

September 25, 2017

To: General Issues Committee

Re: TSCA Inventory Reset Survey and Related Impacts

On August 11, 2017, the [TSCA Inventory Notification \(Active-Inactive\) Rule](#) was published in the Federal Register. 82 Fed. Reg. 37520. The final rule initiates an industry survey for reporting of chemicals manufactured or processed in the U.S. over the past 10 years (June 21, 2006 – June 21, 2016). This survey will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce. EPA will eventually publish a revised TSCA Inventory divided into active and inactive lists of chemicals.

As explained more fully below, reporting under this rule is not required for chemicals already reported in response to either the 2012 or 2016 Chemical Data Rules or in a Notice of Commencement of manufacture submitted since June 21, 2006. EPA has published a list of all such chemicals, which includes a long list of inorganic and organic pigments. Importantly, however, anyone wishing to maintain a claim of confidentiality for a substance listed on the confidential portion of the TSCA Inventory must do so in a submission pursuant to this rule, even if the chemical is exempt from mandatory reporting.

This memorandum provides an overview of the TSCA Inventory Reset rule. It also highlights several respects in which the final rule is less burdensome than its proposed version, thanks to comments from CPMA and others.

Manufacturers and Importers: The mandatory reporting period for manufacturers, including importers, began on August 11, 2017 and will end on **February 7, 2018**. Manufacturers, including importers, are required to notify EPA of chemical substances on the TSCA Inventory that they manufactured or imported during the ten-year time period ending on June 21, 2016. Under TSCA, manufacturing and importing are equivalent activities. Hereafter, references to manufacturing are intended to mean manufacture or import.

Processors: The optional reporting period for processors began on August 11, 2017 and will end on **October 5, 2018**. (Manufacturers cannot use the processor period to report; they must finish by February 7, 2018.)

Forms: All information must be submitted electronically to EPA via EPA's Central Data Exchange (CDX) <https://cdx.epa.gov/>. Prior to submission to EPA via CDX, Notices of Activity (NOA) and any associated information must be generated and completed using the e-NOA software module. The proposed forms are based on the well-known TSCA Notice of Commencement form, since the proposed information requirements are substantially similar. 82 Fed. Reg. 37541.

NOA Form A: Will be used by manufacturers, importers, and processors for reporting on existing chemicals on the TSCA Inventory. Form A requires the following information:

- Company
- Official technical contact
- Chemical Abstract Service ("CAS") Registry Number
- TSCA Inventory name
- Accession Number (if the substance is on the confidential portion of the TSCA Inventory) and required certification statements

NOA Form B: Will be used by manufacturers, importers, and processors, after publication of the revised active/inactive Inventory, for moving a chemical from the inactive list to the active list. Form B submissions require the same information as Form A, as well as the anticipated date by which substance is to be manufactured or processed in the United States.

For the benefit of processors, EPA will publish a *draft* active TSCA Inventory “as soon as practicable” after the 180-day manufacturer reporting period for the survey ends on February 7, 2018. The draft active TSCA Inventory will not legally designate any substance as inactive, so manufacturing may continue even if a chemical is not on the draft active TSCA Inventory. 82 Fed. Reg. 37525.

Processor Reporting: Processing of a chemical substance will be prohibited under TSCA Section 8(b)(5) after the effective date of EPA’s designation of the chemical as inactive. 82 Fed. Reg. 37541. If a substance is not reported as active by manufacturers, a processor has the option of reporting the substance during the extended survey period provided to processors. Processors can also elect not to report at all. In the case of imported ingredients used by processors, this provision may be very important for maintaining uninterrupted raw material supplies from foreign sources, which may not respond to the survey.

“Forward-Looking” Reporting:

Substances reported in commerce since June 21, 2006 will, in the future, be listed on the "active" portion of the TSCA Inventory. Substances that are on the current TSCA Inventory and have not been reported as being in commerce since June 21, 2006 will, at the same time, be listed on the "inactive" portion of the TSCA Inventory. Thereafter, any person who intends to manufacture or process an inactive substance for a non-exempt purpose will have to file a Form B notice in order to move the substance to the active portion of the TSCA Inventory.

Form B should be submitted not more than 90 days prior to the anticipated date of manufacturing or processing the inactive substance. 82 Fed. Reg. 37541. This effectively creates a notice period and allows manufacturers and processors an opportunity to submit a Form B before the effective date of the inactive designation.

Substances in commerce exempted from reporting:

EPA will not require reporting for chemical substances where EPA already has equivalent notice of active status. This includes all chemicals reported in either the 2012 or 2016 Chemical Data Reports (regardless of public or confidential TSCA Inventory status) and all chemicals added to the TSCA Inventory during the look back period (June 21, 2006 - June 21, 2016) pursuant to a Notice of Commencement form under the Premanufacturing Notice regulations. 82 Fed. Reg. 37523.

EPA has already published an “[Exemption List of Active Substances](#)” containing approximately ten thousand chemicals exempt from the survey on this basis, which will eventually be transferred to the active portion of the TSCA Inventory. This list includes substances on the confidential portion of the existing TSCA Inventory identified by generic name with applicable accession numbers. Many inorganic pigments are identified on that list by Colour Index name. All of the organic pigments and some inorganic pigments on that list are identified by CAS number and generic name.

