in accordance with 40 CFR

260.20(c) and (e).

B. What is corrosivity and why are corrosive wastes regulated as hazardous?

The term “corrosivity” describes the strong chemical reaction of a substance (a chemical or waste) when it comes into contact with an object or another material, such that the surface of the object or material is irreversibly damaged by chemical conversion to another material, leaving the surface with areas that appear eaten or worn away. That is, the corrosive substance chemically reacts with the material such that the surface of the contacted material is dissolved or chemically changed to another material at the contact site. Chemical reaction and damage at the contact site may continue as long as some amount of the unreacted corrosive substance remains in contact with the material. In situations in which corrosive substances are being handled by people, key risks of corrosive damage are injury to human tissue, and the potential to damage metal storage containers (primarily steel) that may hold chemicals or wastes. Corrosive substances cause obvious damage to the surface of living human tissue by chemically reacting with it, and in the process, destroying it. The strength of the corrosive material and the duration of exposure largely determine the degree or depth of injury. Corrosive injury is at the extreme end of a continuum of effects of dermal and ocular chemical exposure, and results in serious and permanent damage to skin or eyes². Corrosive injury is distinguished from irritation of the skin or eyes based on the severity and permanence of the injury, with irritation generally being reversible (see Globally Harmonized System for the Classification and Labelling of Chemicals (“GHS” or “GHS guidance”) Chapters 3.2 and 3.3; Organization for Economic Cooperation and Development (OECD) Test Methods 404 (rev. 2015) and 405 (rev. 2012); Grant and Kern 1955).

² As with thermal burns, chemical burns may heal over time, but will typically leave scarring, or in more severe cases, may affect the function of the exposed body part. Ocular corrosive injury may lead to blindness or other vision problems.

In 1980, EPA identified “corrosivity” as a characteristic of hazardous waste because it determined that improperly managed corrosive wastes pose a substantial present or potential danger to human health and the environment (see Background Document for Corrosivity, May 1980; hereafter referred to as Background Document, 1980). While other international and domestic regulatory programs address corrosivity in other contexts (e.g. exposure to non-waste hazardous substances), RCRA is the United States’ primary law governing the management of solid and hazardous waste from cradle to grave. Consideration of RCRA’s corrosivity characteristic therefore requires consideration of whether a particular threat of harm is one that would be addressed within RCRA’s waste management framework.

When in contact with steel, corrosive substances (primarily acids) can react with the iron to change its chemical form and weaken it, potentially leading to a hole in the container and a release of the corrosive substance to the environment. In a waste management setting, extreme pH substances may also mobilize toxic metals, react with other co-disposed wastes (e.g., reaction of acids with cyanides, to form hydrogen cyanide gas), or change the pH of surface water bodies, causing damage to fish or other aquatic populations. However, the Agency focused primarily on the potential for injury to humans when it initially developed the corrosivity regulation:

“Corrosion involves the destruction of both animate and inanimate surfaces.”

(Background Document page 3, 1980)

...

“Wastes exhibiting very high or low pH levels may cause harm to persons who come in contact with the waste. Acids cause tissue damage by coagulating skin proteins and forming acid albuminates. Strong base or alkalis, on the other hand, exert chemical

action by dissolving skin proteins, combining with cutaneous fats, and severely damaging keratin.” (Background Document page 5, 1980)

...

“The Agency has determined that corrosiveness, the property that makes a substance capable of dissolving material with which it comes in contact, is a hazardous characteristic because improperly managed corrosive wastes pose a substantial present or potential danger to human health and the environment.” (Background Document page 1, 1980)

In the previous discussion, the corrosivity regulation background document describes corrosives as having a severe effect on human tissue. Dissolving of skin or other tissue proteins by chemicals, and chemically combining with fats (stored body fat in adipose or other human tissue) are chemical processes which clearly destroy the surface of human tissue and may penetrate beyond surface layers of skin. These adverse effects on skin have also been described by the term “chemical burns” because of their similarity to burns caused by fire or other sources of intense heat.

Highly acidic and alkaline (basic) substances comprise a large part of the universe of corrosive chemicals. The strength of acids and alkalies is measured by the concentration of hydrogen ions, usually in a water solution of the acid or alkali. The hydrogen ion concentration is expressed as “pH”, which is a logarithmic scale with values generally ranging from zero to 14. On the pH scale, pH 7 is the mid-point, and represents a neutral solution. That is, it is neither acidic nor basic. Solutions having pH values of less than 7 are acidic while solutions with pH

greater than 7 are basic. As pH values move toward the extremes of the scale (i.e., 0 and 14), the solution becomes increasingly acidic or alkaline.

Under current RCRA regulations, aqueous wastes having pH 2 or lower, or 12.5 or higher, are regulated as hazardous waste. Liquid wastes that corrode steel above a certain rate are also classified as corrosive under RCRA. These values were set in consideration of wastes' potential to cause injury to human tissue as well as waste management issues, as discussed in greater detail in section IV below (Background Document, 1980).

Federal regulatory agencies other than the EPA also regulate human exposure to corrosive materials. These include the Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT), and the Consumer Product Safety Commission (CPSC). Further, international organizations have also made recommendations about controlling human exposure to corrosive chemicals or wastes. These include the United Nations Guidance on the Transport of Dangerous Goods (UNTDG), the GHS, the International Labor Organization (ILO), and the Basel Convention on the Transboundary Movement of Hazardous Waste (Basel, or the Basel Convention).

C. What approaches are used in testing and evaluation of materials for corrosivity?

Before 1944, there was no systematic method for evaluating the dermal toxicity and corrosive or irritating properties of chemicals on human tissue. Advances in chemistry and medicine in the mid-20th century led to development of a broader range of therapeutic, cosmetic, and personal care products (e.g., soaps, shampoo, hair conditioner) and prompted the need to move beyond an anecdotal collection of largely qualitative information on corrosivity to a systematic approach for determining the potential for irritation or corrosivity. Scientists working for the U.S. Food and Drug Administration (FDA) were the first investigators to develop an

approach that tried to be objective and quantitative, so that differences in the impact of different chemicals or formulations could be systematically identified (Draize et al. 1944, Draize 1959). Their testing approach involved application of chemicals or formulations directly to animal skin or eyes (primarily rabbits), with the results graded by the severity of the adverse effect and the duration of exposure required to produce those adverse effects³. The skin and eyes of the test animals were assumed to be similar to that of humans, and results were either used directly to classify chemicals or sometimes, for less irritating materials, were confirmed by testing on human subjects. The pH of chemicals or formulations was also correlated with the occurrence of adverse effects on test animals in much of the basic research that occurred during this time period (Hughes, 1946; Friedenwald et al., 1946; Grant and Kern, 1955; Grant, 1962). Testing for pH is a routine and easily performed test for many materials (although it does require the presence of water or another source of hydrogen ions in the sample). However, pH testing of very high concentration acids or alkalis can be problematic, and high concentrations of sodium ions in solution can cause analytical interferences (Lowry et al., 2008).

The animal testing approach described above evolved to become the standard method for assessing the corrosivity of chemicals to humans (Weltman et al., 1965; Balls et al., 1995; OECD Methods 404 and 405). Variability in test results and some differences in effects on humans were identified as the tests were further developed and refined. Sources of variability included different results when chemicals were applied to different areas of skin, and different reactions of animal eyes as compared with those of humans, among others (Weil and Scala, 1971; Phillips et al., 1972; Vinegar, 1979). One key approach to facilitating greater reproducibility (precision) in testing was a standardized grading scheme published by the FDA (Marzulli, 1965). A version of this testing approach has also been adopted as guidance by the OECD to provide an international

³ Testing on live animals is described as *in vivo* testing.

approach to chemical classification, with the goal of facilitating international commerce (see OECD Methods 404⁴ and 405). Over the intervening time, significant amounts of animal test data have been collected and used for classifying chemicals or formulations as corrosive.

However, concern about testing for corrosivity on live animals has been expressed within the scientific community (Balls et al., 1995) and by non-government animal welfare advocacy organizations (Animal Justice, “Medical Testing on Animals: A Brief History” retrieved from <http://www.animaljustice.ca/blog/medical-testing-animals-brief-history/>). The result of this concern has been the development of alternative, *in vitro* testing approaches⁵, intended to reduce reliance on *in vivo* animal testing. Among the first such tests was a commercially developed test named the “Corrositex®” test in 1993 (InVitro International, “What is Corrositex?” 2007, retrieved from <http://www.invitrointl.com/products/corrosit.htm>). In this test, a “bio-barrier” material is placed in a tube such that it blocks the tube, which contains an indicator solution. The test material is placed on the collagen plug, and breakthrough to the indicator solution is timed⁶. Other somewhat similar testing approaches have also been developed, which use cultured human skin cells or skin from a laboratory animal that has been euthanized. Extensive work to validate these new testing approaches against the existing data has been done (Barratt et al., 1998; Kollé et al., 2012; Deshmukh et al., 2012; Vindarnell and Mitjans, 2008), and several are now considered validated to some degree (see OECD Tests 430, 431, 435, 437, 438). A number of

⁴ OECD Methods 404 and 405 continue to rely on live animal testing as the definitive test method for assessing corrosivity and irritation potential of chemicals and formulations. The current version of Method 404 (2015) and Method 405 (2012) allow for use of other tests in a weight-of-evidence approach. However, if results are inconclusive, live animal testing is used as a last resort. Dermal corrosion is defined as “...visible necrosis through the epidermis and into the dermis...”. For corrosivity to the eye, “A substance that causes irreversible tissue damage to the eye...”

