Bloomberg BNA

Daily Environment Report™

NUMBER 16 JANUARY 26, 2012

REPORTING

TOXIC SUBSTANCES

Based on written communications from the Environmental Protection Agency's Office of Pollution Prevention and Toxics, questions have been raised as to the agency's interpretation of the six chemical categories created under Toxic Substances Control Act Section 8(b)(2) authority. Chemicals long considered part of these well-established categories identified decades ago are complex reaction products that fall under the TSCA Section 8(b)(2) category listing. Given the statements from EPA over the past several years and recognizing that reporting under the TSCA Chemical Data Reporting (CDR) rule is just around the corner, a critically important question is whether chemicals that would otherwise fit within the Section 8(b)(2) categories are subject to reporting under the CDR. This article examines this question by considering the regulatory history and guidance, prior reporting that has occurred, and business issues associated with the question.

Are TSCA Section 8(b)(2) Statutory Mixture Categories Subject to Reporting Under the Chemical Data Reporting Rule?

By Lisa R. Burchi, Charles M. Auer, Kathleen M. Roberts, Lynn L. Bergeson

Introduction

The Toxic Substances Control Act regulates chemical substances.[1] Few TSCA requirements apply to mixtures,[2] which are expressly excluded from the

[1] TSCA §§ 2-412, 15 U.S.C. §§ 2601-2692. Chemical substance is defined as ''any organic or inorganic substance of a particular molecular identity, including - (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical'' except ''[s]uch term does not include - (i) any mixture,'' or other specifically excluded subjects including pesticides, food, food additives, drugs, cosmetics or medical devices. TSCA § 3(2), 15 U.S.C. § 2602(2).

[2] Mixture is defined as ''any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.'' TSCA § 3(8), 15 U.S.C. § 2602(8). *See also* 40 C.F.R.§ 710.4(c)(2) (excluding mixtures from the Inventory). A note to 40 C.F.R. § 710.4(c)(2) states: ''Note: A chemical substance that is manufactured as

 ISSN 1060-2976

TSCA statutory definition of chemical substance.[3] TSCA does not regulate products *per se*, but instead regulates the chemical components that may constitute products, unless expressly excluded in the statutory definition of chemical substance.

TSCA Section 8(b)(1) directs EPA to ''compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States.''[4] This list is known as the TSCA Chemical Substance Inventory (TSCA Inventory or Inventory). TSCA Section 8(b)(2) states: ''To the extent consistent with the purposes of this [Act], the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.''[5] Section 26(c)(1) discusses the concept of ''categories'' more generally under TSCA and clarifies that ''[a]ny action authorized or required . . . under any provision of this [Act] with respect to a chemical substance'' may be taken ''in accordance with that provision with respect to a category of chemical substances.''[6] Section 26(c)(2) goes on to state that ''[t]he term 'category of chemical substances' means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties. . . . ''[7] Interestingly, Sections 8(b)(2) and 26(c) are the only TSCA provisions where the category authority is specifically enumerated.

The initial Inventory reporting rules were published on Dec. 23, 1977.[8] EPA identified six statutory chemical categories under its Section 8(b)(2) authority when the Inventory was first established, with some input from industry.[9] They are:

- Cement, Portland, Chemicals (CASRN 65997-15-1)
- Cement, Alumina, Chemicals (CASRN 65997-16-2)
- Glass, Oxide Chemicals (CASRN 65997-17-3)
- Frits, Chemicals (CASRN 65997-18-4)
- Steel Manufacture, Chemicals (CASRN 65997-19-5)
- Ceramic Materials and Wares, Chemicals (CASRN 66402-68-4)

Once the Inventory was created, those chemical substances on the Inventory were referred to as ''existing'' chemical substances. ''New chemical substance'' refers to any chemical substance not listed on the TSCA Inventory.[10] Under the authority of TSCA Section 5, EPA requires companies to submit premanufacture notifications (PMN) before the commercial manufacture or importation of ''new'' chemical substances. Accordingly, the Inventory establishes the TSCA regulatory status of and requirements on new versus existing chemical substances. The Inventory is thus critically important for companies and other regulated entities to know whether chemical substances commercially manufactured or imported are listed on the Inventory, either individually under Section 8(b)(1) or because they are part of a ''category of chemical substances'' under Section 8(b)(2), or are new chemical substances subject to Section 5 requirements.

EPA has in the more recent past indicated that it intends to publish a ''clarification'' notice in the *Federal Register* for comment, in which EPA will clarify ''the guidance on chemical identification of certain statutory mixtures for purposes of the . . . TSCA Inventory.'' EPA stated that ''[f]or the initial reporting period that established the TSCA Inventory, EPA developed broad listing criteria ('category listings') for the complex reaction products known as statutory mixtures'' and that EPA will clarify which chemical substances comprise complex reaction products that fall under the TSCA Section 8(b)(2) ''category listings'' and those chemical substances ''not currently on the TSCA Inventory'' would be considered to be new chemical substances under TSCA and thus subject to notification under TSCA Section 5. The TSCA Inventory status of the chemical substances contained in these six categories is thus a significant issue to be resolved.

