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Compliance of Glass Packaging with Human and Environmental Health and Safety Toxics –in – Packaging Requirements

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Compliance of Glass Packaging Materials with

Relevant Human and Environmental Health and Safety Regulatory Requirements

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EXECUTIVE SUMMARY

Glass has been recognized for thousands of years as the premier option for packaging, due to its inherent safety, purity, stability, durability, and ability to preserve the integrity of the package contents. Glass is virtually inert, meaning that, regardless of the conditions in which it is used, it does not react chemically with or break down into the substances contained by it. Consequently, glass has been recognized worldwide throughout written history for its ability to store and preserve food, drink, medicines, and other substances without compromising the qualities of the container contents. Glass has long been concluded by the Food and Drug Administration ("FDA") to be a "generally recognized as safe" ("GRAS") substance, meaning that it is accepted by FDA for use in contact with foods and beverages as a packaging product under all circumstances. For these reasons, glass packaging continues to be viewed as the gold standard by the most discerning consumers, ranging from natural product market retailers and child caregivers to manufacturers of vaccines and foods.

Over the past two decades, federal, state, and international laws have sought to limit the presence of certain heavy metals in packaging, based on a generalized concern that packaging products may disintegrate upon disposal, potentially releasing their chemical components into and/or causing damage to the environment. Despite the focus of these laws on reducing the release of heavy metals into the environment upon disposal and disintegration of packaging containing such metal in order to minimize environmental harm, the statutory language in these laws may be interpreted as limiting total heavy metal content in finished (*i.e.*, whole, not disintegrated) packaging products, and may not distinguish between the various types of packaging materials and/or the relative ability of those materials to disintegrate and release heavy metals into the environment upon disposal. Moreover, such laws ordinarily do not provide guidance on the specific testing protocols or mechanisms by which total heavy metal content in or migration of such substances from finished products should be tested, in order to ensure compliance.

In the absence of clear, standardized protocols or guidelines for testing, packaging manufacturers are forced to surmise, based on available industry and potentially analogous government standards, and a myriad of varying and widely-recognized testing protocols, which methodology

is most accurate and appropriate for testing their products to determine compliance with the various requirements applicable to waste products. Established testing protocols vary dramatically in purpose and intended focus, due to the wide variety of statutory and other bases for developing the testing protocols (e.g., for finished, new children's products in contrast to used packaging products disposed of in landfills), and the wide variation in the starting materials used to manufacture different packaging products. As a result, applying some existing testing protocols, methodologies, and related instruments to determine the compliance of packaging materials in a landfill (or other waste-related context) results in testing data and analyses that are not meaningful or able to be replicated. For example, recent research and results concludes that a handheld or other spectrographic testing device, which might be considered for use on finished packaging products because of its ease of use and relative low expense, has been demonstrated to yield results that are significantly less accurate than other, more comprehensive, available laboratory-based testing protocols and mechanisms, as well as not replicable. Similarly, testing protocols developed for completely disparate contexts, such as the Consumer Product Safety Commission's ("CPSC") protocol designed to measure total lead content in new children's products (based on the presumption that such products may be ingested or at least mouthed), were not designed for nor have they been used to assess used packaging products that are disposed of in a landfill, with consequently no history of use or replicability in the waste context.

By contrast, testing by accepted, standard Environmental Protection Agency ("EPA") protocols, such as the Toxicity Characteristic Leaching Procedure ("TCLP") not only is justified by reason of their having been developed precisely for the environmental waste context, but also by reason of the long history of use of these tests in the waste context. Such accepted EPA protocols should be expected to provide results that are both more accurate and consistently replicable than tests developed for other contexts and purposes.

The TCLP test was designed by the EPA to mimic the fate of waste disposed in an improperly managed, unlined landfill. This test involves exposing the waste material to a solution of acetic acid, which is meant to simulate rainwater flowing through the landfill, and tumbling the material in the acetic acid for 18 hours to simulate harsh leaching conditions. The material tested is then removed, and the resultant extraction fluid tested for the analytes in question, typically

utilizing inductively coupled plasma mass spectroscopy (ICP-MS) in the case of metals. This resultant fluid will contain the materials which were mobilized from the matrix of the material after exposure to the leaching conditions, and provides an accurate assessment of the quantity of an analyte that could potentially enter the environment. In general, under state and federal hazardous waste regulations, if a waste material leaches 5 parts per million (ppm) of lead, 1 ppm cadmium, 5 ppm chromium, or 0.2 ppm of mercury, it is considered a hazardous waste. Given that the structure of glass is difficult to disrupt without extremely high temperatures or chemical conditions much more severe than those found in the environment, it is highly unlikely glass packaging will leach toxic levels of metals into the environment.

EPA recognizes that there is a valid, measurable correlation between content of a given substance in the original solid and the maximum possible content of that substance in the resulting leachate. While the TCLP test was designed to accurately quantify levels of toxicants in the leachate, the EPA also developed a calculation method by which maximum leachable quantities could be estimated from the total content of a potential toxicant. This calculation requires that the total content of the toxicant be divided by 20, and this value was considered the maximum leachable content. This calculation assumes that if a packaging material contained 100 ppm of a toxicant, its maximum leachable quantity would be 5 ppm, which could result in classification as a hazardous waste. It can be readily seen from this calculation that the structure of the waste material is not taken into account, and therefore glass would be viewed as having the same ability to leach toxicants as paper, for example. When this relationship is applied in the reverse, migration or extraction test results can be extrapolated to indicate the total accessible content of the constituent(s) being measured in the original sample. In the context of glass packaging, which is virtually inert and thus does not completely dissolve under normal environmental conditions, this application of the correlation set forth in EPA's TCLP test results in a total available content value for constituents being measured, including heavy metals (*i.e.*, the true amount of material capable of migrating from the original sample into the environment). Moreover, as no state has published guidance reflecting its interpretation of statutory requirements, nor has any state established or endorsed use of a particular testing protocol for demonstrating compliance with toxics in packaging standards, states remain free to interpret and

enforce their laws to as they deem appropriate to protect the environment from risks posed by the total leachable content of toxic substances.

Under this analysis of the state laws on toxics in packaging, use of TCLP, therefore, can both assure compliance with federal hazardous waste requirements and those of the Model Toxics-in-Packaging Legislation. Such a conclusion cannot be made with regard to any test that measures only gross total heavy metal content without consideration of leachability. This is because, based on a test of total content alone, a package could pass the thresholds established under the Model Toxics-in-Packaging Legislation, but still may be a hazardous waste when discarded and conversely, as in the case with glass, a package could fail the thresholds established under the Model Toxics-in-Packaging Legislation, but remain non-hazardous and inert when discarded.

Testing of glass packaging using traditional testing methods (*i.e.*, those designed to be applied to waste products or finished food packaging products) has continually demonstrated compliance by glass packaging with U.S. and international requirements concerning heavy metals content. Consensus on the use of EPA's TCLP to ensure compliance of glass packaging waste with regulatory requirements for the appearance of heavy metals thus would be consistent with the purposes of state and federal requirements and would be an effective and replicable way for the glass packaging industry to establish compliance. Unlike testing on other packaging materials, the results of testing on glass packaging using such traditional testing protocols continue to support the basic scientific premise that glass is a chemically stable material that does not allow for virtually any leaching or migration from any substances into or out of it. Consequently, glass continues to be demonstrated as being the uniquely superior packaging option from both an environmental and human health and safety perspective.

COMPLIANCE OF GLASS PACKAGING MATERIALS WITH RELEVANT HUMAN AND ENVIRONMENTAL HEALTH AND SAFETY REGULATORY REQUIREMENTS

The following discussion provides information regarding statutory and regulatory standards currently applicable to glass packaging and current testing methodologies used to measure them to assess any human health and environmental safety implications of glass packaging. This White Paper is intended to address the principal regulatory and testing issues regarding the potential presence of heavy metals in finished glass containers.

I. Introduction

A. Glass

Preference for glass has persisted throughout the ages and in all cultures due in large part to its safety, impermeability, and durability. In food packaging applications, glass has long been recognized as the gold standard, due in significant part to its being virtually inert, meaning that it does not react with other elements and forms no new compounds when it comes into contact with other chemical agents or compounds. As a result of this virtually inert quality, glass does not interact with the foods or beverages contained in it, and consequently does not affect the flavor of its contents. Similarly, glass is virtually impermeable to oxygen, so does not affect -- and is indeed protective of -- the freshness of its contents. Consequently, glass does not require the addition of any food additives or preservatives in order to maintain flavor or freshness, unlike many other food packaging materials. Glass has long been recognized as the preferred material for food packaging, due to this virtually inert quality and its protection of the food or beverage that it contains.

Also by reason of this virtually inert quality of glass, glass containers (*e.g.*, vials and ampoules, tubing, and other packaging components) have been preferred in numerous medical applications for hundreds of years. Glass also is routinely used as a means by which to dispose of nuclear and other hazardous waste materials through a process called vitrification, whereby the materials are permanently encased in glass. Similarly, because of the inert quality of glass, glass containers

are extensively used for toxicological testing further illustrating scientific recognition that glass is one of the most chemically and biologically inert materials known.[1]

Made from three ingredients—sand, lime, and soda ash—glass is endlessly recyclable and retains the same high quality through recycling after recycling, making it a superior option for food packaging. Because it is virtually inert and highly stable, and does not intentionally contain, nor is manufactured with the addition of, extraneous contaminants, virgin or recycled glass is preferable to other packaging options from an environmental perspective, because it does not break down into harmful chemicals in the earth or bodies of water. Moreover, because glass is virtually inert and non-reactive to its contents, and can be cleaned and sterilized easily, glass can be endlessly reused, regardless of the qualities of the food or drink that it contains (*e.g.*, acidic foods, alcoholic beverages, base foods) or temperature conditions in which it is used (*e.g.*, microwave use, high heat, refrigeration).

The glass packaging industry is committed to continuously increasing its recycled glass content in view of the positive impact on sustainability from reducing energy consumption and certain emissions (NOx, SOx, PM, and CO2). Due to the potential for contamination of the recycled glass supply stream — for example from improperly discarded cathode ray tubes, fluorescent bulbs, and crystal tableware — this increased use of recycled glass can result in the inadvertent presence of trace amounts of metals that have not been intentionally added. However, due to the chemical and physical qualities of glass, and based on appropriate testing methodologies for conformance with regulatory requirements as described in this White Paper, this potential and unintentional incorporation of trace amounts of metals properly can be concluded to present no adverse human health or environmental concerns.