⁵ *In vitro*, literally translated means “in glass”. In this context it means testing in a laboratory vessel, rather than using a live animal.

⁶ The Agency has added this test to its analytical chemistry technical guidance for evaluating waste, as Method 1120. While at one time the Agency considered revising the corrosivity regulation to rely on this test, no regulatory proposal was ever published.

studies applying chemical quantitative structure/activity relationships (QSAR) to assessing chemical corrosivity have also been published (Hulzebos, et al., 2003; Verma and Matthews, 2015a; Verma and Matthews, 2015b). However, these new tests are not yet fully integrated into the evaluation and classification guidance and regulations used in the U.S. and internationally, and most guidance and regulations rely first on existing animal and human data. The new testing approaches and QSAR analysis are primarily used as alternatives to reduce to a minimum the use of live animal testing on new, untested chemicals or formulations.

IV. Review and Evaluation of the Petition and Relevant Information

A. Review of requested regulatory revisions and supporting information

This action is based on the petition and its supporting materials⁷, the Agency's review and evaluation of this information, information submitted by other stakeholders, and relevant information compiled by the Agency. All materials and information that form the basis for this decision are available in the public docket supporting this action.

The petition presents a number of arguments and information supporting the requested revisions to the RCRA corrosivity regulation. The petition's arguments and supporting information are summarized and discussed below.

The petition seeks two specific changes to the 40 CFR 261.22(a) definition of a corrosive hazardous waste:

1. Reduction of the pH regulatory value for alkaline corrosive hazardous wastes from the current standard of pH 12.5 to pH 11.5; and

⁷ In reviewing the petition the Agency identified a number of statements and/or assertions that are factually incorrect or inaccurate or are otherwise misstatements. The Agency has not responded to all such statements, but rather has limited its responses to those related to the substantive discussion of the petition's requests and supporting arguments in the petition. The petition also alleges certain instances of fraud; while the Agency denies all such allegations, the Agency is not addressing those allegations in this document because they are not relevant to considerations about whether a regulatory change to the current RCRA corrosivity characteristic is warranted.

2. Expansion of the scope of the RCRA hazardous waste corrosivity definition to include nonaqueous wastes, as well as currently regulated aqueous wastes.

In evaluating the petition, the Agency considered whether these specific changes are warranted based on the evidence in the petition and additional, relevant information compiled by the Agency⁸.

1. Request to lower RCRA's corrosivity characteristic pH threshold to 11.5

The current RCRA corrosivity regulation classifies aqueous waste having pH 12.5 or higher as corrosive hazardous waste (40 CFR 261.22(a)(1)). The petition seeks revision of the pH regulatory value for alkaline corrosive hazardous wastes from the current standard of pH 12.5 to pH 11.5⁹.

In urging the Agency to make this regulatory change, the petition argues that a pH value of 11.5 is widely used in other U.S. regulatory programs and guidances, as well as in global guidance. The petition also argues that in promulgating the final regulation in 1980, the EPA did not give appropriate weight to guidance by the ILO on corrosivity that the petition considers definitive for identifying corrosive materials; and therefore expresses the belief that the current standard is not adequately protective of human health and the environment¹⁰.

⁸ While the petition requests the inclusion of nonaqueous wastes in the corrosivity characteristic regulation, the petition does not provide any information regarding nonaqueous acidic wastes having pH 2 or lower. The petition appears to only be alleging harm from nonaqueous wastes in the upper pH, alkaline range. As such, the Agency has similarly focused its analysis. To the extent that petitioners allege the need to include nonaqueous acidic wastes having pH 2 or lower as part of the RCRA corrosivity characteristic regulation, additional information should be submitted in the comment period for the Agency's evaluation.

⁹ The corrosivity characteristic potentially applies to any aqueous RCRA solid waste, unless exempted from hazardous waste regulation. In 2011, more than 8 million tons of waste were regulated as corrosive hazardous waste (see RCRA Biennial Report for 2011, Exhibit 1.8).

¹⁰ Petitioners allege that EPA misrepresented the pH levels cited in a 1972 ILO encyclopedia. As mentioned above at footnote 7, the Agency denies all such allegations. However, the Agency is not addressing those allegations in this document because they are not relevant to considerations about whether a regulatory change to the current RCRA corrosivity characteristic is currently warranted. While the petitioners place great weight on the mention of a pH of 11.5 in the 1972 ILO encyclopedia, that encyclopedia was one among multiple factors considered in

a. History of RCRA's corrosivity regulation

The corrosivity regulation was promulgated on May 19, 1980 as part of a broad hazardous waste regulatory program that was finalized that day (45 FR 33084, 33109, and 33122). As no timely challenges to the final corrosivity regulation were filed in the appropriate court pursuant to 42 U.S.C. 6976(a), the rule, including the regulatory thresholds used to define solid waste as exhibiting the hazardous characteristic of corrosivity, has been in effect since 1980.

The record supporting the May 19, 1980 rulemaking for the corrosivity hazardous characteristic includes three Federal Register actions (an Advanced Notice of Proposed Rulemaking (ANPRM), a Proposed Rule and a Final Rule), draft and final technical background documents, and comments from and Agency responses to a range of stakeholders. Review of these materials identifies the Agency's proposed and final approaches to this regulation, as well as public views on the proposed regulation.

In the 1977 ANPRM, the Agency discussed waste corrosivity only with regard to the potential for waste to damage storage containers, which could result in waste release to the environment. The Agency solicited public comments on this approach to regulation of corrosive wastes (42 FR 22332, May 2, 1977).

Following publication of the ANPRM, the Agency released several draft versions of the regulations under development, including the corrosivity regulation. Draft documents dated September 14, 1977, November 17, 1977, and September 12, 1978 can be found in the rulemaking docket for the 1980 regulation, as well as several comments on these drafts. The September 1977 draft included a preliminary corrosivity definition based on pH values outside

developing the regulation and it is in no way binding on the Agency. No challenge to the 1980 regulation was filed, and the statute of limitations to challenge that 1980 regulation has long since passed.

the range of pH 2-12, applied to liquid waste or a saturated solution of non-fluid waste. The November 1977 draft would have defined as hazardous those wastes having a pH outside the range of pH 3-12, and would have potentially applied to aqueous wastes and nonaqueous wastes when the latter was mixed with an equal weight of water. In a September 1978 draft, corrosive wastes would have been defined as aqueous wastes having a pH outside the range of pH 3-12.

In the 1978 proposed regulations, the Agency proposed to identify corrosive hazardous waste based on the pH of aqueous solutions, and an evaluation of the rate at which a liquid waste would corrode steel. Waste aqueous solutions having a pH less than or equal to pH 3, or greater than or equal to pH 12 were proposed to be classified as RCRA corrosive hazardous waste (43 FR 58956, December 18, 1978). Concerns identified by the Agency in the proposal included the ability of corrosives to mobilize toxic metals, corrode waste storage containers, corrode skin and eyes, and cause damage to aquatic life (by changing the pH of waterbodies). The background support document for the proposal elaborated on EPA's concerns about corrosion to skin, noting that the regulation was intended to include as corrosive those waste "...substances that cause visible destruction or irreversible alteration in human skin tissue at the site of contact." (Draft Background Document on Corrosiveness page 5, December 15th, 1978; hereafter referred to as "Draft Background Document, 1978"). The pH of wastes was used as the basis of the regulation because it could be used to evaluate both skin damage and toxic metal mobility (see Draft Background Document pages 13 and 14, 1978). The Agency also expressed some concern about solid corrosives, and requested that the public provide information on the potential hazards of solids that may be corrosive.

The Agency received many comments on the regulatory proposals made that day, as significant parts of the RCRA program were proposed. The comments received addressed a

number of topics raised by the proposal, including the proposed corrosivity regulation.