Another important and uniquely pressing issue that EPA's ''clarification,'' and any potential change in policy, may raise concerns the reporting requirements that may apply to these chemical substances. It is important to note that the six statutory mixture categories are composed of inorganic chemicals. Although inorganic chemicals had been fully exempted from Inventory Update Rule (IUR) reporting commencing with the initial reporting in 1986, EPA amended the reporting requirements in 2003, in part to phase-in reporting for inorganic chemicals beginning with the 2006 IUR. Inorganic chemicals are also now subject to somewhat ex-

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part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term ''mixture'' includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.''

[3] Mixtures may be subject to TSCA § 4 test rules, direct regulation under TSCA § 6, and TSCA § 8 recordkeeping and reporting requirements.

[4] TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).

[5] 15 U.S.C. § 2607(b)(2).

[6] 15 U.S.C. § 2625(c)(1).

[7] 15 U.S.C. § 2625(c)(2).

[8] 42 Fed. Reg. 64,572 (Dec. 23, 1977).

[9] *EPA, Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures* (1995) at 4, available at http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/policy.html (1995 Statutory Mixtures Policy) (''When the initial Inventory was being developed, both EPA and industry recognized that the individual substances comprising these mixtures are complex solids and would be very difficult to identify. Therefore, instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include the various substances formed when cement, glass, frit or ceramic are produced.'')

[10] TSCA § 3(9), 15 U.S.C. § 2602(9).

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panded reporting requirements (relative to those in the 2006 IUR) under the recently issued Chemical Data Reporting (CDR) rule for which reporting will begin on Feb. 1. EPA changed the name of the reporting rule from IUR to CDR.[11] Under the CDR rule, inorganic chemicals are potentially subject to reporting if they are a ''chemical substance that is in the Master Inventory File at the beginning of a submission period.''[12] The ''Master Inventory File'' is defined as ''EPA's comprehensive list of chemical substances which constitutes the TSCA Inventory compiled under TSCA section 8(b).''[13] Considering the above, a key question is whether chemical substances that would otherwise fall within the Section 8(b)(2) categories are chemical substances subject to reporting as the category under the CDR. This article examines this question and the issues this core question inspires.

TSCA's Sections 8(b)(2) and 26(c) Legislative History

TSCA emerged from S. 3149 and H.R. 14032. S. 3149 did not include a TSCA Section 8(b)(2) or any similar provision.[14] The Senate bill did contemplate providing EPA with authority to take action with respect to categories of chemical substances or mixtures under TSCA Section 26(c), which provides:

ACTION WITH RESPECT TO CATEGORIES. —

(1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term ''category of chemical substances'' means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term ''category of mixtures'' means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.[15]

When discussing the authority to take action with respect to categories of chemical substances or mixtures, the Senate Report (S. Rep. No. 94-698) accompanying S. 3149 states:

> This authority is given to the Administrator to facilitate the efficient and effective administration of this act and is not to be used in any way that would frustrate the intent of any provision of this Act. Thus, for example, categories might be appropriately used for purposes of compiling the inventory of section 8(b) so that every variation in the distribution of a polymer chain length would not be automatically subject to the premarket notification requirement. However, categories are not to be used in the section 8(b) inventory so as to effectively provide exemptions for new chemical substances intended to be covered under the premarket notification provision.[16]

H.R. 14032 included the following language, which is the same as the current TSCA Section 8(b)(2):

> To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.[17]

The House report (H.R. Rep. No. 94-1341) that accompanied H.R. 14032 states the following with regard to Section 8(b)(2):

> Paragraph 2 of subsection (b) provides that to the extent consistent with the purposes of this bill, the Administrator may in compiling and maintaining the inventory, list a category of chemical substances rather than list individually each chemical substance within the category. By listing a category of chemical substances, minor modifications or variations in the formulation or structure of a chemical substance which would have insignificant health or environmental consequences would not automatically be subject to the notification requirements of section 5. For instance, the Administrator could use categories so that reporting would not be required as a result of changes such as the following: polymers or co-polymers which vary only in the proportion of starting materials or catalysts used, or in molecular weight, molecular weight distribution, chain structure or crystallinity; changes within an existing chemical substance in the proportions of colorants, stabiliz-

[11] 76 Fed. Reg. 50,816 (Aug. 16, 2011) (to be codified at 40 C.F.R. Part 711). *See also* 149 DEN A-3, 8/3/11.

[12] 76 Fed. Reg. 50,860 (to be codified at 40 C.F.R. § 711.5).

[13] *Id.* (to be codified at 40 C.F.R. § 711.3).

[14] Legislative History of the Toxic Substances Control Act Together with a Section-By-Section Index Prepared by the Environment and Natural Resources Policy Division of the Library of Congress for the House Committee on Interstate and Foreign Commerce (Dec. 1976) at 113-114 (Legislative History). *See also id.* at 178,281.

[15] Legislative History at 47.

[16] Legislative History at 187.