[1] *See* Organisation for Economic Co-operation and Development, *Guidelines for Testing of Chemicals*, ISSN 1607-310X (January 2007), available at: http://www.oecd.org/document/22/0,3746,en_2649_34377_1916054_1_1_1_1,00.html. Environmental and toxicology studies typically require the inclusion of a vehicle or saline negative control group that comes in direct contact with glass, and that has not shown toxic or environmental effects.

B. Heavy Metals

Due in large part to legislation and regulations limiting the content of lead and other similar elements, the phrase "heavy metals" has come to be publicly associated with a generalized concern that, when physically ingested in certain quantities on a prolonged and/or repeated basis, such toxic elements can pose health risks. Such legislation and regulations limiting heavy metal content have different scopes (*i.e.*, their scope may include foods, food packaging, consumer products, or children's toys, etc.). Relevant toxics in packaging legislation and regulation uses the phrase "heavy metals" to include specifically four substances: lead, mercury, cadmium, and hexavalent chromium, in their elemental forms. Because oxidized forms of these elements (such as lead oxide) have distinct physical properties, including distinct internal nuclei arrangements and variable energy associations, they differ from the elemental forms of the heavy metals and consequently are not within the scope of current toxics in packaging regulatory requirements, which apply only to elemental forms of heavy metals and do not include compound (*e.g.*, oxidized) forms of them.[2]

In addition to potential health concerns associated with direct ingestion of heavy metals, the presence of heavy metals in consumer and other waste presents certain environmental concerns. Unlike other packaging materials, glass packaging is manufactured at extremely high heat with simple components,[3] resulting in oxidation of most trace amounts of heavy metals that may be present in the raw production materials. For this reason, and because glass packaging is virtually inert, glass packaging properly does not present any significant health and safety or environmental concerns.

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[2] *See e.g.*, July 18, 2006 Memorandum from D. Deitrich, Director, Office of Emergency Management, EPA, to Superfund National Policy Managers, Regions 1-X (July 18. 2006) (confirming that only those particular elements and/ or compound forms of elements that are specifically listed in the Comprehensive Environmental Response, Compensation, and Liability Act ["CERCLA"] are hazardous substances under CERCLA).

[3] Due to increased recycled content, which includes glass from electronic applications, some glass manufacturing products may be manufactured with starting materials that contain trace amounts of heavy metals. However, even in such instances (i) heavy metals are present at extremely low levels, if at all; and (ii) the virtually inert qualities of glass prevent any such impurities from migrating into the food/ drink contained by the glass or leaching into the environment. *See* Section IV, *infra*.

The below analysis discusses relevant laws limiting heavy metals content in food packaging and waste, and provides a critical assessment of various testing methodologies to determine both: (1) overall heavy metal content in packaging, and (2) the potential for migration of heavy metals present in packaging into the foods they contain or into the environment, if any. Through this critical assessment, the analyses and conclusions set forth in this White Paper confirm that, when appropriate and accurate testing methodologies are used, glass packaging properly should be considered not to present any significant human health and safety or environmental concerns due to heavy metals content.

II. Regulatory Background

A. Environmentally-Focused Regulations Concerning the Presence of Heavy Metals in Waste

1. Model Toxics in Packaging Legislation and Related State Laws

In 1989, in furtherance of its general mandate to encourage cooperation in the Northeast on "economic, environmental and social well-being of the Northeast states,"[4] the Coalition of Northeastern Governors ("CONEG") developed model legislation, entitled the Model Toxics in Packaging Legislation ("Model Legislation"), which was intended to help prevent heavy metals from entering municipal solid waste streams. The Model Legislation was intended to limit the presence of four specified heavy metals -- mercury, lead, cadmium, and hexavalent chromium -- in packaging materials,[5] with the hope of reducing the possibility that packaging waste materials that are incinerated or disposed of in landfills would, over time, release compounds that may be harmful to the environment. There are currently 19 states with legislation based on the Model Legislation: California, Connecticut, Florida, Georgia, Illinois, Iowa, Maryland, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and Wisconsin.[6]

The Model Legislation enacted by the several states is not intended to address general health and safety issues associated with use of food or beverages contained in packaging products prior to their disposal, which aspects of a product lifecycle are regulated separately by the FDA (as discussed below).

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[4] *See* CONEG Website, available at: http://www.coneg.org/.

[5] The Model Legislation provided for a gradual lowering of permissible heavy metals in the packaging materials. As of the date of this White Paper, 100 ppm is the limit in effect for states that have adopted the CONEG Model Legislation.

[6] In 1992, in order to promote the Model Legislation, ten of these states formed the Toxics in Packaging Clearinghouse ("TPCH"). The TPCH purports to disseminate information about the CONEG laws, and assesses the extent of packaging industry compliance.

The Model Legislation cites as a central "finding" or guiding principle that it intends to regulate the presence of heavy metals in packaging "in light of their likely presence in emissions or in ash when packaging is incinerated, or in leachate when packaging is landfilled...."[7] Based on this presumption of environmental toxicity of packaging products containing heavy metals after disposal, the Model Legislation proposes limiting the intentional addition of heavy metals to packaging products during their manufacture, as a "first step in reducing the toxicity of packaging waste.…"[8] Thus, the intent of the Model Legislation is to attempt to preempt potential environmental concerns that could arise from the disposal of packaging products, and the Model Legislation is not intended to relate to any general health and safety issues potentially associated with use of packaging products prior to their disposal.

Additionally in the "findings," or central tenets, underlying the Model Legislation, the model language states that "the intent of this Act is to achieve this reduction in toxicity without impeding or discouraging the expanded use of recycled materials in the production of packaging and its components."[9] Placing continued emphasis on environmental improvement, the Model Legislation is carefully worded so as not to deter use of recycled materials in the manufacture of packaging products.

The Model Legislation is careful not to chill the environmentally favorable practice of using recycled content as a feedstock for packaging, or to pose other unreasonable limitations on heavy metals that are not *intentionally* added or introduced to the packaging products during manufacture or distribution.[10] The statute defines "intentional introduction" as:

> [t]he act of deliberately utilizing a regulated metal in the formation of a package or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.

[7] *See* Section 2(c), Model Toxics in Packaging Legislation (1998 revision). This language, or language that is conceptually similar, is present in the majority of state statutes based on the Model Legislation

[8] Model Toxics in Packaging Legislation (1998 revision), Section 2(e).

[9] Model Toxics in Packaging Legislation (1998 revision), Section 2(f).

[10] Model Toxics in Packaging Legislation (1998 revision), Section 4(a).

Heavy metals that are incidentally present in packaging materials due to the use of recycled materials as feedstock for the manufacture of those packaging products are deemed by the legislation not to have been "intentionally introduced."[11] The model language carves out from "intentional introduction" the presence of heavy metals used as processing agents or intermediates that are intended to impart certain chemical or physical changes during manufacturing.[12] Likewise, the Model Legislation is careful to carve out from its scope any heavy metals that are "incidentally present" (*i.e.*, are unintended or undesired ingredients in packaging or packaging components).[13]

2. EU Regulation

Similar to the Model Legislation in intending to further general environmental goals, European Union ("EU") Directive 94/62/EC on Packaging and Packaging Waste (the "Packaging Directive") regulates packaging waste, and also generally promotes energy recovery through re-use and recycling of packaging materials. The directive restricts the same four heavy metals -- lead, cadmium, mercury, and hexavalent chromium -- to a sum total concentration of 100 ppm by weight, and requires a reduction of "noxious and other hazardous substances and materials" in packaging, with the ultimate goal of minimizing emissions occurring as a result of incineration or disposal in a landfill.[14] In 2006, the EU extended, indefinitely, an exemption for compliance with the heavy metal concentration limitations in glass packaging.[15] Similarly, under Council Decision 2003/33/EC, glass is accepted at landfills without the need for further testing to demonstrate that it does not contain toxic substances that might cause concern once the glass packaging waste is placed in the landfill environment.

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[11] *See* Model Toxics in Packaging Legislation (1998 revision), Section 3 (definition of "intentional introduction").

[12] *Id.*

[13] *See* Model Toxics in Packaging Legislation (1998 revision), Section 4.

[14] EU Directive 2004/12/EC amended the Packaging Directive, increasing the recycling targets to 60% overall recovery of packaging waste and 55% minimum and 80% maximum recycling of packaging waste. The 2004 Directive also established recycling targets based on specific materials, with a target of 60% for glass, 60% for paper and board, 50% for metals, 22.5% for plastics, and 15% for wood.

[15] *See* Commission Decision 2006/340/EC (amending Decision 2001/171/EEC of the European Parliament and of the Council for the purpose of extending, indefinitely, a derogation for glass packaging in relation to the heavy metal concentration limits established in the Packaging Directive.

Continuing its focus on restricting heavy metal content in all waste with the ultimate goal of reducing potential environmental concerns, on June 1, 2007, the EU implemented a new regulatory system for the registration, evaluation, authorization, and restriction of chemicals ("REACH"), which applied to chemical substances imported into the EU in quantities over one ton per year. REACH covers additives, inks, and dyes, but exempts polymers and intermediates. Due to the virtual inertness and non-toxic properties of glass, however, most types of glass and, specifically, the type of glass used for almost all container applications (*i.e.*, "soda-lime glass") is exempt from registration under REACH.

B. FDA Regulatory Status of Glass Packaging Materials

Food and food additives,[16] including food packaging,[17] are regulated by the Food and Drug Administration. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. Food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food are known as "indirect food additives." "GRAS substances," such as glass, are thus not within the statutory definition of "food additive" under the FDCA.

[16] A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives. "GRAS substances" thus are not within the statutory definition of "food additive."

[17] Indirect food additives are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. *See, e.g.*, 21 C.F.R. §§ 175 (adhesives and coatings), 176 (paper and paperboard), 177 (polymers), 178 (adjuvants and production aids). Additional indirect food additives are authorized through FDA's food contact notification program, or may be authorized through 21 C.F.R. § 170.39.

Under sections 201(s) and 409 of the FDCA, and FDA's implementing regulations at 21 C.F.R. §§ 170.3 and 170.30, a food or packaging substance may be GRAS either through scientific procedures or, for a substance used in or in contact with food before 1958, through experience based on common use in food.[18]

Glass is considered by FDA to be GRAS based on its long history of safe use in packaging applications. Moreover, glass is generally formed by very high temperature fusion of three materials that are also considered by FDA to be GRAS substances: silica (sand), soda ash (sodium carbonate), and lime (calcium oxide). Silica, per FDA's regulations, may be used in food packaging applications.[19,20] Sodium carbonate and calcium oxide also are affirmed as GRAS,[21] and consequently, both are GRAS for use in food-contact applications.[22]

Unlike packaging materials that are not considered GRAS, the GRAS status of glass packaging means that glass can be used without limitation for food and beverage packaging applications. Glass is the only widely-used packaging material considered by FDA to be GRAS.