The majority of public comments urged expanding the range of pH values that would not be classified as corrosive. For example, some commenters urged the Agency to raise the alkaline range pH regulatory value to either pH 12.5 or 13, in part, because they believed the proposed pH value would have resulted in lime-stabilized wastes, which when treated were otherwise non-hazardous, being classified as hazardous because of their pH. These commenters also believed treatment to de-characterize these wastes (i.e., make them less corrosive) would potentially allow the mobilization of toxic metals that were stable in the waste at the higher pH. The Agency generally agreed with these concerns and set a final alkaline range pH value of 12.5 and above for defining corrosive hazardous waste¹¹. The petition reflects concern about this as part of the basis for the pH regulatory value, and argues that it is no longer necessary or a valid basis for the regulation because of other changes in the regulations of wastewater treatment sludges in particular. However, there is no documentation in the petition supporting these assertions. High alkalinity materials continue to be used as an important option in the treatment of metal-bearing wastes to reduce metal mobility (see LDR Treatment Technology BDAT Background Document pages 101-109, January 1991; Chen et al., 2009; Malvia and Chaudhary, 2006).

b. Other corrosivity standards

Among the arguments made by the petition is the assertion that a pH value of 11.5 is widely used in other U.S. regulatory programs and guidances, as well as in global guidance¹². This assertion, however, is largely inaccurate and fails to support a regulatory change for several reasons. As discussed in more detail below, the classification of materials as corrosive and use

¹¹ The pH of wastes is determined using EPA Method 9040.

¹² Use of a pH value of 11.5 was apparently suggested by Hughes (1946) and Grant (1962) based on empirical observations of the effects of sodium hydroxide solutions on the eyes of test animals. It is not clear whether the 11.5 value was systematically assessed to determine its applicability to other alkaline solutions or to dermal exposures.

of pH 11.5 in this process is far more complicated than portrayed by the petition. Moreover, even where pH 11.5 is incorporated as a presumptive benchmark in other regulatory programs or guidance (for example, pH 11.5 is identified by the 1972 ILO Encyclopedia of Occupational Safety and Health (“1972 ILO Encyclopedia”)), that fact alone is insufficient to demonstrate that the same benchmark is appropriate for regulation of hazardous waste under RCRA. While it is useful to consider information on how corrosivity is measured and regulated by other organizations, EPA is not bound under RCRA to rely on voluntary standards or the decisions of other regulatory agencies, or even regulations or guidance developed by EPA under other statutory authorities.

The corrosive potential of materials is addressed by a number of national and international organizations. Among the organizations that address corrosivity, the following rely on information from human exposure, animal tests, or other tests (as discussed previously) as the primary determinative factor in classifying a material as corrosive, rather than relying on pH: the UNTDG, the GHS, the DOT, the OSHA, the U.S. National Institute for Occupational Safety and Health (NIOSH), the CPSC and U.S. EPA regulations of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)^{13,14}.

The UNTDG guidelines include criteria for classifying materials as corrosive, and reference the OECD test methods for applying the UNTDG corrosivity criteria. Classification as corrosive under the UNTDG guidelines is based on full thickness destruction of intact skin.

(UNTDG Model regulations Chapter 2.8, Rev. 18, 2013, and UNTDG test methods Section 37,

¹³ These organizations rely primarily on human experience (reported case studies) and the results of animal testing, including test results that may be reported in scientific publications or from other sources. Recently developed *in-vitro* tests are beginning to replace animal testing.

¹⁴ The FDA does not directly regulate cosmetics and related products based on their corrosive potential. FDA does require that the safety of cosmetic products be adequately substantiated before they are sold, unless they bear a warning label noting that the safety of the product has not been determined (see 21 CFR 740.10) While the original protocol for testing on animals resulted from its needs, and was developed by FDA scientists (Draize et al., 1944, 1959), the FDA does not specify required testing for cosmetics.

Rev. 5 2009).

In 2003, the UN published its GHS guidance, which addresses corrosivity, among other chemical hazards. The 2013 version of GHS (Rev. 5, 2013) addresses chemical corrosivity to skin and eyes in separate sections of the guidance. For classification as corrosive to skin (GHS Chapter 3.2), a material must result in skin tissue destruction. The GHS tiered evaluation approach (Figure 3.2.1) relies primarily on available human data (case studies) for making a corrosivity determination, then animal data, and references the use of material pH in the third tier of the evaluation.

The UN expert groups responsible for developing the UNTDG and GHS guidances have been working for a number of years (since at least 2010) to harmonize the corrosivity definitions of the two guidance documents. As of April 2015, there was no consensus on how to define corrosivity, and work of the two groups is ongoing (see: UN working document ST/SG/AC.10/C.3/2015/21 and ST/SG/AC.10/C.4/2015/2, April 2015, retrieved from: <http://www.unece.org/fileadmin/DAM/trans/doc/2015/dgac10c3/ST-SG-AC.10-C.3-2015-21e-ST-SG-AC.10-C.4-2015-2e.pdf>).

Current ILO guidance in the ILO Encyclopedia of Occupational Safety and Health urges reliance on international agreements, and the UNTDG guidance in particular for chemicals and the Basel Convention for waste (see ILO Encyclopedia, freely available at http://www.ilo.org/safework/info/publications/WCMS_113329/lang--en/index.htm). As discussed previously, the UNTDG guidance does not refer to either pH in general or to a particular pH range.

Finally, the Basel Convention also has a physical and chemical hazard classification system for waste that addresses corrosivity and which is described in several Annexes to the

Convention. The Basel Convention does not rely on the 11.5 pH value in defining corrosive waste as a general matter in Annex III, but does rely on it as a rebuttable presumptive value for corrosive solutions in the Annex IX (non-hazardous) waste listings. Under the Basel Convention, listed hazardous waste can be delisted by showing that it exhibits no Annex III characteristics.

Unlike many of the other regulatory frameworks that the petitioners cite, the Basel Convention classification system, like RCRA, applies specifically to hazardous waste management. However, the Basel Convention and its hazardous waste classification system take into account the limited capabilities of the developing countries to manage hazardous waste and other waste (see Preamble to the Basel Convention). The Basel Convention takes a precautionary approach, broadly characterizing materials as hazardous out of an abundance of caution. The U.S., on the other hand, has substantial capacity for proper management of both hazardous and non-hazardous wastes, and therefore current RCRA regulations do not incorporate the level of precaution that the Basel Convention does in classifying waste as hazardous under RCRA¹⁵.

Additionally, the EPA considers degrees of risk in classifying waste as hazardous, taking into account the comprehensive nature of the U.S. waste management system. The United States has extensive regulatory and physical capacity for environmentally sound waste management, including capacity for management of both hazardous and non-hazardous waste. Many forms of mismanagement that may occur in developing nations are already illegal in the U.S., and so any

¹⁵ A significant purpose of the Basel Convention is to control the export of hazardous waste from developed to developing countries, because many developing countries do not have the capacity to safely manage either hazardous or non-hazardous waste. Most Basel hazardous waste listings do not include concentration values for hazardous constituents below which the waste would be considered non-hazardous, because many developing nations do not have adequate capacity to safely manage even non-hazardous waste. Basel listings are written so wastes posing any degree of hazard may be subject to the Basel notice and consent provisions, thereby enabling developing countries to refuse waste shipments they are unable to safely manage.

such mismanagement would not be considered a basis for revising or developing new hazardous waste regulations (that is, types of waste mismanagement that are already illegal under RCRA would be addressed as enforcement/compliance issues, rather than as the basis for new regulations). Further, the structure of the Basel hazardous waste classification system is different from that of RCRA. While the presumption of corrosiveness at pH 11.5 under Basel is rebuttable using the Annex III criteria, the RCRA corrosivity definition is a hard value, and there is no opportunity in the RCRA regulations to show that a waste is non-corrosive despite its exceedance of the regulatory criteria. Seen in this light, the degree of precaution incorporated in Basel's use of pH 11.5 may not be warranted in U.S. waste regulations.

In the U.S., the DOT hazardous materials regulatory definition of "corrosive material" is a narrative that does not reference the pH of materials. Rather, corrosive material is defined as "...a liquid or solid that causes full thickness destruction of human skin at the site of contact within a specified period of time" (see 49 CFR 173.136(a)). DOT referenced the 1992 OECD testing guideline #404, among other international guidances, when it updated its regulations to harmonize with the UNTGD Guidance (59 FR 67390, 67400 and 67508, December 29, 1994). The OECD Testing Guideline #404 is based on results of live animal testing or other direct experience with the chemical, although testing on live animals is being phased out where possible.

OSHA identifies the hazards of chemicals to which workers may be exposed, including corrosivity hazards. OSHA recently harmonized its Hazard Communication Standard (HCS) with the GHS classification criteria, including a modified version of the GHS criteria for corrosivity (GHS Revision 3, 2009; see: 77 FR 17574, 17710, and 17796 March 26, 2012). The CPSC implements the Federal Hazardous Substances Act (FHSA), and includes corrosives as

hazardous substances in its implementing regulations. Under FHSA regulations, “*Corrosive* means any substance which in contact with living tissue will cause destruction of tissue by chemical action...” 16 CFR 1500.3(b)(7). This definition is further elaborated at 16 CFR 1500.3(c)(3), where a corrosive substance is one that, “...causes visible destruction or irreversible alterations in the tissue at the site of contact.”