[17] Legislative History at 358.

ers, antioxidants, fillers, solvents, carriers, surfactants, plasticizers, and other adjuvants which are themselves reported as existing substances; variations in the proportion of alloyed metals in iron and steel products and other metal alloys; variations in naturally occurring substances or mixtures (such as crude oil, natural gas, minerals, or ores) and the resulting variations in extracts or refined products therefrom; variations in reported reactive mixtures whose commercial or end-use product is electric energy (batteries); and sales which result from the combination of an existing inorganic anion with an existing inorganic cation.

The Committee realizes that many chemical companies, particularly small ones, are able to compete in the chemical industry only by continually reformulating or making slight changes in existing chemical substances. It would be extremely burdensome on them as well as on the Administrator if every insignificant change were subject to the premarket notification requirements of section 5. By using categories in the inventory, the Administrator will be able to minimize such burdens. However, the Committee also realizes that minor modifications of innocuous compounds may produce highly toxic chemicals. Thus, the use of categories should be limited to areas where the effects of such minor modifications are well understood to have insignificant health and environmental consequences.[18]

The House bill also included the same language for Section 26(c) that appeared in S. 3149 and became the language that ultimately was enacted.[19] When discussing this provision in the report accompanying H.R. 14032, the report includes as an example of EPA's authority under Section 26(c) that EPA could issue a Section 4(a) test rule with respect to a category of chemical substances upon making the necessary findings. The report states further: ''It should be noted that in taking action under any provision of the bill respecting a category of chemical substances, the Administrator will not have to make the requisite finding for such action with respect to every chemical within the category.''[20]

When the House was considering H.R. 14032, the following was stated by Sen. James Broyhill (R-N.C.):

There is one thing that I would like to bring out in this colloquy. The gentleman from Nebraska has referred to the premarket notification section of the bill [Sec. 5] and indeed that is perhaps the most controversial portion. He did mention certain exemptions and perhaps one other thing needs pointing out. This is on page 163 with respect to the administrative authority in identifying a chemical substance. It states:

[Sec. 8(b)] (2) To the extent consistent with the purposes of this Act the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

I may say to the gentleman, I think this is an extremely important leeway to the Administrator. Say for instance a chemical substance is manufactured and produced inhouse in an oil and chemical refinery. That chemical substance may be a catalyst that undergoes successive changes. Under these provisions we felt that instead of requiring a 90-day notice every time a change was made that had the result of changing the chemical constituency of the substance, the single category comment.

I think that the gentleman will agree with me this is one of the provisions in which we carefully examined difficulties which could result from too rigid an act and met those possible objections.[21]

The conference report that accompanied the final bill, which included what is now Section 8(b)(2), does not address Section 8(b)(2):

Senate bill (section 8) . . . To determine which substances are new chemical substances for the purpose of the pre-market notification provisions of section 5, subsection (b) requires the Administrator to publish an inventory of existing chemical substances or mixtures which any person report to be commercially manufactured or processed within the United States under subsection (a) or under section 5(a). The Administrator shall publish such list not later than 270 days after the date of enactment.

. . .

House amendment (section 8) . . . With respect to the inventory of existing chemical substances required by subsection (b), the House amendment provides that the inventory shall include at least each chemical substance which any person reports under section 5 or under section 8(a) was commercially manufactured or processed in the United States within 3 years before the effective date of the rules promulgated under section 8(a). The House amendment requires the publication of such inventory within 1 year after the effective date of the Act.

. . .

Conference substitute (section 8) . . . The conference substitute adopts, with some clarification, the House amendment in subsection (b) which requires the Administrator to compile, keep current, and publish an inventory of chemical substances and mixtures manufactured or processed in the United States. The conference committee compromised on the date that the Administrator shall first publish the inventory, which publication shall take place 315 days after the effective date of the Act.[22]

The conference report states that the House amendment includes a Section 26(c) provision similar to S. 3149, and further states that the ''conferees expect that the Administrator will find the authority to categorize especially helpful in promulgating rules under section

[18] Legislative History at 451.
[19] Legislative History at 400-401.
[20] Legislative History at 468.
[21] Legislative History at 523 (excerpted from *Congressional Record*).
[22] Legislative History at 691-694.

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5(a)(2) concerning what constitutes significant new use of chemical substances.''[23]

Section 8(b)(2) Regulatory History

When EPA issued regulations implementing the initial TSCA Inventory over 30 years ago, EPA provided examples of the types of ''mixtures'' that were excluded from Inventory listing by ''definition of section 8(b) of TSCA.'' Specifically, in the December 1977 *Federal Register* notice establishing the TSCA Inventory reporting regulations, EPA stated:

> 710.4 Scope of Inventory
>
> (c) *Substances excluded by definition or section 8(b) of TSCA.* The following substances are excluded from the inventory: . . . (2) Any mixture as defined in § 710.2(q); NOTE.—A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term ''mixture'' includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.[24]

EPA also provided the following commentary:

> Comment 33: Manufacturers of alloys including steel, glasses, ceramics, enamels, Portland cement, and similar combinations of chemical substances should not be required to report for the inventory.
>
> Response: The Administrator agrees with this comment. Alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement, are mixtures under TSCA; manufacturers of these products are not required to report them. However, as stated in a note at § 710.4(c), the exclusion of these products applies only to the mixture and not to the chemical substances of which the mixture is comprised. Thus, the metals in the case of alloys, or oxides in the case of glasses and ceramics, and any additives or components other than impurities, should be included on the inventory. The manufacturers of the metals, oxides, and additives would be responsible for reporting them.[25]