C. FDA and EPA Standards for Heavy Metal Content in Glass Packaging

Due to the GRAS status of glass, glass packaging materials are not subject to any particular FDA requirements concerning heavy metal content. Likewise, because the Environmental Protection Agency ("EPA") does not regulate direct or indirect food additives (*i.e.*, food packaging), EPA

[18] General recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers. 21 C.F.R. §§ 170.30(c) ,170.3(f). General recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. 21 C.F.R. § 170.30(b).

[19] The Select Committee on GRAS Substances (SCOGS) Opinion on Silicon Dioxides determined in 1979 that there was no evidence to suggest a hazard to the public health when silicon dioxides were used in food packaging. *See* SCOGS Report Number 61.

[20] 21 C.F.R. § 174.5(d)(1) ("Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include … substances generally recognized as safe in or on food.")

[21] *See* 21 C.F.R. §§ 184.1191 and 184.1210, respectively.

[22] *See* 21 C.F.R. § 184.1(a); 21 C.F.R. § 174.5(d)(1).

regulation of heavy metal content in the environment is not relevant to food contact applications of finished glass packaging products. Moreover, because of its virtually inert qualities and the resultant fact that there is virtually no migration of any substances composing glass packaging into the foods or beverages it contains or into the environment, no EPA regulations address or reference permissible amounts of heavy metals in waste made only of glass.

While there are thus no direct environmental concerns regarding glass packaging from these Agencies, we provide below a brief overview of those instances in which FDA and EPA have affirmatively regulated heavy metal content in other products within the scope of their respective jurisdictions.

1. FDA Limitations on Heavy Metal Impurities in Food Additives

FDA has established heavy metal limits for several other substances regulated as food additives, as set forth in 21 C.F.R. Part 184. (These are not specifically applicable to glass packaging, since glass is regulated under FDA's statute as a GRAS substance and not as a food additive.) For example, for numerous substances regulated as food additives, FDA provides limits of total heavy metal impurities of 10 ppm.[23] Similarly, FDA's regulations set forth a maximum permissible limit of arsenic for several additives, including, *e.g.*, aconitic acid, licorice and licorice extracts.[24] The regulation applicable to baker's yeast extract limits the following chemicals and heavy metals: arsenic (less than 0.4 ppm), cadmium (0.13 ppm), lead (0.2 ppm), mercury (0.05 ppm), selenium (0.09 ppm), and zinc (10 ppm).[25]

An FDA regulation on bottled water limits various toxic chemicals, including some heavy metals, setting forth a maximum allowable content of cadmium, arsenic, lead, and mercury.[26]

[23] *See* 21 C.F.R. § 184.1259.

[24] *See* 21 C.F.R. §§ 184.1007, 184.1408.

[25] 21 C.F.R. § 184.1983.

[26] *See* 21 C.F.R. § 165.110.

Similarly, the EPA regulates allowable levels of these four heavy metals in "community water systems and non-transient, non-community water systems."[27]

Aside from examples similar to those set forth above, and more general limitations on mercury content in seafood[28] and ceramic ware,[29] FDA's regulations do not provide significant guidance concerning maximum permissible amounts of heavy metals in foods or finished packaging materials. Moreover, glass packaging's GRAS status based on its long safe use with food confirms that FDA does not currently and has not historically viewed glass packaging as posing any health or safety concerns due to any heavy metals content.

As discussed above, due to its GRAS status, glass packaging is not subject to particular limitations on migration. For analytical comparison with Model Legislation compliance requirements, we provide below a brief overview of the types of testing that would ordinarily be required by FDA of other widely-used packaging materials (*e.g.*, plastics, aluminum cans, paper and paperboard, composite packaging) to demonstrate that they are compliant with existing regulations concerning food contact substances and do not migrate in improper amounts into the foods or beverages they contain.

FDA's food additive regulations list numerous chemical components of packaging materials that have been pre-determined to be acceptable for food contact use, provided that certain specified conditions are met. Thus, manufacturers of packaging using these materials must demonstrate compliance with the existing standards and conditions set forth in the relevant food additive regulation or food contact substance notification. Compliance specifications set forth in the regulations often are stated in terms of extraction limitations. Because compliance specifications

[27] 40 C.F.R. § 141.62; 40 C.F.R. § 141.80.

[28] *See, e.g.*, U.S. Department of Health and Human Services and U.S. EPA. *What you need to know about mercury in fish and shellfish* (2004), available at http://www.fda.gov/food/foodsafety/productspecificinformation/seafood/foodbornepathogenscontaminants/methylmercury/ucm115662.htm.

[29] *See* FDA Compliance Policy Guides Sub Chapter 545, *Food Related, Pottery (Ceramics), Imports and Domestic-Lead Contamination*, available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074516.htm .

often take the form of extraction limitations, testing is thus necessary to assure conformity of the substance or package with regulatory limits of substances of potential concern.

For indirect food packaging products not already approved for use in food contact applications, or which are not the subject of an existing food contact substance notification, what is known as migration testing is required to be performed prior to submission of data to the FDA to establish whether the novel material or compound migrates to food, thus rendering it a "food additive" within FDA's regulatory purview. Once migration testing has been completed, during which the packaging substance is subjected to the simulated conditions of use for which it will be marketed, the results of the analyses are used to determine how much, if any, of the chemical component(s) of the packaging product enters into the food under the intended conditions of use.

2. EPA Limitations on Heavy Metal Impurities in Waste

Like FDA, neither EPA's regulations nor enforcement policies focus on limiting hazardous material content in finished glass packaging materials in any respect. Rather, consistent with EPA's statutory mandate to protect the environment, EPA enforces various requirements that apply to materials that potentially can pose a deleterious effect on the environment or water supply. A significant focus of EPA's enforcement efforts in this regard is waste.

The Resource Conservation and Recovery Act ("RCRA"), is the relevant regulatory law that governs waste management in the U.S.[30] Under RCRA, EPA regulates the management and disposal of solid wastes that are considered environmentally hazardous, because they are corrosive, toxic, ignitable, or reactive (*i.e.*, characteristically hazardous wastes).[31] Specific waste streams also are listed as hazardous by regulation (*i.e.*, listed hazardous wastes). Heavy metals that can cause a waste to exhibit a hazardous characteristic under RCRA include arsenic, barium, cadmium, chromium, lead, mercury, selenium and silver.

Over the past several decades, EPA has published and refined numerous testing protocols intended to measure the toxicity of waste materials to determine if they are considered hazardous

[30] 42 U.S.C. §6901 et. seq.

[31] 40 C.F.R. Part 261 Subpart C.

under RCRA, wherein samples are digested (dissolved) for the purposes of determining the precise levels of impurities that are able to be released into the environment. EPA's specific methodologies, which are directly relevant and comparable to the Model Legislation in many respects, are explored in detail in Section III, below.

3. EPA Regulation of Waste Incineration

EPA regulates the incineration of waste materials under the Clean Air Act. However, given the nature of glass manufacture, recycling and disposal, these air regulations are not relevant to glass container manufacturers or to glass packaging, as outlined in the following section.

Because incineration of solid waste involves the process of combusting solid waste for the purpose of reducing the volume of the waste by removing combustible matter, glass container manufacturing plants are not incinerators.[32] Glass manufacturers do not incinerate or combust glass, they simply heat the recycled glass to the melting point to make new glass products from the molten glass. EPA evaluated a similar issue in the context of whether or not cement kilns are considered incinerators due to the use of secondary materials as ingredients. EPA concluded that no cement kilns combust their ingredients:

> In this analysis, the EPA finds that none of the cement kilns would have been potentially CISWI due to the use of secondary material ingredients (though some kilns would potentially have been CISWI due to secondary fuels burned). This is because none of these secondary ingredient materials identified by [Portland Cement Association] as being used in cement kilns is considered to be combusted. A typical dictionary definition of 'combustion' is 'an act or instance of burning' or 'a chemical process (as an oxidation) accompanied by the evolution of light and heat.' Cement kiln dust is also used as an ingredient and is sometimes processed in the hot end of the cement kiln. Due to its inorganic, essentially inert composition, this material is not combusted.[33]

Like cement kiln dust that goes back into a cement kiln as an ingredient, glass cullet that is returned to a glass furnace as an ingredient is inorganic and essentially inert, and as such, is not combusted.

[32] See, e.g., 40 C.F.R. 60.2265 (definition applicable to commercial and industrial solid waste incineration (CISWI)).
[33] 76 Fed. Reg. 28318, 28322 (May 17, 2011) .

Recycling glass cullet as an ingredient to make new glass is not an activity that is regulated under the Clean Air Act regulations which pertain to the combustion of waste because glass cullet is not a waste. Most glass cullet is collected directly for recycling via container deposit programs or bar and restaurant collection programs. This glass is clean and is never discarded and can be used directly as a substitute for raw materials. EPA's longstanding position under the Resource Conservation and Recovery Act (RCRA) is that materials are not considered waste if they can be directly reused in an industrial process, are not discarded, are not first reclaimed, where the material is an effective substitute for a commercial product, or where a material is returned as feedstock to the original process from which it is generated, without first being reclaimed.[34] Given this definition, recycled glass cullet is not considered waste.

Other glass cullet used by glass manufacturers is obtained through the separation of the glass from a municipal solid waste stream. This material often goes through several stages of beneficiation before it is sufficiently processed into a cullet product that can be used by glass manufacturers as a substitute for raw materials. Once it is processed, this material also is not a waste, as EPA expressly recognizes:

> The principle that products can be produced from a waste is common to industrial processes and commercial recycling markets. Newspaper and aluminum cans discarded by consumers are then collected, sorted and processed into new recycled paper and aluminum products that are not considered solid waste. Collected plastic is generally sent to a reclaimer, who will sort, grind, and clean the plastic. The cleaned and sorted plastic is sent to a manufacturer who will use it as feedstock. These are clear examples where discarded materials are processed into legitimate non-waste products. Recycled fuel products are no different from recycled paper and aluminum cans with respect to discard. If non-hazardous secondary materials that are discarded by being abandoned, disposed of or thrown away, but are later collected, segregated, and processed into a homogenous fuel product that is marketed and sold as a valuable commodity and are no different than traditional fuels used today, then they should no longer be considered solid waste, just as recycled paper is not a solid waste.[35]

[34] 40 C.F.R. 261.2(e) (identifying materials that are not solid wastes when recycled and therefore are not hazardous wastes).
[35] 75 Fed. Reg. 31844, 31876 (June 4, 2010) (proposed rule on identifying non-hazardous secondary materials that are solid waste when combusted).