The petitioners also argue that EPA pesticides regulations rely on a pH value of 11.5 to define corrosivity. However, that characterization misunderstands the regulatory framework for product pesticides. EPA regulation of pesticides under the FIFRA require evaluation of the potential for chemicals to cause primary eye or dermal irritation as part of the required toxicology evaluation (see 40 CFR 158.500). Test guidelines (EPA 1998a, b) describe live animal testing as the basis for dermal or ocular irritation, although pre-test considerations note that substances known (based on existing data) to be corrosive or severely irritating, or that have been assessed in validated *in vitro* tests, or have a pH of 11.5 or greater (with buffering capacity accounted for) may be considered irritants and need not be tested in live animals, if the applicant so chooses. As noted in the preamble to the relevant rule, the Agency considered the importance of minimizing animal testing, and stated that it would consider data from validated *in vitro* tests as a way to reduce animal testing requirements (see 72 FR 60934, October 26, 2007). Because pH 11.5 may be used as an optional presumption for toxicity categorization, the regulatory framework contemplates that chemicals having pH 11.5 may *not be* corrosive, and it allows the applicant to submit live animal testing data demonstrating that a particular pesticide is not a dermal or ocular irritant.

While the pH of a material can play some role in corrosivity determinations in these other regulatory frameworks, pH 11.5 is not the primary means of identifying corrosive materials

except in the Basel Convention. In FIFRA, it may be used as part of the basis for precautionary labeling of pesticides, if the registrant elects to rely on it. It is a third-tier criteria in the GHS system, but is not referenced by the regulations of DOT or by the UNTDG guidance. Further, the experts of GHS and UNTDG are continuing work to harmonize model regulations for corrosive materials, illustrating the fact that corrosivity assessment methods and criteria are not well settled matters.

In fact, historically, *in vivo* animal test data has been the primary basis for classification, and because of increasing animal welfare concerns with live animal testing, development of new methods for evaluating the corrosivity of materials has been an active research area, involving the development of new *in vitro* tests and structure-activity relationship models. Alternative test development has been driven largely by the desire to reduce the use of live animals, in particular, for making corrosivity determinations for chemicals. These alternatives to animal testing have been validated in some cases (Barratt et al., 1998; Kolle et al., 2012), and incorporated into the corrosivity evaluations of the OECD testing framework (see OECD tests 430, 431, 435, 437, and 438, in particular). A number of studies attempting to correlate chemical structure with corrosive potential, or QSAR evaluations have also been published in recent years. These have focused primarily on the corrosivity potential of organic chemicals, and attempt to address both corrosivity and irritation potential. (Hulezebos et al., 2005)

In addition, the pH 11.5 value in these other frameworks is used only as an optional approach or a rebuttable presumption of corrosiveness. That is, chemical manufacturers or waste generators have in all cases the opportunity to conduct additional testing if they believe their product or waste is not corrosive despite exhibiting pH 11.5 or higher.¹⁶ However, as used in the

¹⁶ A number of researchers have identified solutions exhibiting pH values higher than pH 11.5 that are nonetheless not classified as corrosive. Murphy, et al., (1982) found that none of the test rabbits exposed to 0.1% and 0.3%

RCRA corrosivity regulation, the pH of an aqueous waste determines whether that waste is a corrosive hazardous waste as a legal matter, and there is no opportunity to rebut this classification for an aqueous waste that exhibits pH 12.5 or higher. Thus, lowering the pH in RCRA has far-reaching implications that are not present in other regulatory systems.

Moreover, many of the standards discussed above are concerned with product chemicals and formulations, not waste. As products are manufactured to a certain specification, they can be evaluated for safety once, and typically that evaluation can be relied on going forward (unless the formulation changes or there is some indication the initial evaluation was flawed). However, waste is not manufactured to a specification, but rather may vary from batch-to-batch, sometimes widely. Therefore, the more careful, thorough evaluation, as described in OECD Method 404, for example, is not practical for use on each separate batch of waste generated. The simpler approach of relying on pH value was therefore used by the EPA in developing the corrosivity regulation, as pH is a useful indicator of hazard potential, and testing for pH is reasonable to perform for many wastes.

Finally, the petitioners argue that the RCRA corrosivity characteristic regulation should be changed because other regulatory frameworks rely on it (see petition at 12 (discussing DOT and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) regulations' cross references to RCRA)). However, to the extent that petitioners are concerned about shortcomings in DOT or CERCLA regulations, the appropriate avenue for changes in those frameworks is to seek changes directly to those frameworks. The RCRA regulatory framework is focused on management of hazardous waste, and should not be amended solely on

NaOH solution (pH 12.3 and pH 12.8 respectively) developed corneal opacity (i.e., 0/6) even when the eyes were not washed after exposure. Young et al. (1988) identified a 1% KOH solution, with pH 13.3 as an irritant but not corrosive. The following solutions were also classified either as irritants or as not dangerous: 1% NaOH, with pH 13.4; 10% NH₃, with pH 12.2; Na₂CO₃, with pH 11.6; and Na₃PO₄, with pH 12.3. Similarly, Oliver, et al., (1988) and Barratt et al. (1998) identified several materials exhibiting pH values higher than pH 11.5 that were nonetheless not classified as corrosive.

the basis of perceived shortcomings in other regulatory frameworks.

In sum, while other regulatory frameworks may use pH 11.5 as part of their corrosivity determinations, the use of pH 11.5 in these frameworks is fundamentally different from the use of pH in the RCRA corrosivity characteristic regulation, and such use, therefore, should not set a precedent for RCRA regulation.

2. Request to include nonaqueous corrosive materials within the scope of RCRA's corrosivity characteristic

a. Exposure to World Trade Center 9/11 dust

In seeking to expand the scope of the corrosivity characteristic to include nonaqueous wastes in addition to revising the regulatory value to pH 11.5, the petition argues that injury to 9/11 first responders, other workers, and potentially members of the public, was caused by corrosive properties of airborne cement dust present in the air as a result of the buildings' collapse. Further, the petition argues that regulation of these airborne dusts as RCRA hazardous wastes would have prompted wide-spread respirator use and prevented first responder lung injury, and can prevent such injury to demolition workers and the general public present at future building demolitions.

However, after a thorough review of the information currently before the Agency¹⁷, the Agency has tentatively concluded that petitioners' arguments to include nonaqueous wastes within the scope of the corrosivity characteristic are not supported by the events of the World Trade Center (WTC) for at least three reasons: 1) it is not possible to establish a causal connection between the potential corrosive properties of the dust and the resultant injuries to

¹⁷ While the Agency has reviewed numerous studies, and we believe we have considered key studies, the body of literature published on the events of 9/11/01 is voluminous. As part of soliciting public comments the Agency is interested in any additional key studies that should be considered as relevant to the issues considered in this document.

those exposed; 2) the injuries documented at the WTC in connection with potentially harmful dust are not consistent with injuries caused by *corrosive* material; and 3) nothing submitted by petitioners demonstrates that injury to human health or the environment was related to improper treatment, storage, transport, or disposal of solid waste (i.e. the petition does not demonstrate how RCRA would or could address the potential exposures alleged to be hazardous). The Agency is seeking comment on these tentative conclusions.

While there is a substantial body of research and broad consensus that exposure to the 9/11 atmosphere for the first hours after the collapse of the towers, and for some time thereafter, caused adverse health effects in first responders and others, this atmosphere was a complex combination of dust, fibers, smoke, and gases. As reported by the New York Fire Department Bureau of Health Services (FDNY 2007; p. 24), “[w]hen the towers collapsed, an enormous dust cloud with a high concentration of particulate matter consumed lower Manhattan.” Analysis of the settled dust from samples collected in the days following September 11 shows that it consisted of a number of materials, including concrete dust, toxic metals, silica, asbestos, wood fiber, fiberglass, and smoke particulates from the fires (EPA 2002, Chen and Thurston, 2002; Landrigan et al., 2004; Lorber et al., 2007; Liroy et al., 2002; Liroy et al., 2006).

Further, while initial exposures are known to be very high for those near the towers when they collapsed, the distribution of exposures is not well documented nor quantitated (Liroy et al., 2006; Lorber et al., 2007). Because of the complex nature of the ambient atmosphere on 9/11, and lack of exposure data (although exposures were clearly very significant for many people), it is not possible to establish a causal connection between the potential corrosive properties of the dust and the resultant injuries to those exposed, to the exclusion of other co-occurring exposures. These co-occurring exposures include glass fiber, silica, cellulose, metals, wood fiber and

fiberglass, a number of minerals (calcite, gypsum, quartz) and a wide range of organic polyaromatic hydrocarbons (PAHs) and dioxin (see docket for OSHA Sampling Results Summary; Lippy, 2001 (NIEHS); EPA, 2002; Liroy, 2002; Chen & Thurston, 2002).