Subsequently, EPA published in 1978 various addenda to assist companies in determining Inventory status from its Candidate List of Chemical Substances. In Addendum III, EPA identified Class 2 substances (*i.e.*, a chemical substance the composition of which cannot be represented by a definite chemical structural diagram) and provided a mechanism for identifying and reporting others.[26] In this addendum, EPA stated the following regarding Section 8(b)(2) category mixtures:

> Certain common materials of commerce, such as inorganic glasses, are defined by the Inventory Reporting Regulations as mixtures. To facilitate reporting, this addendum defines certain categories which *encompass the individual chemical substances* manufactured in the production of these mixtures.
>
> *[A]ny* persons who manufacture such substances may use the nomenclature presented in this addendum to *report for the Inventory* if this nomenclature accurately describes the chemical substances they manufacture.[27]

EPA went on to describe six mixtures and the ''chemical substances manufactured in the production of'' steel, Portland cement, high-alumina cement, inorganic glass, and frit,[28] including providing a CAS Registry Number for each of the six category mixtures.

Attempts were made to develop a summary of the reporting on the Section 8(b)(2) statutory mixture categories which occurred during the initial Inventory reporting, however, the authors were not able to find a publicly accessible copy of the information. Nonetheless, EPA has stated that initial Inventory reporting occurred.[29]

In a letter in 1986, EPA responded to a question posed about the TSCA Inventory status of substances formed during the production of ceramic materials by stating that it ''intends that the TSCA definition of ceramics include all chemical substances formed as a result of the process used in the production of the ceramic material, i.e., heating and scintering, and concurrently incorporated in the ceramic mixture as stated in the Inventory definition of Ceramic materials and wares, chemicals [CAS Registry Number 66402-68-4].''[30] In 1989, EPA responded to another question about the TSCA Inventory status related to the Ceramic Section 8(b)(2) category definition, and went perhaps a bit farther in recognizing that these category definitions were not permanently restricted to only those materials specifically listed by EPA:

> During the TSCA Initial Inventory reporting period, the Agency, in cooperation with the Ceramic Industry, developed a generic Inventory definition to cover all ceramic materials and processes known to be in use by the ceramic industry at that time. Recognizing the fact that the ceramic industry technology would likely change with time, EPA did not intend that the category be limited to those materials made by the processes known to be in use to produce ceramic materials at the time that the original definition was developed. In fact, the Agency has subsequently modified the definition of a ceramic material to extend the list of elements that may be used in the manufacture of ceramics.[31]

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[23] Legislative History at 715.

[24] 42 Fed. Reg. 64,577.

[25] 42 Fed. Reg. 64,585.

[26] EPA, *Toxic Substances Control Act (TSCA) Pub. L. No. 94-469, Candidate List of Chemical Substances, Addendum III, Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials* (Mar. 1978) at 1 (Candidate List of Chemical Substances, Addendum III), available at http://op.bna.com/env.nsf/r?Open=jsun-8qu3sq.

[27] *Id.* (emphasis added)

[28] *Id.* at 41, 77-80.

[29] *See, e.g.*, 1995 Statutory Mixtures Policy at 4.

[30] Letter from Carol A. Farris, Ph.D., Chief, Chemical Inventory Section, EPA, to Ms. Alison A. Kerester, McKenna, Conner, and Cuneo (Oct. 9, 1986).

[31] Letter from Henry P. Lau, Ph.D., Chief, Chemical Inventory Section, EPA to Mr. John S. Kazazis, Chemical Substance Control Manager, AT&T (June 20, 1989).

In 1995, EPA issued its Statutory Mixtures Policy.[32] This guidance was not issued following notice and comment rulemaking, as EPA states that the ''policies set out in this document are not final Agency action, but are intended solely as guidance.''[33] In this guidance, EPA states the following regarding certain ''Combinations that are considered to be statutory mixtures under TSCA,'' which appears to be the first time EPA referred to these as ''statutory mixtures:''[34]

1. Certain alloys, inorganic glasses, ceramics, frits and cements, including Portland cement are considered to be statutory mixtures by the Agency.

Inorganic glasses, ceramics, frits and cements, including Portland cements, are considered to be statutory mixtures under TSCA. Manufacturers of these products are not required to report them. When the initial Inventory was being developed, both EPA and industry recognized that the individual substances comprising these mixtures are complex solids and would be very difficult to identify. Therefore, instead of requiring industry to identify and report every such substance for the Inventory, several special categories were created to include the various substances formed when cement, glass, frit or ceramic are produced. These categories were reported during the initial Inventory reporting period and *are currently listed on the TSCA Inventory*. Each category contains a definition that describes the various components of that category in terms of the elements and the various types of chemical substances that may be formed with these elements. These categories of substances are:

Cement, Portland, Chemicals	[65997-15-1*]
Cement, Alumina, Chemicals	[65997-16-2*]
Glass, Oxide, Chemicals	[65997-17-3*]
Frits, Chemicals	[65997-18-4*]
Steel Manufacture, Chemicals	[65997-19-5*]
Ceramic Materials and Wares, Chemicals	[66402-68-4*]