EPA's longstanding position under RCRA is that even if reclamation takes place, a commercial chemical product is not a waste when it is recycled.[36] The exemption for products that are reclaimed applies whether or not the product appears on EPA's list of commercial chemical products.[37] By EPA definitions, glass obtained directly from recycling centers or that which is obtained after beneficiation is not considered a waste.

Glass packaging is not typically disposed of in incinerators. Because glass is not combustible, it can damage an incinerator if it is inadvertently introduced into one. To address this issue, the material separation plans that municipal solid waste incinerators must develop under Clean Air Act regulations expressly call for the removal of glass and other recyclables from combustible municipal solid waste. [38]

When glass inadvertently remains in the waste stream and enters the incinerator, it is mixed in with the bottom ash as solid pieces of glass after organic material is combusted, where it typically remains. If the temperatures used in the incinerator are high enough, it can melt into slag, which, like the intact glass pieces, remains virtually inert. However, it is highly unlikely that municipal solid waste combustors operate at temperatures high enough to melt the glass and subsequently release constituents from a glass matrix such that they would end up in fly ash or emissions. In a study examining soda-lime glass cullet melted with grate ash from a municipal incinerator, temperatures of 1400-1500°C (2552-2732°F) were required to melt the glass.[39] Given that this temperature is much higher than the normal operating temperature of a waste incinerator, this scenario would be rare. It is important to note that the volatilization many of the chemicals within the matrix, such as lead, would require temperatures even higher than those needed to melt the glass, as the volatilization point of lead is 1749°C. [40] As a result, any lead in

[36] 40 C.F.R. 261.2(c)(3) and letter dated July 24, 2001, from Robert Dellinger, Acting Director, Hazardous Waste Identification Division to Mitchell Mace, Aaron Oil Co. (RCRA On-Line No. 14555) (agreeing that petroleum vapors from product storage terminals that are captured in vapor recovery units, condensed, and returned to the front end of a petroleum refinery are considered commercial chemical products that are being reclaimed).
[37] 50 Fed. Reg. 14219 (Apr. 11, 1985).
[38] See, e.g., 40 C.F.R. §60.1065 (small municipal waste combustors); 40 C.F.R §60.57(b): (large municipal waste combustors).
[39] Saccani, A., Sandrolini, F., Barbieri, L., Corradi, A. and Lancellotti, I. (2001). Structural studies and electrical properties of recycled glasses from glass and incinerator wastes. Journal of Materials Science. 36:2173-2177.
[40] Schumacher, R.F., et al., Volatilization Studies of a Lanthanide Lead Borosilicate Glass, Westinghouse Savannah River Co. (WSRC-MS-98-00240) (investigating risks of using leaded glass to encapsulate radioactive material by

the fly ash of a municipal waste incinerator will not be from glass, and therefore there is no practical concern of heavy metal emissions from the inadvertent introduction of glass into a municipal waste incinerator. [41]

Because it is an unlikely scenario that temperatures high enough to melt glass will be in a municipal waste incinerator, any glass that enters the incinerator will likely become part of the bottom ash. Bottom ash from municipal waste incinerators is disposed of in accordance with regulations governing the disposal of solid waste. [42] The analysis of any risk associated with glass inadvertently introduced into incinerators is the same as the analysis for the landfill disposal of glass, *i.e.*, an analysis of the potential for constituents to leach. Given the stability of the glass matrix, very high melting point and low probability of leaching of constituents held within the matrix, the inadvertent inclusion of glass waste in a municipal incinerator does not pose a threat to the public welfare.

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measuring the volatilization of lead oxide at temperatures between 1200° C and 1400° C), available at http://sti.srs.gov/fulltext/ms9800240/ms9800240.html.

[41] *See* EPA, AP 42, Fifth Edition, Volume I, at 2.1-13; see also EPA, Emission Factor Documentation for AP-42, Section 2.1, Refuse Combustion, at 30 ("If the condensation temperature of a vaporized metal is such that condensation onto particulates in the flue gas is possible, the metal can be effectively removed by the PM control device. With the exception of Hg, most metals have condensation points well above 300° C (570° F) which is greater than the normal operating temperatures of most control devices. Therefore, removal by the PM control device for these metals is high.").

[42] Guidance for the Sampling and Analysis of Municipal Waste Combustion Ash for the Toxicity Characteristic (EPA 530-R-95-036).

III. Federal Standards for Sample Digestion and Analysis of Heavy Metal Content

Although particular testing standards have not yet been adopted or recommended by TPCH or the various states for purposes of demonstrating compliance with toxics in packaging limitations, various protocols and testing methodologies have been developed and/or endorsed by other Federal agencies as a means to demonstrate compliance with similar standards, such as RCRA and others described above. Industry and scientists familiar with concerns associated with waste disposal, including limitations on heavy metal content, have implemented EPA's testing protocols for decades in order to test for compliance with those standards. In addition, in implementing long-standing limitations on lead in paint, and newer (2008) statutory requirements enforced by the Consumer Product Safety Commission ("CPSC") for children's products, CPSC has established protocols intended to measure heavy metal content in lead in paint and coatings as well as overall lead content in children's products, which are frequently chewed or mouthed by small children. The following summarizes testing protocols potentially relevant to, or which have been considered in the context of, demonstrating compliance with the various states' and TPCH's toxics in packaging standards.

A. EPA Testing Methods for Solid Waste

RCRA, as enforced by EPA, governs hazardous waste from the "cradle-to-grave," including the generation, transportation, treatment, storage, and disposal of hazardous waste.[43] Consequently, although the testing methodologies developed by EPA in furtherance of RCRA generally are focused on determining the potential for toxic components of waste products to enter into the environment, these testing methodologies also provide a logical potential framework for determination of overall content of toxic elements within waste. Moreover, the testing protocols employed under RCRA are recognized for their reproducibility and consistency and, as such, are widely accepted by the scientific community.

[43] *See* EPA Website: *Summary of the Resource Conservation and Recovery Act* (updated August 2011), available at: http://www.epa.gov/lawsregs/laws/rcra.html.

EPA's *Test Methods for Evaluating Solid Waste, Physical/ Chemical Methods* (SW-846), which was first published in 1980, serves as the Agency's official compendium of analytical and sampling methods approved for use in complying with the RCRA regulations. This document sets forth acceptable, although generally not required, methods for use in responding to RCRA-related sampling and analysis requirements.[44] SW-846 includes approximately 35 methods for digestion (dissolution) of waste products in order to determine heavy metal and other contents,[45] as well as numerous methods for analysis of various matrices (*i.e.*, either having been digested, or samples not requiring digestion, such as liquids and soil).[46] These tests were developed not by industry but by EPA as a means to determine the leachability of certain constituents (including heavy metals) from waste products.

In addition to the testing methodologies included in the EPA's 3000 series of tests encompassed in EPA's SW-846, which focus solely on digestion (dissolution) of samples under various conditions,[47] EPA's regulations (and, accordingly, SW-846) provide methodologies for assessing

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[44] *See* EPA Website: *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*, SW-846 (Updated July 2011), available at: http://www.epa.gov/epawaste/hazard/testmethods/index.htm; Some tests are specified in RCRA regulations, such as the use of TCLP to determine if a waste exhibits the hazardous characteristic of toxicity. 40 C.R.R. § 261.24.

[45] *See* EPA Website: *3000 Series Methods* (updated July 2011), available at: http://www.epa.gov/osw/hazard/testmethods/sw846/online/3_series.htm.

[46] *See* EPA Website: *6000 Series Methods* (updated July 2011), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/online/6_series.htm. EPA SW-846 methodologies applicable to analysis of prepared/dissolved samples include: EPA SW-846 Method 6010C ("Inductively Coupled Plasma-Atomic Emission Spectrometry") (February 2007), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6010c.pdf; EPA SW-846 Method 6020A ("Inductively Coupled Plasma-Mass Spectrometry") (February 2007) available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6020a.pdf; EPA SW-846 Method 6200 ("Field Portable X-Ray Fluorescence Spectrometry for the Determination of Elemental Concentrations in Soil and Sediment") (February 2007), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6200.pdf.

[47] EPA SW-846 methodologies for dissolution/ digestion of samples that have been examined in the context of heavy metals present in packaging waste products include: EPA SW-846 Method 3010A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by FLAA or ICP Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3010a.pdf; EPA-SW-846 Method 3015A ("Microwave Assisted Acid Digestion of Aqueous Samples and Extracts") (February 2007), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3015a.pdf; EPA SW-846 Method 3020A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by GFAA Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3020a.pdf; EPA SW-846 Method 3050B ("Acid Digestion of Sediments, Sludges, and Soils") (December 1996), available at: http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/3050b.pdf; EPA SW-846 Method 3051A ("Microwave Assisted Acid Digestion of Sediments, Sludges, Soils, and Oils") (February 2007), available at:

the potential toxicity of waste in landfill conditions through protocols used to measure the leachability of constituents, including heavy metals, from the dissolved matrices. EPA's published protocols for measuring the potential for leaching of contaminants from waste products into the environment contemplate use of the laboratory-based technologies described below, including graphite furnace atomic absorbance spectroscopy ("GFAA"),[48] direct aspiration or flame atomic absorption spectroscopy ("FLAA"),[49] inductively-coupled plasma-atomic emission spectroscopy ("ICP-AES"),[50] inductively-coupled plasma-mass spectroscopy ("ICP-MS"),[51] and X-ray fluorescence spectrometry ("XRF") (which may be either laboratory- or field-based).[52]

Under EPA's regulations, a solid waste exhibits the characteristic of toxicity if, using the Toxicity Characteristic Leaching Procedure ("TCLP") known as EPA Method 1311, the extract from a representative sample of the waste is shown to contain any of certain contaminants (including the various heavy metals discussed in this White Paper) at concentrations equal to or

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http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/3051a.pdf; and EPA SW-846 Method 3052 ("Microwave Assisted Acid Digestion of Siliceous and Organically Based Matrices") (December 1996), available at: http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/3052.pdf.