Other factors also argue against the use of the 9/11 disaster as an event that would support changing the RCRA corrosivity regulation. Most, but not all, outdoor dust samples tested for pH were below pH 11, and so would not be classified as corrosive hazardous waste under the regulatory changes proposed by the petition. These include data in studies by EPA, 2002; USGS, 2001; ATSDR, 2002; McGee et al., 2003; and Lorber et al., 2007. Some indoor dust samples had pH values as high as pH 11.8 (USGS, 2001). While the petition discounts these data as not representing actual exposures to the 9/11 airborne dust, and expresses concern that the samples were evaluated using several different protocols¹⁸, they are nonetheless the only pH data known to the Agency.

The pH values found for the WTC dust are generally consistent with pH testing of waste concrete fine aggregates being recycled, for which pH values are often less than pH 11.5 (Poon, 2006). This is supported by information from Material Safety Data Sheets (MSDS) for crushed concrete aggregate, which reported pH 7 for this material (LaFarge MSDS, revised 3/1/2011), although Gotoh et al. (2002) found pH values ranging from 11.6-12.6 for five samples of concrete dust generated by building demolition resulting from an earthquake.

In addition, numerous studies of exposed workers and laboratory test animals fail to identify the gross damage to human tissue used as a benchmark in defining corrosive materials as an effect resulting from exposure to WTC dust. The 1980 RCRA background document

¹⁸ Water must be added to a dust in order to test its pH, as in EPA Method 9045. Dust pH was evaluated by different investigators using methods they believed appropriate for the particular studies being conducted. Investigators used different liquid/solid ratios, and for one data set, pH was tested in the course of running a deionized water leaching test (initial pH of the water approximately pH 5.5).

supporting the corrosivity regulation notes that “[s]trong base or alkalis...exert chemical action by dissolving skin proteins, combining with cutaneous fats, and severely damaging keratin.” Typical injury endpoints used in guidance for defining a material as corrosive describe “...visible necrosis through the epidermis and into the dermis...”. “Corrosive reactions are typified by ulcers, bleeding, bloody scabs....” (GHS 3.2.1).

In reviewing the published literature describing injury to 9/11 exposed workers and residents, none describe gross respiratory tissue destruction or other injuries of the severity identified in definitions of corrosivity. Rather, adverse effects in various studies describe respiratory irritation and other adverse effects. Chen & Thurston (2002) identified “World Trade Center Cough”, and noted that exposure to the larger particles cause temporary nose, throat, and upper airway symptoms. In a review of exposure and health effects data, Liroy et al. (2006) identified the major health consequences of WTC exposure as “aerodigestive and mental health related illnesses.” The WTC aerodigestive syndrome is identified as consisting of “...WTC cough, irritant asthma or reactive airways dysfunction syndrome and gastroesophageal reflux disorder.” In September of 2011, The Lancet published a series of articles reviewing and updating the research on adverse health effects suffered by those exposed to the WTC atmosphere. Perlman et al. (2011) identified upper and lower respiratory effects, including asthma, wheezing, tightness in the chest, and reactive airway dysfunction syndrome, as well as gastroesophageal reflux symptoms. Wesnivesky et al. (2011) identified updated occurrence rates of the adverse effects described by Perlman through a longitudinal cohort study, and it found a 42% incidence of spirometric abnormalities nine years after the exposures. Jordan et al. (2011) studied mortality among those registered in the World Trade Center Health Registry. No significantly increased mortality rates (SMR) for respiratory or heart disease were found,

although increased mortality from all causes was found in more highly exposed individuals compared with the low exposure group. Finally, Zeig-Owens et al. (2011) studied cancer incidence in New York firefighters, including those exposed to the WTC dust, and found a modest increase in the cancer rates for the exposed group. However, the authors remained cautious in their conclusions, as no specific organs were preferentially affected, and the nine years since exposure does not represent the full latency period for development of many cancers. While the WTC-exposed populations in these studies experienced adverse health effects related to exposures, they are not effects of the nature and severity that the corrosivity regulation was intended to prevent¹⁹.

The petition identifies several particular studies that the petitioners believe demonstrate corrosive effects of the WTC dust, and it cites to several passages, apparently taken from these studies as supporting the petition (see page 30; the referenced publications are identified in footnotes (FN) to the petition).

The first passage identifies papers by Weiden et al. (2010; FN 88) and Aldrich, et al. (2010; FN 89) as the source of information. The petition extracts a quotation from the Weiden (2010) paper's discussion section that noted, "The WTC collapse produced a massive exposure to respirable particulates, with the larger size dust fractions having a pH ranging from 9 to 11, leading to an alkaline "burn" of mucosal surfaces." However, this publication presented research on pulmonary capacity, and it states its primary conclusion in the paper's abstract as follows:

"Airways obstruction was the predominant physiological finding underlying the reduction in

¹⁹ This may raise the question of whether the Agency should consider regulating waste dusts that are respiratory irritants as hazardous waste under RCRA. However, that question is outside the scope of the petition. As discussed herein, the petition fails to show how RCRA regulation could address any of the alleged exposures, and therefore does not support such regulation. Evaluation of whether the Agency should regulate respiratory irritants as hazardous waste would require additional information and analysis, including evaluation of whether "respiratory irritants" meet the statutory and regulatory definition of hazardous waste; and, if so, which tests or criteria would be appropriate to identify such irritants.

lung function post September 11, 2001, in FDNY WTC rescue workers presenting for pulmonary evaluation.” The idea of an alkaline “burn” is at best inferred; it is not an effect directly observed or evaluated by the researchers, nor is it one of the findings of the study. The Aldrich et al. (2010; FN89) study similarly conducted spirometry (lung function) studies of exposed firefighters and others. This abstract of this study reported that, “Exposure to World Trade Center dust led to large declines in FEV1 (1-second forced expiratory volume) for FDNY rescue workers during the first year. Overall, these declines were persistent...”. The paper found there was no association between time of first responder/worker arrival at the WTC site and chronic effects. The paper discussion did note that the intensity of initial exposure was linked to acute lung inflammation, although there was no reference to “chemical burns” or other possible descriptors of chemical corrosive effects on workers’ tissues.

The petition also cites an October 2009 poster presentation/abstract (Kim et al., 2009; FN90) from an American College of Chest Physicians meeting providing the results of a study of asthma prevalence in WTC responders. The petition is generally accurate in reflecting the researchers’ conclusion that asthma in WTC responders doubled over the study period 2002-2005, and in noting exposures to dust and toxic pollutants following the 9/11 attacks. There was no report in the paper of corrosive injuries to the workers.

Footnote 91 references a New York Times newspaper article of April 7, 2010, reporting on the pending publication of the paper by Aldrich et al. (2010; FN89) in the New England Journal of Medicine. The petition quotes from the New York Times article, noting that, “The cloud contained pulverized glass and cement, insulation fibers, asbestos and numerous toxic chemicals. It caused acute inflammation of the airways and the lungs. Dr. Prezant said.” The article also noted, “This was not a regular fire,” Dr. Prezant said. “There were thousands of

gallons of burning jet fuel and an immense, dense particulate matter cloud that enveloped these workers for days.” This article again illustrates the complex nature of the exposures to first responders and others at the WTC site, and does not include corrosive injury when noting the acute effects of this exposure.

The petition next quotes from a NY Fire Department, Bureau of Health Services report (FDNY, 2007; FN 92) which reports on upper respiratory symptoms in firefighters (cough, nasal congestion, sore throat) from the day of the attacks as well as at intervals up to 2-4 years in the future. The report notes that “Particulate matter analysis has shown a highly alkaline pH of WTC dust (like lye), which is extremely irritating to the upper and lower airways.” Earlier discussion in the report (p.24) notes that firefighters were exposed to “...an enormous dust cloud with a high concentration of particulate matter consumed lower Manhattan.” The WTC dust not only had very high particulate concentrations, but was also a complex mixture of materials.