For example, a category such as Ceramic Material and Wares, Chemicals includes any combination of the elements listed in the Inventory definition, as oxides, borides, carbides, etc., in multiple oxidation states, or in more complex compounds. The listed elements included in the definition of each of these categories are not intended to be inclusive. EPA recognizes that the list of elements may need to be updated from time to time as the state of the technology changes.[35]

In 2007, although not in the context of Section 8(b)(2), EPA stated the following regarding its broad authority to regulate chemical categories under TSCA Section 26:

> EPA has broad discretion to determine whether to regulate by category under TSCA section 26(c). Beyond the language of TSCA section 26(c), this discretion is evidenced by the fact that TSCA section 21(b)(4)(B)(i) provides an opportunity for a *de novo* hearing with respect to petitions for testing of chemical substances, but not for categories of chemicals or mixtures. As with mixtures, Congress left the complex issues associated with regulation by category to the Administrator's discretion. Congress intended this authority to ''facilitate the efficient and effective administration'' of TSCA. S. Rep. No. 94-698, at 31.[36]

Recent Activities

When EPA developed the IUR, it provided an exemption for inorganic substances. With EPA's 2003 IUR amendments (IURA), manufacturers of inorganic chemical substances were required to report these substances for the first time under the 2006 IUR.[37] It does not appear that the Section 8(b)(2) category mixtures were discussed in detail prior to EPA's promulgation of its 2003 IURAs with its new requirements for inorganic chemical substances and a 2006 document, *Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database: Inorganic Chemicals Addendum*, does not address the six statutory mixture categories established under TSCA Section 8(b)(2).[38] Moreover, EPA's response-to-comment document does not include any references to Section 8(b)(2) or statutory mixtures.[39]

In a 2004 draft version of its *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database*, EPA states the following when discussing how companies can determine whether it manufactures or imports 25,000 pounds of a reportable chemical substance:

> In many cases, reportable substances are contained within a mixture. Although mixtures are not reportable, the chemical substances making up a mixture are reportable. If you manufacture the substances as part of a mixture, you should determine whether the production volume for each substance in the mixture is 25,000 pounds or more. Note, however, that a person who produces a mixture by combining existing substances without a chemical reaction is not a manufacturer of those substances and, therefore, does not have to report those substances under the IUR. Appendix D contains a paper explaining the conventions

[32] 1995 Statutory Mixtures Policy, *see supra* note 9

[33] *Id.* at 1

[34] Thus this term was not used in developing the initial Inventory nor has it been the subject of a rulemaking.

[35] 1995 Statutory Mixtures Policy at 4 (emphasis added).

[36] 72 Fed. Reg. 72,886, 72,892 (Dec. 21, 2007) (denying a TSCA Section 21 petition asking EPA to issue regulations pertaining to ''air fresheners''). *See also* 245 DEN A-5, 12/21/07.

[37] 40 C.F.R. Part 710, subpt. C.

[38] EPA, *Questions and Answers for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database: Inorganic Chemicals Addendum* (Nov. 2006), available at http://www.epa.gov/iur/pubs/guidance_qanda_inorganics.pdf.

[39] EPA, *Summary of EPA's Responses to Public Comments Submitted in Response to the Proposed TSCA Inventory Update Reporting Modifications Rule* (July 2011), EPA-HQ-OPPT-2009-0187-0449, available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0187-0449.

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that are applied to listings of certain mixtures in the TSCA Inventory.[40]

Appendix D referred to by EPA is its 1995 Statutory Mixtures Policy. None of this language or the policy is included in EPA's final instructions.[41] There does not appear to be a publicly available explanation clarifying the reasons for its deletion.

A summary of the reporting on the Section 8(b)(2) statutory mixture categories which occurred during the 2006 IUR reporting based on EPA's publicly available IUR database[42] is as follows:

- Cement, Portland: 18 entities at 32 production sites, reported > 1 billion pounds (total);
- Cement, Alumina, Chemicals: Four entities at four sites, reported 1 to 10 million pounds;
- Glass, Oxide, Chemicals: Seven entities at eight sites reported 50 to 100 million pounds;
- Frits, Chemicals: Four entities at five locations reported 50 to 100 million pounds;
- Steel Manufacture, Chemicals: 47 entities at 87 sites reported > 1 billion pounds; and
- Ceramic Materials and Wares, Chemicals: 10 entities at 18 sites reported > 1 billion pounds.