[48] EPA SW-846 Method 3020A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by GFAA Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3020a.pdf.

[49] EPA SW-846 Method 3010A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by FLAA or ICP Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3010a.pdf

[50] *See* EPA SW-846 Method 3010A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by FLAA or ICP Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3010a.pdf ; and EPA SW-846 Method 6010C ("Inductively Coupled Plasma-Atomic Emission Spectrometry") (February 2007), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6010c.pdf.

[51] *See* EPA SW-846 Method 3010A ("Acid Digestion of Aqueous Samples and Extracts for Total Metals for Analysis by FLAA or ICP Spectroscopy") (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/3010a.pdf; and EPA SW-846 Method 6020A ("Inductively Coupled Plasma-Mass Spectrometry") (February 2007) available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6020a.pdf.

[52] EPA SW-846 Method 6200 ("Field Portable X-Ray Fluorescence Spectrometry for the Determination of Elemental Concentrations in Soil and Sediment") (February 2007), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/6200.pdf.

greater than the respective values listed in the procedure.[53] The TCLP was first made available for comment in 1985,[54] and is the principal method outlined under SW-846 to determine the leaching behavior of waste materials under simulated landfill conditions. By simulating the leaching that will occur in waste that is disposed of in a landfill, the TCLP is designed to determine not only the potential mobility of both organic and inorganic analytes present in liquid, solid, and multiphasic wastes, but also (in order to determine the potential for mobility) can provide a method by which overall content of analytes available to leach can be determined. Accordingly, while EPA's TCLP is focused on the potential for leaching rather than content, this testing methodology is directly relevant to the potential impact of toxic components in waste materials, based on an initial determination of overall content.

In addition to its broad and historic acceptance and recognized accuracy and replicability in measuring the amount of a constituent that can migrate from a sample, the TCLP provides for significant flexibility in demonstrating compliance with RCRA. Specifically, while the TCLP provides a testing protocol by which to measure the amount of constituent that is able to migrate out of a sample, section 1.2 of the TCLP permits a correlation between the results of total content testing and the maximum possible total leachate constituent result, based on the assumption that the matrix is able to be dissolved completely.[55] Under TCLP, if a waste is 100% solid, the results of a total constituent analysis (representing the total amount of the constituent available or accessible in the matrix) may be divided by twenty to convert the total results into the maximum leachable concentration.[56] Based on this approach by EPA, accurate extraction or migration analysis results, when multiplied by twenty, thus should also be able to be extrapolated to a reliable number for the total content of certain constituents (such as heavy metals) available to

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[53] 40 C.F.R. § 261.24. *See* EPA Website: *Maximum Concentration of Contaminants for the Toxicity Characteristic* (table), available at: http://www.epa.gov/bpspill/maxcontaminant_table.pdf. *See also*, EPA Method 1311, *Toxicity Characteristic Leaching Procedure* (July 1992), available at: http://www.epa.gov/epawaste/hazard/testmethods/sw846/pdfs/1311.pdf.

[54] Note that the TCLP was designed to replace EPA SW-846 Method 1310, titled "Extraction Procedure Toxicity Test" (or "EP"), which is an older protocol that also was used to measure toxicity characteristics of wastes under the RCRA. *See* EPA Guide for Industrial Waste Management, at Chapter 2 ("Characterizing Wastes") (updated July 2011), available at: http://www.epa.gov/osw/nonhaz/industrial/guide/pdf/chap2.pdf.

[55] *See* EPA Website – TCLP Questions ("Total Constituent Analysis Instead of TCLP Analysis") (July 2011), available at: http://www.epa.gov/osw/hazard/testmethods/faq/faq_tclp.htm.

[56] *Id*.

leach or become separated from the subject matrix. Because glass is virtually inert, and, unlike most other packaging materials, is generally not able to be completely dissolved, interpolation of extraction or migration analysis data will result in a total available content measurement that consistently confirms compliance with total content limitations for certain substances such as those set forth in toxics in packaging regulations.

The above approach, relying on EPA testing protocols developed in the context of environmental waste analysis, and with a long history of accurate and replicable use, thus properly could be utilized for purposes of determining compliance with the total content requirements of the Model Legislation and those state statutes adopting it. Given that neither the Model Legislation nor any of the state statutes includes a particular testing protocol, adoption of this approach in the context of the Model Legislation, for recommendation to the various states, would be consistent with the purposes of the Model Legislation, harmonize with other testing conducted for EPA statutory purposes, and provide guidance to the glass industry regarding establishing compliance with content limitations.

EPA's development of, and continued emphasis in its regulations on, the TCLP (which was initially published in the Federal Register in 1986), along with the other EPA-developed protocols for dissolution and analysis of waste that are described in this White Paper, reflect that, in order to pose risks to the environment, a material must not only possess toxic elements but those elements also must leach into the environment (*i.e.*, have the ability to be freed from the waste materials into the environment). EPA's view in this regard is consistent with FDA's conclusions concerning the potential human health and safety risks posed by toxic components in food packaging materials. FDA considers only those substances that migrate from packaging materials into foods at unsafe levels to pose any potential risks to humans. In addition, the fact that the TCLP historically has been designed and applied in a manner that recognizes the utility of flexibility in its application, with the capability for results from total content testing to be extrapolated to produce migration data, provides a strong scientific and policy basis for endorsing a similar extrapolation approach to demonstrating compliance with total content requirements of the toxics in packaging requirements of the various states using EPA testing protocols focused on migration of substances in the environmental waste context.

Unlike the TCLP, which simulates environmental conditions associated with waste disposal, EPA's SW-846 Method 3052 provides a means for *total* digestion or dissolution of a matrix to determine constituents.[57] The applicability of this test is limited with respect to glass, however, due to the physical and chemical properties of glass, which make total dissolution (and, similarly, leaching of constituents from the glass) extremely difficult. Consequently, although EPA's protocol SW-846 Method 3052 has been examined generally in the context of evaluating packaging waste for compliance with toxics in packaging regulations, and may continue to prove useful and desirable for evaluation of certain packaging materials with much different dissolution profiles than glass, this protocol is not optimal or likely effective for use in assessing glass packaging.

B. CPSC Testing Methods for Children's Products

The CPSC also has published standards for the dissolution of finished products in a matrix and analysis of those products for total lead content. However, unlike EPA's protocol SW-846 Method 3010A (which is appropriate for sample digestion in the context of packaging waste), SW-846 Method 1311 (for extraction of metals from a sample of digested packaging waste), and SW-846 6010C (for analysis of those metals extracted from the sample), CPSC's testing protocols for dissolution and analysis are not as relevant or useful in the developing tests for packaging as encompassed by the Model Legislation, because the CPSC's protocols focus on total content, not the amount of a potentially hazardous compound that can be extracted from the product. This focus of the CPSC differs from those of FDA, EPA, or the Model Legislation by reason of the types of products which CPSC regulates and the segments of the population it intends to protect, for example, many of the products are small parts or toys which can be ingested by children. As a result of the enactment of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), which amended the Consumer Product Safety Act ("CPSA") to impose maximum total lead content limits for products intended for children under the age of 12, CPSC published Method CPSC-CH-E1002-08 as a standard protocol for the dissolution and analysis of

[57] EPA SW-846 Method 3052 ("Microwave Assisted Acid Digestion of Siliceous and Organically Based Matrices") (December 1996), available at: http://www.epa.gov/osw/hazard/testmethods/sw846/pdfs/3052.pdf.

matrices for the purpose of testing overall lead content.[58] This test, however, is not properly or readily applicable to glass packaging because, unlike children's toys and other children's products, for example, glass packaging cannot reasonably be expected to be subject to regular potential ingestion in part or whole by children.

C. Testing Methods to Assess Presence of Heavy Metals in Municipal Solid Waste Combustion Ash

Municipal solid waste combustion ash is not exempt from federal hazardous waste regulations. Accordingly, a generator of such ash must determine if it is a hazardous waste under RCRA before disposing of it, using the same solid waste test methods discussed above.[59] Glass introduced into an incinerator may fall to the bottom ash, and would be disposed of as part of the ash as solid waste. The analysis of any risk associated with glass inadvertently introduced into incinerators is the same as the analysis for the landfill disposal of glass, *i.e.*, an analysis of the leachate using the TCLP.

As is demonstrated from the use of TCLP, metals are contained in the glass matrix, and as such, the metals do not leach from the glass. This property of glass has presented a potential method for disposal of incinerator fly ash. In a study examining the vitrification of incinerator ash (by heating it at 1400° C for 20 minutes) as an environmentally protective means of managing this material, the researchers found lead present in incinerator fly ash at 2.5 mg/l was not detectable in the glass formed by vitrification of the ash.[60] The researchers explained this result as follows: "In the case of low leachability characteristics for the Cr. Pb, and Cu are due to heavy metal ions replacing other ions and hold in the framework of glass."[61] The properties of glass which make it safe for disposal in landfills due to its low leachability also present a possible safe method for disposal of incinerator fly ash.

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[58] *See* Test Method: CPSC-CH-E1002-8 ("Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children's Products") (February 2009), available at: http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08.pdf.

[59] See, e.g., Guidance for the Sampling and Analysis of Municipal Waste Combustion Ash for the Toxicity Characteristic (EPA 530-R-95-036).

[60] "Characterization of glass ceramics made from incinerator fly ash," Chen and Chen, Ceramics International 30 (2004) 343-349

[61] *Id*.

IV. Analytical Methods Used to Measure Heavy Metal Content in Conjunction with Testing Protocols

There are a variety of analytical testing methods available to measure heavy metal levels in packaging or other materials. Generally, laboratory-based methods, including FLAA, GFAAS, ICP-AES, and ICPMS are considered to offer the highest level of sensitivity and precision. When used to calculate total content, these methods are often expensive, time-consuming, and rely on digestion (dissolution) of the sample using strong, concentrated acids. These methods can be useful however for accurate determination of metal content in the extraction fluid generated during the TCLP, which would provide the most precise measurement of the potential harm to the environment that disposed waste would pose.

Another instrumental method to measure total content, XRF, is more affordable and takes less time (because it does not require dissolution of the sample), and also offers the added convenience of being available as a hand-held or portable device that can be used in the field in the case of some models. As a result of this portability, ease of use, and relatively low investment (in terms of both time and cost), XRF has been used notwithstanding its lack of sensitivity and accuracy as compared with laboratory testing methods
Each of these methods are employed to varying extents in the context of the more widely-recognized testing protocols used for measuring the presence of certain elements, including heavy metals, in waste compounds. The following provides a brief overview of each of these testing methods and a description of potentially relevant testing protocols.