Finally, the petition cites a portion of the discussion in a paper published by Reibman, et al., (2009; FN 94), which notes that, “[m]easurements of settled dust documented that these particles were highly alkaline (pH 11), and this property alone has been shown to be associated with respiratory effects. Occupational exposure to inhaled alkaline material induces chronic cough, phlegm, and dyspnea, as well as upper respiratory tract symptoms.” This paper presented the results of spirometry (lung function) testing, and concluded that the exposed population had, “...persistent respiratory symptoms with lung function abnormalities 5 or more years after the WTC destruction.” As in describing the results of other research on the WTC exposed populations, these studies identify a number of adverse effects attributable to WTC exposures from the day of the towers’ collapse, as well as subsequent exposures occurring during site rescue and demolition and clean-up activities. While the adverse effects identified represent

serious injuries to many workers, these injuries do not appear to include the type of gross tissue destruction of skin or the respiratory tract that is the underlying basis for defining materials as corrosive (i.e., destroying tissue by dissolving or coagulating skin proteins). Rather, these effects are associated with inflammatory and irritant properties of inhaled materials.

Similarly, laboratory toxicity studies in which mice were exposed to collected 9/11 dust samples (PM2.5), adverse effects were limited to mild to moderate degrees of airway inflammation. The test animals did experience increased responsiveness to methylcholine aerosol challenge (EPA, 2002), suggesting an irritant response to the WTC particulate matter. While these studies again suggest an irritant response to the 9/11 dust samples, they do not demonstrate corrosive injury.

If one were to apply the criteria for classifying dusts as corrosive, such as GHS (which does provide guidance for identifying nonaqueous corrosives) to the WTC data, WTC dust would not have been assessed as corrosive. GHS defines skin corrosion as "...visible necrosis, through the dermis and into the epidermis... Corrosive reactions are typified by ulcers, bleeding, bloody scabs..." (GHS 3.2.1.). None of these reactions to the WTC dust have been identified in the published literature cited by the petition, nor in studies identified in the Agency's review. The background information for the current RCRA corrosivity characteristic regulation references dissolution of skin proteins, combination of the corrosive substance with cutaneous fats, and severe damage to keratin as the adverse effects the regulation is intended to prevent. These kinds of injuries have not been reported in the published scientific literature presenting studies of WTC adverse effects.

The petition also argues that classification of the 9/11 dust as RCRA hazardous may have impacted workers' respirator use at the 9/11 site. However, this argument does not appear to

have support. OSHA's regulations govern worker safety (e.g., respirator use) when workers are handling hazardous substances in emergency response (see 29 CFR 1910.120(a)). While the petitioner is correct that CERCLA regulations incorporate RCRA hazardous wastes as part of the universe of "hazardous substances," (see petition at 8 (citing 40 CFR 302.4(b)), the universe of substances that give rise to worker safety regulations is much broader than RCRA hazardous wastes (see 29 CFR 1910.120(a)). Petitioners provide no support for the contention that broadening the universe of waste classified as RCRA-hazardous for corrosivity would have had any impact on the level of worker safety regulation imposed at the WTC site²⁰.

Finally, nothing submitted by petitioners indicates that injury to human health or the environment at the WTC was related to improper treatment, storage, transport, or disposal of solid waste²¹. Similarly, petitioners fail to explain how the exposures they are concerned about at the WTC site were related to waste management activities. The complexity and duration of exposures and the lack of documentation makes it infeasible to distinguish the ambient air exposures directly resulting from the initial collapse of the towers (and ongoing fires) from exposures potentially related to waste management. Without any support for the proposition that petitioners' concerns are RCRA concerns, there is similarly no indication that amending the RCRA regulations would address similar concerns during future emergency response events.

In sum, it is not possible to establish a causal connection between the potential corrosive properties of the dust and the resultant injuries to those exposed. The injuries documented at the WTC in connection with potentially harmful dust are not consistent with injuries caused by

²⁰ Petitioners also argue that regulating nonaqueous wastes with a pH between 11.5 and 12.5 would have made the first responders "more motivated" to wear respirators. Petition at 23. However, there is no support for this argument, and EPA does not find this type of unsupported suggestion sufficient to warrant regulation of a new universe of waste as hazardous.

²¹ See 42 U.S.C. 6903(5); the definition of hazardous waste includes, in part, solid wastes that may "pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

corrosive material. And finally, nothing submitted by petitioners demonstrates that injury to human health or the environment was related to improper treatment, storage, transport, or disposal of solid waste (i.e. the petition does not demonstrate how RCRA would or could address the potential exposures alleged to be hazardous).

b. Exposure to concrete dust

Petitioners also argue that corrosive injury could result from the corrosive properties of inhaled concrete dust present in the air as a result of building demolition by implosion. While the petition illustrates the potential for exposure to concrete dust from several building demolitions, no documented evidence of corrosive (or other) injury from building demolition is provided. The petition, therefore, fails to support the argument that concrete dust should be regulated as corrosive hazardous waste.

Concrete is among the most common construction materials used in the US. It is a mixture of Portland cement (10 -15%) and aggregate (60-75%), with water added (15-20%) to allow hydration of the cement, which results in its solidification (Portland Cement Association, 2015). Concrete may include some entrained air, and in some cases, a portion of the Portland cement may be replaced with combustion fly ash, particularly coal fly ash. Cement is made when lime (CaO), silica (SiO₂), alumina (Al₂O₃), iron oxide (Fe₂O₃), and sulfate (SO₃) are burned together in a cement kiln at approximately 2600 degrees Fahrenheit (°F). The resulting material, called “clinker”, which contains more complex mineral forms of the ingredients, is ground to a fine powder, and gypsum is added (CaSO₄-2 H₂O). This powder is cement; when added to aggregate and hydrated, it becomes concrete.

The other key component of concrete is the aggregate. Both fine and coarse aggregate are used, with their proportions varying depending on the particular use of the concrete. A

variety of materials may be used as aggregate, with recently increasing emphasis on use of recycled materials as aggregate (e.g., glass, ceramic scrap, crushed concrete; Marie and Quaisrawi, 2012; Castro and Brito, 2013). However, traditional aggregate is sand and gravel from different types of rock. These include silica sand, quartz, granite, limestone and many others. There exists a whole field of study dedicated to understanding the properties and best uses of different kinds of aggregate materials in making concrete (PCA, 2003). Many of the materials used as concrete aggregate include silica minerals, and crystalline silica dust exposure is a significant occupational exposure concern, as it can cause respiratory injury known as silicosis (see 78 FR 56274, September 12, 2013). In silicosis, inhaled crystalline silica dust can cause fluid accumulation and scarring of the lungs, which can reduce respiratory capacity (American Lung Association, “Learn about Silicosis.” retrieved from <http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/silicosis/learn-about-silicosis.html>). Various MSDS for ready mix concrete (i.e., cement pre-mixed with aggregate; just add water) identify its crystalline silica content as, in one case, 20-85%, in another, as 0-90% (MSDS-Ready Mixed Concrete, April 14, 2011; MSDS-Lafarge Crushed Concrete, March 1, 2011).

Many of the compounds and oxides present in concrete are already regulated by OSHA when they occur as airborne dust. These include calcium silicates, calcium hydroxide, calcium oxide, and silicates. OSHA sets worker exposure standards for these chemicals, known as “permissible exposure levels” (PELs; see 29 CFR 1910.1000, tables Z-1 and Z-3, in particular). The PEL for airborne calcium oxide dust is 5 mg/m^3 ; those for calcium hydroxide and calcium silicate are 15 mg/m^3 for total dust, and 5 mg/m^3 for respirable dust; all measured as 8 hour time weighted average (TWA) values.

There appear to be few studies published in the peer-reviewed scientific literature that

have examined the adverse health effects of exposure specifically to concrete dust. OSHA includes concrete dust among the materials that would be covered under their proposed regulation to revise the PEL for respirable crystalline silica (September 12, 2013; 78 FR 56274). OSHA's "Occupational Exposure to Respirable Crystalline Silica--Review of Health Effects Literature and Preliminary Quantitative Risk Assessment" (OSHA, 2013), developed in support of its proposed regulation, identifies concrete production as among the industries whose workers are likely to be exposed to crystalline silica, and notes that several of the health effects studies OSHA relied on in its assessment consider exposure to brick or concrete dust as risk factors for cancers caused by silica. The one study that specifically considered the adverse health effects of concrete dust exposure to 144 concrete workers identified "...mild chronic obstructive pulmonary disease at respirable concrete dust levels below 1 mg/m³, with a respirable crystalline silica content of 10% (TWA 8 hr.)." (Meijer et al., 2001). Neither this report, nor the OSHA silica rule risk assessment document noted any corrosive effects in workers exposed to respirable concrete dust. Other OSHA literature on concrete does identify potential effects from exposure to cement dust or wet concrete, ranging from moderate irritation to chemical burns (OSHA Pocket Guide on Concrete Manufacturing; available online at https://www.osha.gov/Publications/3221_Concrete.pdf). However, neither the petition nor information gathered through the Agency's independent review of the literature provides sufficient specificity for the Agency to analyze whether this "Pocket Guide" supports the regulatory changes requested. For example, it is not clear whether any of the potential exposures cited in the document involved actual waste management scenarios. Given the wide range of potential effects cited, it is also not clear how the pH of the material would relate to that range of potential effects. Finally, as discussed above, many of the compounds and oxides present in

concrete are already regulated by OSHA, and, where OSHA evaluated the risks of respirable concrete dust as part of its silica rule, its studies did not cite potential corrosive effects of concrete dust as part of the worker health concern the regulation was focused on controlling.