These numbers may reflect an inconsistency in how statutory mixture categories were reported under the 2006 IUR, since certain categories have volumes in the millions and others having volumes in the billions, although these differences may also be explained if certain manufacturers claimed their data as confidential business information. In the final CDR rule, EPA stated that it was replacing the 5-digit NAICS codes with 48 Industrial Sector (IS) codes, and one of the codes is for ''Non-metallic Mineral Product Manufacturing (includes clay, glass, cement, concrete, lime, gypsum, and other non-metallic mineral product manufacturing)'' although there is no discussion of how this IS code relates to any reporting obligations on statutory mixture categories.[43]

When industry sought clarification in 2007 regarding the Section 8(b)(2) chemical categories and potential PMN requirements, EPA's response raised several concerns about EPA's current interpretation of its Section 8(b)(2) Statutory Mixtures Policy. The first EPA letter, dated September 18, 2007, responded to four questions related to the TSCA Inventory status for ''Glass, oxide, chemicals'' and ''Ceramic material and wares, chemicals.''[44] In response to a question asking EPA to ''reaffirm EPA's longstanding guidance on the use of CASRNs that were established for the six categories,'' EPA responded in part:

> Consistent with this regulatory text [at Section 710.4(c)(2) and its Note], EPA did not intend for these six chemical descriptions and CASRNs, which the Agency sometimes refers to as ''statutory mixtures,'' to be used to establish chemical nomenclature and determine Inventory status for actual chemical substances manufactured or imported for commercial purposes that may in a generic sense be thought of or described as either Portland cement, alumina cement, glass, frits, steel, or ceramics. The CASRNs for these ''statutory mixtures'' were included in the Initial Inventory for the purpose of defining the scope of these very broad categories of substances, with the expectation that particular substances or mixture components that fall within one of these categories of materials and that are intended to be commercially manufactured would be subject to TSCA reporting if they were not already explicitly listed in the Inventory.[45]

In response to another question regarding EPA's view whether manufacturers and importers of chemical materials covered by the category descriptions should obtain unique CASRNs, EPA responded in the letter as follows:

> Regarding substances that may fit within the definitions of the six ''statutory mixture'' categories, specific chemical identifications that represent reaction products instead of starting materials should be used for TSCA purposes whenever the manufacture of the substances involves new chemical bond formation. In these types of materials, the new bonding may yield crystalline or semi-crystalline matrices. It is the specific identity of the chemical reaction product composition that must be either already included in the Inventory or reported as a new chemical.
>
> For example, with a ceramic type of material, if a particular chemical substance is to be manufactured as a result of a high temperature calcination process that causes new bond formation, the specific chemical identity of that chemical product needs to be included in the Inventory before manufacture may commence for a non-exempt commercial purpose. Such a chemical product must be either listed in the Inventory or reported in a TSCA Section 5 new chemical notice according to its synthesized chemical composition. It is not considered covered for TSCA purposes by the ''statutory mixture'' category ''Ceramic materials and wares, chemicals'' (CASRN 66402-68-4).
>
> On the other hand, if a product associated with one of these categories does not involve intended chemical reactions, such that no chemical bonds form during its manufacture, the product composition is considered a mixture and identified by the starting materials charged in the manufacture of the material.
>
> It has always been TSCA Inventory policy to list substances as specifically as possible. For materi-

[40] EPA, Draft *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (Nov. 2004) at 2-11, available at http://www.regulations.gov by searching for EPA-HQ-OPPT-2005-0008-0003.

[41] EPA, *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database* (Nov. 2006), available at www.epa.gov/iur/pubs/2006_inst_tsca_cheminv.pdf.

[42] EPA, IUR Data for 2006, available at http://www.epa.gov/iur/tools/data/2006archivedata.html.

[43] 76 Fed. Reg. 50,827.

[44] Letter from Tracy C. Williamson, Ph.D., Chief, Industrial Chemistry Branch, EPA, to Greg McCarney, 3M Toxicology and Regulatory Services (Sept. 18, 2007) (2007 EPA Letter).

[45] *Id.* at 2.

> als that can be grouped within the six categorical descriptions you mentioned, many individual chemical substances that constitute chemical reaction products actually formed during the manufacture of the materials have been reported and listed in the Inventory since the Initial Inventory reporting period.[46]

On May 28, 2008, EPA issued another letter ''regarding materials that EPA and the regulated community have sometimes referred to as statutory mixtures.''[47] In the letter, EPA states:

> EPA believes that, consistent with this regulatory text [Section 710.4(c)(2)], the Agency did not intend for the descriptions and corresponding Chemical Abstracts Service (CAS) Registry Numbers (CASRNs) for the very broad existing categorical chemical names – including materials such as ceramics, cements, inorganic glasses, and frits – to be used to establish chemical nomenclature, TSCA reportability, Inventory listing policy, or Inventory status, for actual chemical substances manufactured or imported for commercial purposes. These categorical descriptions and their CASRNs, each of which represents a broad class of substances, were included in the Initial Inventory for the purpose of defining their scope to the public. Section 710.4(c)(2) of the Inventory Reporting Regulations again indicates that these categories are excluded from reporting. Specific chemical substances that might fall within one of these broad categories of materials, and that are intended to be commercially manufactured, are subject to TSCA reporting if they are not already individually listed in the Inventory. Since by regulation the individual chemical substances manufactured as part of mixtures cannot be excluded from reporting for TSCA purposes, the manufactured component chemical substances of the materials referred to as statutory mixtures can in this respect be treated the same under TSCA as the component substances produced in other types of synthesized mixtures.[48]

After noting that EPA has had a longstanding policy to list chemical substances on the Inventory as specifically as possible, EPA further states with regard to chemical mixtures:

> EPA has observed an industry trend toward the commercial development of ceramic-like materials that are better defined compositionally, are chemically more specific, and often require relatively precise stoichiometric and compositional control during their manufacture. These substances also can exhibit definite elemental ratios, and unit cell structure and atomic coordination sites may be able to be determined. These characteristics typically enable them to perform in more specified and higher technological uses. These characteristics also lend them to be more appropriately identified and described using much more specific chemical names than the categorical description of ceramics. . . . EPA believes that it is consistent with long-standing policy for the Agency to review and/or list particular substances of a ceramic or inorganic glass nature, for example, that are commercially manufactured or imported.[49]

Several industry trade associations and individual companies requested that EPA withdraw its September 2007 and May 2008 letters, finding EPA's statements inconsistent with the statute and EPA's longstanding guidance and interpretations of the Section 8(b)(2) category listings. It was argued that the six products (*e.g.*, Portland cement, glass, steel) are mixtures that are exempt from Inventory listing regardless of any ''statutory mixture'' classification; it is the chemical substances that are manufactured during the production of these mixtures that are ''existing'' chemical substances as part of the statutory mixture categories created by EPA when the Inventory was first developed. Industry also noted its concern that EPA's decision potentially to revise significantly the manner in which it interprets TSCA Section 8(b)(2) would have potentially devastating impacts on business, costs, and innovation.[50]

In the most recent development, and notwithstanding industry's comments, EPA appears to be moving forward, albeit slowly, with its ''clarification'' of Section 8(b)(2) and how it applies to TSCA Inventory category listings. In its December 2009 Action Initiation List and its spring 2010 semiannual regulatory agenda, EPA provided a notice of its intent to continue with its ''clarification'' of the scope and coverage of the Section 8(b)(2) category listings, and indicated that the effort would affect at least three of the statutory mixture categories. While describing the planned action as a ''clarification,'' EPA has indicated that this action is in the proposed rule stage. EPA describes its planned action in 2009 and 2010 as follows:

> *TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes*
>
> EPA is clarifying the guidance on chemical identification of certain statutory mixtures for purposes of the [TSCA] Chemical Substance Act Inventory (TSCA Inventory). For the initial reporting period that established the TSCA Inventory, EPA developed broad listing criteria (''category listings'') for the complex reaction products known as statutory mixtures. These include ceramics, cements and frits. Since that time, there has been inconsistent guidance for manufacturers of such substances with regard to whether new chemical notification

[46] *Id.* at 3.

[47] Letter from Tracy C. Williamson, Ph.D., Chief, Industrial Chemistry Branch, EPA, to Michael P. Walls, American Chemistry Council (May 28, 2008) at 1 (2008 EPA Letter).

[48] 2008 EPA Letter at 1-2.

[49] 2008 EPA Letter at 3.

[50] Letter from Alan J. Olson, P.E., Director of Product Stewardship, Ferro Corporation to Stephen A. Owens, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, EPA (Feb. 4, 2011); Letter from J. Lawrence Robinson, President, Color Pigments Manufacturers Association Inc., to Stephen A. Owens, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, EPA (Aug. 31, 2010); Letter from American Chemistry Council Coalition to Stephen A. Owens, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, EPA (June 16, 2010).

  DEN ISSN 1060-2976

> under Section 5 of TSCA was required for such new substances. Under this action, EPA will clarify which chemical substances comprise complex reaction products that fall under the ''category listings'' and which chemical substances (not currently on the TSCA Inventory) would be considered to be ''new'' chemical substances under TSCA and thus be subject to new chemical notification under TSCA Section 5.[51]

Statutory mixtures are not the only substances for which EPA has indicated an intent to clarify TSCA Inventory status. On February 24, 2010, EPA issued in the *Federal Register* notice a ''final clarification'' describing those ''activated phosphors'' that are not on the TSCA Inventory and thus ''new'' chemical substances for which PMNs would be required.[52] In the notice, EPA states that:

> Partly as a result of the Agency's incomplete information and understanding of the chemistry involved in manufacturing activated phosphors, from 1978 through 2003, EPA was inconsistent in its statements to potential submitters and in its actions regarding whether activated phosphors are considered distinct chemical substances for purposes of the TSCA Inventory.[53]

EPA states further:

> Because EPA does not view activated phosphors as mixtures, some previous EPA statements that such materials may not need to be reviewed through the new chemicals process were incorrect. As a result of certain past EPA statements, some manufacturers of activated phosphors have not submitted new chemical notices under TSCA section 5 because those statements incorrectly indicated that activated phosphors were covered for TSCA purposes if the phosphors and activators were already on the TSCA Inventory.[54]

As a result of this clarification, EPA provided companies with 18 months to submit PMNs for any commercial manufacture or import of any activated phosphors that were not on the TSCA Inventory but for which PMNs were now required. If EPA were to issue a ''clarification'' for statutory mixtures, the way in which EPA addressed activated phosphors could be a model that it attempts to apply to statutory mixture categories. It appears that in both cases, EPA has noted that increased understanding of the chemistry at issue and ''inconsistent'' guidance from EPA are some of the reasons EPA has sought to ''clarify'' these issues.