A. Direct Aspiration or Flame Atomic Absorption Spectroscopy ("FLAA")

Direct aspiration determinations, such as FLAA, are normally single-element analyses and are relatively free of inter-element spectral interferences. FLAA relies upon the electrochemical properties of metals that allow them to absorb energy from light of specific wavelengths. FLAA uses either a nitrous-oxide/acetylene or air/acetylene flame as an energy source for dissociating the aspirated sample into the free atomic state, making analyte atoms available for absorption of light and spectrophotometric detection. The temperature or type of flame used is critical in the analysis of concentration of the distinct elements contained in the sample. If the proper flame

and analytical conditions are not used, chemical and ionization interferences can occur, resulting in inaccurate reading of the various elements being assessed.

B. Graphite Furnace Atomic Absorbance Spectroscopy ("GFAAS")

GFAAS replaces the flame used in FLAA (a potentially variable aspect of the test which, as described above, can be a limitation of the FLAA technique) with an electrically-heated graphite furnace or tube. As a result of the use of the furnace environment, the process of dissolution, drying, and decomposition of organic and inorganic molecules and salts, and formation of atoms, can be directed to the entire sample (rather than the area on the sample to which a flame is directed) and takes place in a controlled environment over a longer period of time than with use of a flame in FLAA. The precision afforded by GFAAS allows an experienced analyst to remove unwanted matrix components by using temperature programming and/ or matrix modifiers. GFAAS has a significantly improved detection limit as compared with FLAA, but also is limited to assessment of a single element at a time. Due to the sensitivity of the test, however, interferences can pose a significant limitation, requiring a precise determination of the optimum conditions (*i.e.*, digestion, temperature, time settings, etc.) for conducting the test.

C. Inductively Coupled Plasma-Atomic Emission Spectroscopy ("ICP-AES")

ICP-AES allows for simultaneous, rapid determination of many elements in a short period of time. In the ICP-AES technique, aerosol samples are introduced into an extremely hot plasma source (argon inductively coupled plasma) that vaporizes, atomizes, ionizes, and electronically excites the sample components, resulting in unstable energy configurations of those atoms. When the atoms return to more stable configurations, the excess atomic energy is then released as characteristic photons (*i.e.*, emitted light). Because the intensity of the emission is a function of the concentration of atoms that are affected, the wavelengths of the energy released are specific to the elements contained in the particular sample, measurable via emission spectrometry.

D. Inductively Coupled Plasma-Mass Spectroscopy ("ICP-MS")

Similar to ICP-AES, ICP-MS retains the sample introduction system used in ICP-AES but the atomic ions produced by the argon plasma are directed into a mass spectrometer ("MS"). The MS separates the ions introduced from the ICP according to their mass-to-charge ratio. Ions of the selected mass-to-charge ratio are directed to the detector, which records the types of ions present, providing for identification and quantification of the specific elements present in the sample. Using MS detection rather than atomic emission spectroscopy ("AES"), this method allows for a sensitive, simultaneous determination of many elements in a short timeframe, and is generally considered to be more sensitive than GFAA, FLAA, or ICP-AES. A disadvantage of ICP-MS, however, is the potential for isobaric elemental interferences, which are caused by different elements forming atomic ions with the same nominal mass-to-charge ratio. Mathematical correction for interfering ions can be used to minimize the impact of these interferences on testing results.

E. X-Ray Fluorescence Spectrometry ("XRF")

As described above, XRF testing for heavy metal and other particular components is a method that is often used, and is viewed by some agencies, such as the Consumer Product Safety Commission (CPSC), as a viable option primarily for superficial, initial screening of samples.[62] XRF uses x-rays to ionize elements, causing electrons to be ejected from the orbit path (scientifically referred to as a shell) of an atom and records the characteristic emissions of dispersed the atoms as they return to more stable energy states. Despite its ease of use, XRF is only moderately sensitive at best, and the results are difficult to replicate.

Additionally, as is discussed in greater detail below, use of XRF to assess total heavy metal content in packaging materials for purposes of compliance with relevant state limits for waste

[62] The Consumer Product Safety Commission ("CPSC") generally regards XRF testing to be acceptable only from a standpoint of screening concentrations of heavy metals in superficial/topical elements of a sample (such as films and coatings). *See, e.g.*, CPSC - *Lead Testing by XRF Frequently Asked Questions (FAQ)* (November 2007), available at: http://www.cpsc.gov/businfo/xrffaq.pdf. *See also,* CPSC - *Study on Effectiveness, Precision, and Reliability of X-Ray Fluorescence Spectrometry and Other Alternative Methods for Measuring Lead in Paint* (August 2009) at 4 (discussing limitations and potential for inaccuracies of using XRF to measure lead content in paint film), available at: http://www.cpsc.gov/about/cpsia/leadinpaintmeasure.pdf.

materials has recently been questioned due to its inaccuracy and inability for results of this testing methodology to be reproduced, as discussed below.

V. Heavy Metal Presence in Packaging Waste - Testing Results Using Various Methodologies

Over the past several years, various organizations and researchers have attempted to assess heavy metals content in packaging materials, in order to determine (1) compliance with the state requirements designed to further environmental concerns regarding the potential for pollution created by some waste materials containing heavy metals and/or (2) the potential for toxic elements within packaging materials to leach into the environment or migrate into foods. Of the studies and published literature examined for the purposes of this White Paper, all studies that employed rigorous testing methodologies demonstrated that, consistent with FDA's long-standing conclusions concerning the safety of use of glass for food packaging, glass packaging does not contain heavy metals at other than trace or undetectable levels. Moreover, even in cases where glass packaging did contain trace detectable amounts of heavy metals, the inert and highly stable nature of glass minimized migration of any such heavy metals out of the glass. The following discussion describes some of these relevant studies.

A. Toxics in Packaging Clearinghouse Studies

As referenced above, the TPCH is an organization formed in 1992 by 10 of the 19 states that have adopted legislation similar or identical to the Model Legislation. The primary focus of the TPCH is to clarify and promote the Model Legislation. Beginning in 2006, TPCH conducted various tests attempting to assess compliance with the state-enacted versions of the Model Legislation by measuring overall heavy metal presence in common packaging products. In conducting this testing, TPCH focused on the overall presence of heavy-metals by using portable XRF technology which, as discussed above, does not require dissolution of the item being tested and is among the least precise methodologies available to measure lead content. XRF technology measures only substance content and does not measure the potential for migration or leaching of compounds out of the material that is the subject of the test. Additionally, XRF testing is unable to distinguish between elements and other related compounds (*e.g.*, hexavalent chromium and non-hexavalent chromium are collectively detected as "chromium"; lead and lead oxide are collectively detected as "lead"), resulting in inaccuracy by over-counting. TPCH has itself repeatedly noted the limitations of using XRF to measure total lead content in connection

with assessing compliance with state requirements, stating that, although XRF analysis has the benefit of offering a "rapid and inexpensive screening tool," "XRF is recognized **only** as a screening tool,"[63] due largely to the fact that the results of comparisons of XRF studies and more comprehensive laboratory studies do not correlate.

The TCPH XRF testing does not, in any respect, however, provide any meaningful assessment of the potential for migration of compounds from packaging into either (1) the foods or beverages contained by that packaging during its useful lifecycle, or (2) landfills or the environment generally upon disposal.

The following discussion provides a detailed overview of TPCH's testing of packaging materials, with a specific focus on the results concerning glass packaging, and the shortcomings of testing methodologies used by TPCH recently.

1. TPCH 2007 Report

Beginning in 2006, TPCH initiated a screening project to determine the compliance of common packaging products with the regulatory restrictions of states that had adopted legislation identical or similar to the Model Legislation. Using a hand-held XRF analyzer, TPCH screened 355 packaging samples for the presence of the heavy metals covered in the relevant state laws and Model Legislation (*i.e.*, lead, cadmium, mercury, and hexavalent chromium). Of the packages tested, 16% exceeded the screening threshold for the presence of one or more of the covered heavy metals, and could be considered in violation of state toxics in packaging laws (which limit heavy metals to a total detectable combined content of 100 ppm).

The majority of failures were attributed to either flexible heavy-duty PVC packaging, or inks and colorants used for printing on packaging, not glass packaging, which comprised only approximately 2 percent of the sample of products tested in this 2007 analysis. Of the glass packaging tested, the results of the XRF analysis suggested that seven samples contained

[63] *See* TPCH *Guidance on Laboratory Analysis for Toxics in Packaging* (2011), available at: http://www.toxicsinpackaging.org/docs/lab_testing_guidance.pdf.

chromium in excess of permissible levels under the state environmental laws; two samples contained lead exceeding permissible levels. Due to the limitations of the XRF technology used, TPCH noted in its 2007 Final Report that six of the seven glass packaging samples that tested positive for chromium "are likely to be 'false positives' due to total chromium reading" that included non-hexavalent chromium along with the heavy metal hexavalent chromium.[64] Non-hexavalent chromium is not a "heavy metal" that is the subject of any environmental or health or safety regulation applicable to packaging products, including the Model Legislation.

After receiving various data from industry that refuted the findings of TPCH's tests (based largely on TPCH's use of inaccurate XRF technology rather than more comprehensive and accurate laboratory studies), TPCH provided various samples to the analytical laboratory of the State of California Department of Toxic Substances Control ("DTSC") for further testing and validation of TPCH results. California DTSC analyzed the samples using XRF technology, as well as ICP-AES, which is widely regarded as the one of the most versatile and accurate analytical techniques used as an elemental determinant. California DTSC then forwarded these same samples to its XRF vendor, Oxford Instruments, for further validation of the XRF test measurements obtained by DTSC.

As noted by TCPH in its 2007 Final Report, the ICP-AES test results obtained by California DTSC:

> …stand in stark contrast to the collective XRF results. The ICP-AES results are at least an order of magnitude less than the XRF results. The ICP-AES only detected metal concentrations over 100 ppm when the XRF results indicated concentrations greater than 1,000 ppm.[65]

[64] *See* TPCH Final Report, *An Assessment of Heavy Metals in Packaging: Screening Results Using a Portable X-Ray Fluorescence Analyzer* (June 2007) (2007 Final Report) at 16, available at: http://www.toxicsinpackaging.org/adobe/TPCH_Final_Report_June_2007.pdf. *See also, id* at 4 ("XRF detects total chromium, not hexavalent chromium, which might have contributed to some false positives for hexavalent chromium.").