OSHA also distinguishes inert, or nuisance dust from fibrogenic dust, such as crystalline silica or asbestos. Nuisance dust is dust containing less than 1% quartz, a form of crystalline silica; the PEL values for nuisance dust are also 15 mg/m³ total dust and 5 mg/m³ for the respirable fraction, the same PEL values as for calcium hydroxide and calcium silicate dusts. (OSHA, “Chapter 1: Dust and its Control,” retrieved from https://www.osha.gov/dsg/topics/silicacrystalline/dust/chapter_1.html)²².

In sum, while the petition alleges harmful exposure to concrete dust from several building demolitions, no documented evidence of corrosive (or other) injury from building demolition is provided in the petition. Similarly, the literature on this topic is limited, and what limited literature does exist does not demonstrate that the petitioners’ requested regulatory changes are warranted.

c. Exposure to Cement Kiln Dust

The petition also argues that corrosive injury could result from the corrosive properties of Cement Kiln Dust (CKD). However, the petition again fails to provide any evidence demonstrating that CKD would be appropriately characterized as corrosive under RCRA.

CKD is an air pollution control residue collected during Portland cement manufacture. CKD was exempted from regulation as hazardous waste under RCRA pending completion of a report to Congress providing an evaluation of CKD properties, potential hazards, current management, and other information, by the Beville Amendment to RCRA (see 42 U.S.C.

²² Some of the exposures that petitioners are concerned about may also be addressed by the National Ambient Air Quality Standards (“NAAQS”) for particulate matter (40 C.F.R. pt. 50) and the National Emission Standards for Hazardous Air Pollutants (“NESHAPs”) for asbestos (40 C.F.R. pt. 61, subpt. M).

6921(b)(3)(A)(i) through (iii)). Following completion of the Report, the EPA was required to determine whether regulation of CKD as hazardous waste is warranted. EPA published its Report to congress on CKD in 1993 (see docket for Report to Congress on CKD, 1993), and published a RCRA regulatory determination in 1995 (60 FR 7366, February 7, 1995). Most CKD is managed on-site in non-engineered landfills, piles, and ponds, which lack liners, leachate collection and run-on/runoff controls. Wind-blown CKD was cited as a concern in a number of the damage cases resulting from CKD management, but the Agency did not identify any cases of corrosive injury either to workers or the general public. The risk assessment portion of the Report examined possible direct exposures to CKD via the air pathway and found:

“Quantitative modeling of air pathway risks to people living near case-study facilities indicated that wind erosion and mechanical disturbances of on-site CKD piles do not result in significant risks at nearby residences via direct inhalation (e.g., central tendency and high end risks estimates were all less than 1×10^{-11} increased individual cancer risk at all five facilities modeled). However, fugitive dust from on-site CKD piles was estimated to be one of two contributors in some cases to higher risk estimates for indirect exposure pathways (which were primarily a result of direct surface run-off from the CKD pile reaching an agricultural field).” See docket for Report to Congress on CKD, page 6-51.

Subsequent screening level modelling found that windblown fugitive CKD could cause violations of the Clean Air Act fine particulate matter ambient air quality standard (PM 10) at plant boundaries and potentially at nearby residences. The Agency’s regulatory determination for CKD concluded that existing fugitive dust controls were ineffective in preventing fugitive

releases to the air, and determined that additional controls were warranted due to risks from fugitive air emissions and runoff to surface waters in particular, and also due to the potential for metals to leach into groundwater. However, no corrosive injuries were identified.

EPA published a proposed rule in 1999 (64 FR 45632, August 20, 1999) to address these concerns. The proposal focused in particular on improving runoff controls from CKD piles, and controlling fugitive dust releases, as well as performance-based controls on release to groundwater. Action on this proposed rule has not been finalized.²³

A number of new studies and data reviews have been published since the 1999 proposal. These include a 2006 review of the effects of Portland cement dust exposure by the United Kingdom Health and Safety Executive (2005) and studies published in the scientific literature by van Berlo et al., (2009); Isikli et al., (2006); Ogunbileje et al., (2013); Ogunbileje et al., (2014); Orman et al., (2005); and Fatima et al., (2001). While several of these studies note that cement dust may be an irritant, or cause contact dermatitis, none identified corrosive injury resulting from exposures to CKD or Portland cement dust.

In sum, while the petition alleges harmful exposure from CKD, the current record before the Agency fails to support that CKD should be regulated as corrosive under RCRA.

B. Wastes that may be newly regulated under the requested revisions

In the process of reviewing and evaluating the petition, the Agency has focused primarily on understanding and responding to the issues raised by the petition. While the petition focuses on exposure and health effects issues, it does not address the issue of the impacts of the petition's proposed regulatory changes. At this point in its review, the Agency has not developed a

²³ While action on RCRA regulation has not yet been finalized, EPA has established standards for emissions of hazardous air pollutants from the Portland cement manufacturing industry under section 112 of the Clean Air Act. See, e.g., 40 CFR pt. 63, subpt. LLL.

systematic assessment of the types and volumes of waste that might be newly regulated as hazardous if the Agency were to make the requested changes to the corrosivity characteristic regulations. However, interested industry stakeholders have reviewed the petition and sent the Agency their estimates of the types and volumes of wastes generated by their industries that might become RCRA hazardous under the petitioners' proposed regulatory revisions. The industry stakeholders believe these wastes are currently managed or reused safely, and that regulating them as hazardous waste would not produce a corresponding benefit to worker, public or environmental safety. The Agency has not evaluated their estimates. While the industry estimates are informal, they may nonetheless provide at least a qualitative, and, to some degree, a quantitative estimate of waste that could become newly regulated were the Agency to make the requested regulatory changes. See Letters of September 30, 2015 and November 30 2015, from Wittenborn and Green. Also see letter of September 4, 2015 from Waste Management, and August 28, 2015 letter from the National Waste and Recycling Association, in the rulemaking docket for this document.

C. Determining what waste is "aqueous"

As a part of the argument regarding regulation of solid corrosives, the petition asserts that the current corrosivity regulation is ambiguous, particularly with regard to the definition of the term "aqueous" as used in 40 CFR 261.22(a)(1) and that this causes confusion in implementing the regulation (see page 36 of the petition). The petition also asserts that inclusion of nonaqueous wastes within the scope of the characteristic is consistent with the approach taken by other federal agencies, and would clarify this issue. Method 9040 (in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," also known as SW-846), which is incorporated into the corrosivity characteristic regulation to test for pH, is used to evaluate

“aqueous wastes and those multiphase wastes where the aqueous phase constitutes at least 20% of the total volume of the waste”. A number of EPA policy letters on determining what wastes are aqueous, referred to in the paragraph below, do identify more than one approach to distinguishing aqueous from nonaqueous wastes. However, while petitioners are correct in noting that the inclusion of nonaqueous wastes within the scope of the corrosivity characteristic would address this issue, the Agency currently lacks data demonstrating that regulation of nonaqueous wastes as corrosive is warranted under RCRA. Therefore any clarification of the term “aqueous” should be appropriately tailored and narrower than the change the petition recommends.

The Agency did address this issue when developing the corrosivity characteristic definition in 1980. The background document discusses how to address the potential for analytical interference in testing wastes that may be suspensions or gel type material. At least one commenter urged the Agency to define the term “aqueous”; however, the Agency considered it as a testing issue, and part of the waste generator’s obligation to determine whether their waste is RCRA hazardous (see 40 CFR 262.11). In 1985, the Agency published the “paint filter liquids test” (PFT) for identifying wastes containing free liquids (Method 9095; 50 FR 18372, April 30, 1985), and recommended its use for distinguishing aqueous from nonaqueous wastes. However, a year later, EPA expressed concern about the reliability and precision of the PFT for separating liquids from solids when it proposed the Toxicity Characteristic Leaching Procedure (TCLP) test, and instead proposed the use of pressure filtration for separating solids from liquids in that test (June 13, 1986; 51 FR 21681). In letters in 1989 (see docket for letter to Mr. Wagner) and 1990 (see docket for letter to Mr. Wyatt) the Agency urged the use of the EP Tox test pressure filtration procedure (Step 7.15; Method 1310) for determining whether wastes contained liquids,

but also noted that the paint filter test could be used to show that a waste was liquid or aqueous (i.e., a positive determination), but not to show a waste was not liquid or aqueous (i.e., a negative determination). Letters in 1992 (see docket for letters titled “ ‘Aqueous’ as Applied to the Corrosivity Characteristic” and “Alcohol-Content Exclusion for the Ignitability Characteristic”) and 1993 (see docket for letter to Mr. Parsons) noted that aqueous wastes need not be liquid, and identified suspensions, sols or gels for which pH could be measured as subject to the corrosivity characteristic. In a 1993 rule proposal updating SW-846, the Agency stated that method 9095 could be used only to demonstrate that a waste is aqueous, and that pressure filtration is necessary to show that a waste is not aqueous (58 FR 46054, August 31, 1993), and proposed to revise the SW-846 guidance for implementing the hazardous characteristics to reflect this. However, in finalizing these proposed revisions to SW-846, the Agency considered industry concerns that the proposed revision to the characteristics implementation guidance was insufficiently clear and determined not to revise the guidance. The Agency also reiterated its assessment of PFT use: that wastes producing no liquid using Method 9095 should be subsequently subjected to the more definitive method for separating liquids from solids, pressure filtration, as described in Step 7.2.7 of Method 1311 (the TCLP test; 60 FR 3089 and 3092, January 13, 1995).