There are, however, significant differences between these cases. Importantly, activated phosphors are not one of the categories of statutory mixtures (and thus EPA did not previously develop a Section 8(b)(2) category for activated phosphors). EPA also appears to admit more freely that EPA's communications regarding the TSCA Inventory status of activated phosphors were ''incorrect'' and not just ''inconsistent.''

Implications/Next Steps

While industry's recent letters and EPA's responses address the TSCA Inventory status of these statutory mixture categories and their components, less attention has been paid to how any such clarification may affect CDR reporting requirements now that manufacturers and importers must report inorganic substances. The issue of reporting Section 8(b)(2) category mixtures was not discussed in detail when either the 2003 IURAs or the 2011 CDR were issued. What is known is that under the CDR, a chemical substance, including an inorganic chemical substance, can be subject to reporting if it is a ''chemical substance that is in the Master Inventory File at the beginning of a submission period.''[55]

It seems clear that, as has been acknowledged by EPA in prior rulemakings and guidance noted above,[56] and despite informal statements offered in more recent EPA correspondence,[57] the Section 8(b)(2) statutory mixture categories are ''listed'' on the TSCA Inventory because they are in the Master Inventory File. It is also the case that reporting occurred on these categories during both the initial Inventory and the 2006 IUR (that was the first IUR not to exempt inorganic chemicals) reporting cycles.

While EPA has stated its intent to issue a clarification on the TSCA Section 8(b)(2) categories and their TSCA Inventory status, it has not yet issued such a notice and thus there is no change from the situation described immediately above. It thus would appear that manufacturers and importers of chemical substances falling within the Section 8(b)(2) statutory mixture categories should be reporting as required under the terms applicable in the 2012 CDR reporting cycle (*i.e.*, included in Master Inventory File and meets other reporting criteria) using the CASRN and chemical name that identifies the relevant statutory mixture category and which includes ''the various substances formed when [such a statutory mixture] is produced.''

While based on the results of this analysis this seems like a reasonable answer, this is admittedly an obscure issue[58] and it is less than clear how widely this understanding is held by the chemical industry. It is clear to the authors that this issue was not discussed when the 2003 IURAs and associated guidance documents were developed. Based on the results of the 2006 IUR reporting, it appears that some—but potentially not all—

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[51] EPA, ''Action Initiation List'' (AIL) Regulation Identifier Number (RIN) 2070-AJ68 (Dec. 2009), available at http://www.epa.gov/lawsregs/search/ail.html. *See also* EPA 2010 semiannual regulatory agenda at 105-106, available at http://www.epa.gov/lawsregs/documents/regagendabook-spring10.pdf. *See also* 27 DEN A-6, 2/11/10.

[52] 75 Fed. Reg. 8266 (Feb. 24, 2010).

[53] *Id.* at 8267.

[54] *Id.* at 8268. It is important to note that the discussion for activated phosphors relates to TSCA's definition and exclusion from TSCA Inventory listings for ''mixtures'' (see *supra* note 2) and not TSCA Section 8(b)(2) statutory mixture categories.

[55] 76 Fed. Reg. 50,860 (to be codified at 40 C.F.R. § 711.5).

[56] *See, e.g., Candidate List of Chemical Substances, Addendum III*, at Introduction; 1995 Statutory Mixtures Policy at 4.

[57] 2007 EPA Letter, 2008 EPA Letter.

[58] This paper presents essentially everything that could be identified and obtained on the topic of Section 8(b)(2) statutory mixture categories. Attempts were made to identify relevant journal articles via searches of bibliographic databases using various combinations of terms such as ''TSCA Section 8(b)(2)'' or ''statutory mixture.'' The searches did not produce any articles relevant to the topic which suggests that it has not received much discussion or recognition over the 30-plus years since the TSCA Inventory was developed, and particularly little attention with regard to IUR/CDR reporting.

affected entities recognized the issue. Surprisingly, the issue did not surface from the public nor was it raised by EPA in the recent proposed revisions to the IUR that were promulgated as the CDR, with reporting to begin early in 2012. All of which may leave the affected industry in a bit of a quandary.

Thus, companies that manufacture or import chemical substances falling within these statutory mixture categories may wish to consider the benefits of compiling the necessary information and submitting reports to EPA consistent with CDR reporting requirements. Seemingly such information would at a minimum be of considerable value in clarifying the scale of production and the scope of the entities that commercially manufacture or import the statutory mixture categories. Such information may be helpful to EPA as it continues to ponder its ''clarification'' of the issue.

About the authors:

Lisa R. Burchi is Of Counsel at Bergeson & Campbell PC, a Washington, D.C., law firm concentrating on the regulation and business issues associated with industrial, agricultural, biocidal, and specialty chemicals and Food and Drug Administration-regulated products. Charles M. Auer is President of Charles Auer & Associates LLC and formerly director of EPA's Office of Pollution Prevention and Toxics. Kathleen M. Roberts is Vice-President of B&C Consortia Management LLC and was previously a Senior Director with Regulatory and Technical Affairs at the American Chemistry Council. Lynn L. Bergeson is a Managing Principal of Bergeson & Campbell PC.

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  DEN ISSN 1060-2976