[65] *See id* at 18.

Thus, had the TCPH testing employed the ICP-AES testing methodology, most of the TPCH samples would have "passed" rather than "failed" under TCPH's XRF testing protocol.[66]

The State of Connecticut Department of Environmental Protection also obtained similar results to the California DTSC's ICP-AES analysis when it submitted four different TPCH flexible PVC samples to an accredited contract laboratory for analysis using ICP-AES, and compared those results to XRF analyses of the same samples.[67]

Although none of the follow-up testing conducted by the California DTSC or the Connecticut Department of Environmental Protection appears to have focused on glass packaging waste, the significant differences in the testing results obtained through use of XRF versus conventional laboratory method results (including the EPA's SW-846 dissolution/ digestion methods), together with the discussion in TCPH's 2007 Final Report concerning the utility of various digestion methods for different materials, support the conclusions that:

(1) XRF results are often inconsistent and imprecise;
(2) there is little in the way of industry or even scientific consensus regarding the preferred testing methodologies for measuring heavy metals in packaging products; and
(3) best practices for testing likely are dependent upon the chemical composition of the finished packaging sample being tested.

Moreover, the TCPH 2007 Final Report underscores that the relative accuracy of the testing methods is tied to a number of variables, in addition to the particular types of samples used, including limits of detection, sample thickness, and even distinctions in protocols or methods used by the different laboratories.

[66] *Id*.

[67] *Id* at 19 – 20.

2. *TCPH 2009 Update*

In 2009, TPCH updated the organization's continued investigation of heavy metals in packaging with a report of the results obtained in studies the organization had conducted in 2008.[68] In the 2008 studies, TPCH screened an additional 409 packages to assess heavy metal presence, still relying on the hand-held XRF analysis to measure total heavy metal content.[69] Of note, due to the relatively high level of compliance of glass packaging products when compared with other food packaging types tested by TPCH in 2007 (*e.g.*, imported flexible PVC and inks colorants used on shopping bags), TPCH purposely targeted packaging products that had lesser compliance rates in the 2006 and 2007 tests,[70] intentionally decreasing the amount of glass packaging test samples from 2% to 1% of the overall test sample.

Consistent with results of the prior studies, the 2009 Update reflected that packaging components that failed the screening test (>100 ppm of one or more of the 4 restricted metals) generally fell into one of three groups: imported flexible PVC, inks and colorants, and solder used in electronic circuitry. The updated studies, which based conclusions solely on XRF analyses, resulted in findings that 14.2% of all samples exceeded the 100 ppm screening threshold for one or more of the restricted heavy metals.

The testing conducted on glass packaging samples resulted in two "failures" of glass packaging materials due to chromium oxide content, which is attributed to the inability of the XRF technology to distinguish between non-hexavalent chromium (which is not a heavy metal and is not subject to any state law or other maximum limit requirements) and the hexavalent form.[71] Consequently, none of the glass packaging samples were deemed by TPCH to contain greater

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[68] *See* TPCH Final Report, *An Assessment of Heavy Metals in Packaging: 2009 Update* (June 2009) (2009 Update), available at: http://www.toxicsinpackaging.org/docs/assessment_of_heavy_metals_in_packaging_09_update.pdf.

[69] *Id.*

[70] *See id* at 11 ("Two types of packaging dominated the non-compliant packages in the 2006 screening project, and were therefore targeted for further screening: 1) flexible PVC packages used to package home furnishings, pet supplies, inexpensive toys, and cosmetics; and 2) inks and colorants on plastic shopping and mailing bags.")

[71] *See id* at 18, fn 1; *see also id* at 19 (referring to results demonstrating positive heavy metal content in glass packaging, "[t]he glass samples, though, are likely to contain chromium oxide (Cr2O3), not hexavalent chromium.")

than permissible levels of heavy metal content. Moreover, inclusion of glass samples in the study once again demonstrated the known imprecision of the XRF hand-held test in determining heavy metal content in glass.

After the release of the 2007 TPCH report, California DTSC released additional test results comparing several sample digestion methods specified in EPA SW-846, followed by analysis using ICP-AES.[72] The concentration of heavy metals in PVC packages detected by ICP-AES analysis increased when more rigorous sample preparation methods were used to digest the sample and liberate the metals from the hard-to-digest PVC matrices. EPA SW-846 Method 3052 achieved the most consistent and comparable results to XRF analysis, while Method 3050B resulted in significantly lower concentrations of heavy metals in all samples tested, compared to Method 3052 and XRF analysis. The comparative analysis of sample preparation methods by the California DTSC demonstrates the importance of selecting appropriate dissolution methods for specific packaging material, as the methods for liberating total metals are variable depending on starting material.

In summary, the 2008 studies, as reflected in the 2009 Update, continued to underscore that

- the accuracy of testing methodologies varies depending upon the subject of the test (including material and physical qualities, such as thickness);
- glass packaging materials do not present significant concerns due to heavy metal content, and
- analysis of total heavy metal content is imprecise, particularly with respect to glass packaging products.

Despite the shortcomings of the XRF technology that TPCH noted in 2007, TPCH did not offer or endorse, in its 2009 Update, any particular testing methodology more appropriate for particular packaging materials, nor did TPCH suggest that any single testing method was suitable for testing heavy metal content in all packaging waste materials.

[72] *See* TPCH 2009 Update, *supra* note 56, at 24.

3. TPCH 2011 Laboratory Round Robin

In 2011, TPCH further updated its efforts to measure heavy metal content in packaging materials, this time extensively discussing alternate analytical testing methods, including EPA's tests intended to determine "total recoverable metals" through complete sample dissolution.[73] The results of this testing, as summarized in TPCH's 2011 Laboratory Round Robin, demonstrate that significant variability exists in laboratory testing methodologies commonly used to assess compliance with state limits for heavy metals in packaging.

As a part of this 2011 assessment, TPCH sent packaging samples to seven separate laboratories (six private laboratories and the California DTSC Laboratory), asking them to provide testing results for total concentration of certain heavy metals in the samples. Reflecting the concerns of TPCH with the difficulty in assessing heavy metal content in PVC packaging materials, each of the participating laboratories received a total of eight samples, seven of which were PVC; the eighth was a control non-PVC plastic material (*i.e.*, no glass packaging waste thus was included in the sample population in this testing).[74] The seven PVC samples contained lead and/ or cadmium. A result was deemed unacceptable if the measured concentration was 25 percent above or below all of three baseline reference points. Due to considerable variability and inaccuracy of testing results, 16% of the lead and cadmium results were deemed "unacceptable" under the protocol.[75]

The findings of TPCH's 2011 Laboratory Round Robin underscore the wide range of variability and potential for inaccuracy inherent in the various testing methodologies used. Whether the variability that has been continually reflected in TPCH's study results is attributable to incomplete sample decomposition (due to difficulty in applying particular dissolution methods to certain materials, *e.g.*, PVC), as TPCH suggests, or for other reasons, TPCH's findings in the 2011 Laboratory Round Robin and, indeed, in its prior studies, strongly suggest that, in order for

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[73] *See* TPCH Final Report, *Laboratory Round Robin Test Project: Assessing Performance in Measuring Toxics in Packaging* (July 2011) (2011 Laboratory Round Robin), available at: http://www.toxicsinpackaging.org/docs/assessing_lab_performance.pdf.

[74] *See id* at 14.

[75] *See id* at 18.

testing to produce accurate results regarding overall heavy metal content, as required for compliance with state laws, testing methodologies must be examined closely to ensure that methods are not only appropriate for use with the particular materials being tested but that such methods are applied in a consistent and standardized manner by the laboratories performing the tests. Moreover, the TPCH studies and resulting reports support the conclusion that, of the most widely-used packaging materials examined, glass packaging does not present significant environmental risks due to heavy metal content.

In March 2011, TPCH has indicated that it has received funding from California DTSC to conduct additional studies in 2011 and 2012.[76] In these studies, we understand that the TPCH will continue to examine discrepancies between XRF and more costly, but more accurate, laboratory-based analytical methods using acid digestion, focusing on heavy metals content in glass packaging materials, under a $50,000 grant from the California DTSC. TPCH intends that these future studies will provide guidance regarding the continuing uncertainty concerning appropriate testing methodologies to determine heavy metal content in packaging products generally, as well as regarding specific issues presented by the virtually inert qualities of glass, which results in extremely low potentials for migration of any impurities contained in the glass. It is imperative, in these additional studies, that TPCH utilize analytically precise and replicable testing protocols, of which the EPA testing protocols noted above appear the most applicable to packaging assessment, to ensure replicable results and proper guidance for industry for compliance with the Model Legislation's requirements in those states that have adopted it.

B. Other Relevant Literature

A comprehensive review of the publically available scientific literature assessing heavy metal content in glass and other packaging materials and/or the ability of heavy metals potentially contained in glass packaging to migrate into either food/ beverages contained in the packaging or into the environment once disposed of, is beyond the scope of this White Paper. We have reviewed a significant sample of the relevant literature, however, and believe that these studies are consistent with and support the aforementioned conclusions that:

[76] *See* TPCH Website, *TPCH Awarded Two Contracts for Testing Packaging* (2011), available at: http://www.toxicsinpackaging.org/package_testing_contracts.html.

- glass packaging contains only trace amounts of heavy metals, unintentionally introduced during manufacture due to use of recycled glass content;[77]
- heavy metal content in glass packaging (*e.g.*, due to recycled material content in the finished glass product) typically appears to be within the limits set forth in state laws for heavy metals; and
- due to the virtually inert qualities of glass, any heavy metals contained in finished glass packaging migrates at only trace or undetectable levels from the finished glass packaging into either food/ beverages contained in the glass or the environment.[78]

Our review of relevant scientific literature further supports that testing methodologies vary greatly and that, currently, no particular methodology has been adopted as the standard test method for determining heavy metals content either for particular packaging or for all packaging products.[79]

We also believe that studies focused on the potential for heavy metals contamination in glass applications other than in packaging are instructive, and further support the conclusion that

[77] The glass packaging industry has been committed to continuously increasing its recycled glass content in view of the positive impact on sustainability from reducing energy consumption and certain emissions (NOx, SOx, PM, and CO2). The increased use of recycled glass can present various challenges because of the potential for contamination of the recycled glass supply stream, for example from improperly discarded cathode ray tubes, fluorescent bulbs, and crystal tableware. In view of the virtually inert characteristics of glass, however, no adverse human health or environmental consequences properly can be concluded to be presented from FDA, EPA, or the Model Legislation perspectives.