As this issue is tangential to the petitioners’ requests for regulatory change, the Agency is proposing no changes to its guidance at this time. The Agency may further consider this issue in the course of revising and updating the SW-846 analytical methods in the future.

D. Other Potentially Relevant Incidents

The purpose of this analysis is to identify whether currently unregulated wastes are causing harm that could be effectively addressed by RCRA regulation (“damage cases.”) The

petition presents several incidents the petitioners consider to be waste-management damage cases. As explained above, the evidence presented in the petition does not appear to justify a regulatory change. In addition to the incidents presented by the petition, the Agency sought to identify incidents of corrosive injuries (i.e., chemical burns) to workers or others that may be attributable to exposure to corrosive materials. In support of revisions to RCRA's regulatory definition of solid waste, the Agency searched for damage cases involving mishandling of wastes at recycling facilities. Several of the 208 cases identified mishandling of "corrosive or caustic wastes" (primarily at drum reconditioning operations); no corrosive injuries to individuals were reported, and the pH of the materials was not identified, so it is not possible to know whether these wastes were in fact RCRA hazardous (EPA 2007; An Assessment of Environmental Problems Associated with Recycling of Hazardous Secondary Materials). A 2015 update of this study similarly identified incidents at several drum reconditioning operations in which caustic solutions were mishandled, but no corrosive injuries to workers were reported (EPA 2015, updating "An Assessment of Environmental Problems Associated with Recycling of Hazardous Secondary Materials").

The Agency also reviewed a worker accident database compiled by OSHA (available by using key word "chemical burn" at <http://osha.gov/pis/imis/accidentsearch.html>). While a number of chemical burns were identified in the database, only a few contained enough detail to know the pH of the material, and all but one of the cases also involved heated materials (most at 136-295°F, and one above 800 degrees °F), making it difficult to attribute the resultant injuries solely to the corrosive properties of the materials. In the case that did not involve heated material, an employee got chemical burns when exposed to effluent with pH estimated to be 9.9 from a clarifier tank leak, although the material was not identified. In light of the pH value,

petitioners' proposed regulatory change would still not have captured this material as characteristic waste.

The Agency also has information describing a 1999 incident in which an employee of a pulp and paper plant apparently slipped and fell into black liquor sludge at the edge of a concrete pad on which it was being stored (see docket materials related to Mr. Matheny). The employee was knocked unconscious, and, as he was working an overnight shift, lay in the material for several hours before being found by co-workers. He suffered chemical burns on more than 50% of his body, and died from his injuries. While this material apparently contained enough absorbed water to cause injury (although the water content was not tested), subsequent information indicated that it passed the paint filter test, and so was not considered to be an aqueous waste under the RCRA corrosivity regulation, and was therefore determined to be outside the scope of the regulation. This may be an instance in which a high sodium concentration in the waste interfered with testing its pH, as it showed a pH reading of 12.45 when tested directly, but with 10% water added to the sample to reduce the sodium interference, its pH was 12.95. Rather than providing support for expanding the definition of corrosivity to include nonaqueous materials however, the Agency believes this damage case may illustrate the value of clarifying the Agency's approach to determining what wastes are aqueous. As mentioned above in section IV.2.C, the Agency may further consider the issue of testing which wastes are aqueous in the course of revising and updating the SW-846 analytical methods in the future.

V. EPA's Conclusions and Rationale for Tentative Denial of the Petition

In urging the Agency to expand the scope of the RCRA corrosivity characteristic, the petition advances a number of arguments. However, the petition fails in several ways to

demonstrate that a regulatory change is warranted. While the petition demonstrates that there has been human exposure to materials identified by the petition as being of concern, such as concrete dust and CKD, it fails to identify injuries of the type and severity addressed by the RCRA corrosivity characteristic that have resulted from these exposures. The injuries that did occur to those exposed to the WTC dust have been attributed to the dust as a whole, but cannot reliably be attributed to any one property of the dust. While WTC first responders and demolition workers clearly have suffered adverse health effects resulting from WTC dust exposure, none of the published research on this population reviewed by the Agency has identified gross tissue damage of the kind incorporated into the RCRA and other regulatory and guidance definitions of corrosivity (e.g., dissolving of skin proteins, combining with cutaneous fats, or chemical burns). WTC dust and concrete and cement dust may be respiratory irritants, but do not appear to be corrosives. Further, many of the dusts identified as of concern often exhibit pH values below the pH 11.5 value advocated in the petition. And finally, the petition fails to demonstrate that the hazards posed by the WTC site dust could have been reduced or controlled through RCRA regulation.

The petition also argues that pH 11.5 is a widely used presumptive standard for identifying material as corrosive, but fails to identify that corrosive injury in animal tests remains the fundamental basis for corrosivity classification, and that pH 11.5 is used as an optional screening value that may be rebutted by *in vivo* or various *in vitro* test data. The use of pH 11.5 in these regulations and guidances is fundamentally different from how the pH 12.5 value is used in the RCRA corrosivity characteristic regulation, and such use does not set a precedent for defining corrosivity under RCRA. Significant precaution can be incorporated into these flexible evaluation approaches without resulting in unwarranted regulation, because the presumption of

corrosivity can be rebutted. RCRA regulations do not include such flexibility and are not rebuttable; a waste meeting the hazardous waste characteristics regulatory criteria (and not otherwise excluded from regulation) is RCRA hazardous, which would trigger the entire RCRA cradle-to-grave waste management system. As noted in the discussion previously, the RCRA corrosivity characteristic reflects the particular concerns of waste management in the United States.

One of the Agency's tentative conclusions in evaluating the petition and related materials is that while the dusts identified by the petition as being of concern are not corrosive materials, they appear to be irritant materials. This raises the question of whether the Agency should consider a new hazardous waste characteristic that would identify and regulate irritant wastes. However, this particular question falls outside the scope of the current petition. Moreover, there remain significant questions about whether RCRA waste management procedures would address any of the exposures identified in the petition.

Finally, the hazardous characteristics regulations are not the only RCRA authority the Agency has for addressing risks related to waste management. If wastes generated by a particular industry, or a particular waste generated by a number of industries, were identified as posing corrosive risks to human health or the environment that could be effectively addressed by RCRA regulation, the Agency could initiate a hazardous waste listing rulemaking to regulate that waste. Given the lack of evidence to demonstrate that a wholesale change of the pH threshold in the corrosivity regulation is warranted, the listing approach would effectively address a specifically identified waste without running the risk of over-including wastes that have a pH greater than 11.5 without demonstrating corrosive properties.²⁴

²⁴ In particular instances, RCRA 7003 authority can also be used to address situations posing threats of imminent and substantial endangerment from waste mismanagement.

VI. Request for Public Comment on EPA's Tentative Denial of the Petition

As part of this document, the Agency is soliciting public comment and data and other information on the issues raised by the petition. These include information on possible health impacts of the current corrosivity regulation (if any), as well as health benefits (if any) that may be anticipated were the Agency to grant the petition's proposed regulatory changes. Further, the Agency is requesting public comment on any other issues raised by this tentative decision to deny the petition, as well as additional information on the types and amounts of waste that may be newly regulated, and the potential cost of such management, were the agency to grant the proposed regulatory changes. Stakeholders intending to provide comments or information to the Agency in this matter are encouraged to review the petition and its supporting documents in their entirety to ensure that they identify any issues not discussed here that they may find of interest.

VII. References

The full bibliography for references and citations in this action can be found in the docket as a supporting document.

List of Subjects

40 CFR Part 261

Environmental protection, Characteristic of corrosivity, and Characteristics of hazardous waste.

Dated: March 30, 2016.

Mathy Stanislaus,

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Office of Land and Emergency Management.

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