[78] *See* J.M. Sharf, *Chemistry of Food Packaging* "Glass Containers as Protective Packaging for Foods," 15 (American Chemical Society, 1974) (concluding that no heavy metal elements were shown as extractives from glass containers at ppb levels of sensitivity); P.V. Tingle, *Assessment of total and elemental migration from UK glass containers*, 31 Glass Technology 109, 114 (1990) ("Migration from all glass containers tested is comparable with, or less than values for the same elements found in the water supply."); E. Guadagnino & R. Dall'igna, *Heavy metal ions in glass and related legislation*, 37 Glass Technology 76, 77 (1996) ("There is no danger of significant leaching from glass because it is an inert material.").

[79] *See* "Glass Containers as Protective Packaging for Foods" at 19 (using an accelerated extraction procedure of double distilled water exposed to glass surfaces for 2 hours in a steam autoclave at 121°C, and analysis by atomic absorption, concluded no heavy metals as extractives from glass); *Assessment of total and elemental migration from UK glass containers* at 114 (using ISO 4802 hydrolytic resistance test and analysis by atomic absorption spectroscopy, concluded heavy metal levels after migration are similar to normal water supply levels); *Heavy metal ions in glass and related legislation* at 77 (using the two methods of Italian waste extraction test [(a) 4% acetic acid, 24 h 22 deg. C, (b) distilled H_2O, 20 min, 121 deg. C] and EPA-SW 864-3050A, concluded that, due to the inert chemical state of glass, there is no danger or likelihood of leaching).

heavy metals do not leach from glass under any normal or even extreme conditions of use. For example, in a study examining the leaching potential of potentially hazardous elements (including heavy metals) in glass beads used in pavement markings,[80] the results supported the conclusion that, even when subjected to various extreme conditions, in the rare instances in which heavy metals are released from recycled glass beads at all, such contaminants are released or leach at levels that are several orders of magnitude lower than those considered to have any potential health, safety, or environmental implications.[81]

Consistent with the results of the above-described study and with the general conclusion that, even if present in glass at trace levels due to the use of recycled content in glass manufacture, a 2010 report issued to Congress by the Federal Highway Administration ("FHA") assessing potential concerns about leaching of heavy metals or other contaminants from glass beads, concluded that "[h]eavy metals in glass beads do not appear to be leachable under the conditions of the EPA Toxicity Characteristic Leaching Procedure ("TCLP") test, which defines toxicity under current hazardous waste regulations."[82] The FHA study went on to note that, due to the inert qualities of glass and the inability of contaminants to leach from the glass into the surrounding environment, vitrification (a process by which materials are combined with, and become a part of, glass) of heavy metals is considered to be "an acceptable method of disposing of heavy metal wastes."[83]

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[80] Recycled glass beads are used in pavement markings is well established to provide the safety benefit of adding a reflective element to the markings.

[81] Boulanger, B., Raut Desai, A., and Carlson, P. *Heavy Metal Content and Leaching Potential of Recycled Glass Beads Used in Pavement Markings*. American Glass Beads Manufacturing Association, Texas Transportation Institute (TTI) (April 2011), available at: http://tti.tamu.edu/documents/TTI-2011-2.pdf. In the study, which was undertaken with the intent of assessing the validity of concerns about the potential for heavy metals, including arsenic and lead, to leach (or otherwise be released) from recycled glass beads currently used in pavement marking systems, the leaching potential of heavy metals contained in glass beads was assessed in a variety of ways, including by exposure to solution pH, ultraviolet light, extreme temperature variation, and bead abrasion.

[82] *See* Federal Highway Administration Report FHWA-HRT-09-039: *Pavement Marking Demonstration Project: State of Alaska and State of Tennessee-Report to Congress* (April 2010) (emphasis added).

[83] *Id*.

Indeed, further confirming the non-reactive nature of glass and its ability to virtually eliminate migration of any hazardous substances from waste, glass is widely recognized in the nuclear industry as an effective means of disposing of radioactive nuclear waste. Vitrification is a commonly used process to immobilize radioactive waste from nuclear plants by mixing it with specially formulated glass-forming materials consisting of sand and/or similar materials and heating the mixture to very high temperatures. Because the radioactive waste components are thus strongly bonded within the glass structure, vitrification produces a radioactive waste storage and containment form that is environmentally stable for thousands of years.

Vitrification has become the most widely used technology for immobilizing radioactive waste in the U.S. and many foreign countries. For example, in the U.S., the Savannah River National Laboratory, which is managed and operated by the U.S. Department of Energy ("DOE"), developed the key technologies and processes used in the Savannah River Site's Defense Waste Processing Facility ("DWPF"), the largest radioactive waste glassification plant in the world.[84] Since its startup in 1996, the DWPF has produced over nine million pounds of glass and has immobilized within the glass over two million gallons of radioactive waste. In this process, a sand-like borosilicate glass is mixed with the waste, and then heated to nearly 2,100 degrees Fahrenheit in the plant's 65-ton steel and ceramic melter. This molten glass-waste mixture is poured in a thin stream into stainless steel canisters to cool and harden. The result is a durable, stable solid glass waste form suitable for disposal in a federal radioactive waste repository (at the time one becomes available). Vitrification also is widely used internationally to successfully immobilize radioactive waste in stable glass structures (*e.g.*, France, Great Britain, Germany, Japan, Belgium, and Russia use vitrification to treat and contain radioactive waste).[85]

[84] *See* Savannah River National Laboratory, *Glass Waste Forms and Vitrification Process Development*, available at http://srnl.doe.gov/facts/glass_waste_forms.pdf . DOE has also contracted with Bechtel National, Inc., to design and build a radioactive waste treatment plant located at the Hanford Site in Richland, Washington. The treatment plant, known as the Hanford Waste Treatment and Immobilization Plant, will use vitrification to immobilize and permanently store radioactive waste by blending the waste with glass-forming materials. Construction of the plant began in 2001, and is currently scheduled to become operational around 2022. *See* Bechtel National, Inc., *The Project*, available at http://www.hanfordvitplant.com/about_us/the_project/.

[85] *See* Vienna, John D. "Nuclear Waste Vitrification in the United States: Recent Developments and Future Options," *International Journal of Applied Glass Science,* Vol. 1, No. 3, 2010, 309–321 (2010).

The use of glass structures to safely contain and dispose of radioactive nuclear waste materials, and the absence of heavy metals release from glass beads used in pavement markings, further support the conclusion that glass packaging should be concluded to be safe and not to present any heavy metals into the environment at other than trace levels of appearance because of its inherently stable and virtually inert qualities.

VI. Conclusions

As the above discussion and analyses demonstrate, glass packaging continues to provide the gold standard as the most environmentally friendly packaging. Considered by FDA as GRAS, glass packaging is recognized by authorities worldwide for its health benefits, safety, and durability as renewable resource.

Glass continues to enjoy preferred status for food packaging applications due to its virtually inert qualities and resultant ability to protect and preserve the qualities of the food it contains. As the literature reviewed above shows, (1) heavy metals are not intentionally added to glass during manufacture,[86] and (2) heavy metals potentially contained in glass do not migrate at more than trace or undetectable levels from finished glass to food contained within that glass or into the environment when disposed as waste. Appropriate scientific testing methodologies developed in the context of environmental waste by EPA and used over a long period of time by industry have consistently demonstrated that glass packaging contains or leaches heavy metals at only trace or undetectable levels, which levels fall several orders of magnitude below the statutory limitations of the Model Legislation, as discussed above. Conversely, such appropriate testing methodologies and studies have continually demonstrated that PVC and other plastic-based packaging products present significant risks of non-compliance with heavy metals content requirements.

As the above discussion demonstrates, however, no single testing methodology to determine heavy metal content in finished packaging products disposed of as waste has yet been adopted either for all packaging materials or for glass packaging particularly. Thus, states have the flexibility to interpret and implement their statutes, to permit compliance based on total leachable

[86] *See supra* note 66. The use of glass cullet derived from recycled sources in the manufacture of glass packaging products may, on occasion, result in the unintentional introduction of metals into the products. However, as discussed above, due to the virtually inert qualities of glass, no heavy metals are released from glass packaging products at other than trace or undetectable levels when made from recycled materials either during use or after their disposal, whether such products are disposed in a landfill, incinerated, or composted. Moreover, consistent with its stated environmental intent, the Model Legislation specifically exempted non-hexavalent chromium, which is not a "heavy metal" and not within the Model Legislation or relevant state or international statutes, and which occasionally is intentionally added to glass during its manufacture in order to impart a green tint or color to the glass.

concentrations of heavy metals. Applicable EPA testing methodologies -- particularly, the TCLP -- appear to be the most relevant and appropriate protocols for use in determining whether and to what extent any heavy metals are present in, or can be expected to leach or be extracted from, packaging waste materials, including glass. Like the Model Legislation, the purpose and primary regulatory intent of EPA's TCLP is to further environmental goals by offering an accurate and scientifically replicable means by which the presence of hazardous constituents in waste materials can be measured. In addition, the TCLP provides a high level of precision, accuracy, flexibility, as well as long history of use, and, consequently, broad acceptance in the waste management and scientific communities that make it superior to alternative testing protocols that might be considered to demonstrate compliance with the Model Legislation. Finally, use of the TCLP can provide a precise calculation of the total leachable content in packaging material, while at the same time ensuring, for the purposes of compliance with hazardous waste disposal requirements, that assessments of the heavy metal content in a given waste product are appropriately focused on leachable content (*i.e.*, content that actually is able to leach into the landfill and pose a hazard). This would ensure that packaging testing does not result in an assessment that could incorrectly cause the packaging to be regulated as a hazardous waste when discarded.

Consequently, TPCH and those states adopting the Model Legislation should carefully examine and determine an appropriate, accurate, and replicable testing methodology for use to show compliance with the Model Legislation, with a focus on those testing protocols that not only are historically well-established, but which are derived from a comparable environmental waste regulatory context. Adoption and application of appropriate testing methodologies, such as the EPA testing protocols discussed above, will enable accurate and replicable determinations of heavy metals content in glass packaging, and can be expected to be accepted and employed in the waste management community. Application of such appropriate testing protocols to glass packaging also can reasonably be expected to further confirm that heavy metals migrate only at trace or undetectable levels, and that glass packaging thus properly does not pose environmental health or safety concerns.

APPENDIX A: BIBLIOGRAPHY

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