We have identified the following inorganic and organic pigments on the Exemption List. These pigments are examples, but this is not a comprehensive list of all pigments contained on the Exemption List. Members should review the list to determine whether pigments and other significant products and raw materials that they care about are already included on the Exemption List:

Inorganic Pigments

C.I. Pigment Black 11
C.I. Pigment Black 12
C.I. Pigment Black 26
C.I. Pigment Black 28
C.I. Pigment Black 30

C.I. Pigment Blue 28
C.I. Pigment Blue 29
C.I. Pigment Blue 72
C.I. Pigment Blue 36

C.I. Pigment Brown 7
C.I. Pigment Brown 24
C.I. Pigment Brown 33
C.I. Pigment Brown 35

C.I. Pigment Green 26
C.I. Pigment Green 50

C.I. Pigment Red 104
C.I. Pigment Red 108
C.I. Pigment Red 231
C.I. Pigment Red 233

C.I. Pigment Violet 15

C.I. Pigment Yellow 35
C.I. Pigment Yellow 34
C.I. Pigment Yellow 42
C.I. Pigment Yellow 53
C.I. Pigment Yellow 119
C.I. Pigment Yellow 159
C.I. Pigment Yellow 163
C.I. Pigment Yellow 164
C.I. Pigment Yellow 184

Organic Pigments

C.I. Pigment Blue 15
C.I. Pigment Blue 61

C.I. Pigment Green 7
C.I. Pigment Green 18
C.I. Pigment Green 36

C.I. Pigment Orange 16
C.I. Pigment Orange 36
C.I. Pigment Orange 62
C.I. Pigment Orange 34

C.I. Pigment Red 2
C.I. Pigment Red 3
C.I. Pigment Red 48:2
C.I. Pigment Red 53:1
C.I. Pigment Red 57:1
C.I. Pigment Red 112
C.I. Pigment Red 122
C.I. Pigment Red 169
C.I. Pigment Red 179
C.I. Pigment Red 224
C.I. Pigment Red 254

C.I. Pigment Violet 19
C.I. Pigment Violet 23
C.I. Pigment Violet 27

C.I. Pigment Yellow 3
C.I. Pigment Yellow 12
C.I. Pigment Yellow 13
C.I. Pigment Yellow 14
C.I. Pigment Yellow 17
C.I. Pigment Yellow 65
C.I. Pigment Yellow 73
C.I. Pigment Yellow 74
C.I. Pigment Yellow 75
C.I. Pigment Yellow 83
C.I. Pigment Yellow 97
C.I. Pigment Yellow 154
C.I. Pigment Yellow 174
C.I. Pigment Yellow 176
C.I. Pigment Yellow 180
C.I. Pigment Yellow 191
C.I. Pigment Yellow 194

The final rule also does not require reporting for:

- Mixtures as defined in 40 CFR 710.3(d).
- Naturally occurring substances (with limited manufacturing and processing prescribed by EPA).
- Impurities and byproducts with no subsequent commercial purpose.
- Manufactured non-isolated intermediates.
- Import or processing of substances solely as part of articles.

- Substances not considered “chemical substances” under 3(2)(B) of TSCA such as pesticides, food, food additives and drugs.
- Substances that are not listed on the TSCA Inventory due to Section 5(h) exemptions: polymers, substances manufactured under a low volume exemption, research and development, test marketing, low release/low exposures.¹

Confidentiality Provisions:

For substances listed on the confidential portion of the existing TSCA Inventory, manufacturers must submit survey reports using Form A if they wish to maintain existing TSCA Inventory confidentiality claims for specific chemical identity.

If EPA does not receive a timely Form A with a confidentiality claim for an active substance on the current confidential portion of the TSCA Inventory, EPA will publicly identify the substance on the active portion of the TSCA Inventory. 82 Fed. Reg. 37527. The exempt active TSCA Inventory contains many confidential substances listed by generic name and accession number. Survey submitters can assert and maintain a confidentiality claim for specific chemical identity even if they were not the original claimant. All claims for confidentiality for specific chemical identity must be reasserted in response to the survey. A claimant does not need to substantiate its claim at the time of submission - substantiation will be required on a schedule to be determined under a separate, forthcoming CBI review plan rule. But EPA will allow companies to submit substantiation for specific chemical identity at the time Form A is filed, and companies that elect to do so will be exempt from the subsequent substantiation requirement, so long as the due date for that requirement is within five years of when the substantiation was received.

After completion of the survey, requests for specific confidential chemical identity for “forward-looking” reporting on Form B for substances on the inactive portion of the TSCA Inventory must be made on Form B and substantiated not later than 30 days after submitting the Form B. 82 Fed. Reg. 37543.

All claims for CBI other than specific chemical identity must be reasserted and substantiated at the time of Form A or Form B submission.

Regardless of exemptions, a Form A will need to be filed to maintain a current confidentiality claim for chemical identity. The exception to this is that chemicals added to the TSCA Inventory on or after June 22, 2016 are already subject to the amended TSCA statute and covered by its CBI assertion and substantiation requirements. (The Reset requirements only apply to CBI claims asserted before June 22, 2016).

Co-manufacturing, Co-processing and Joint Submissions. The rule allows companies that co-manufacture or co-process a chemical substance to file a single submission. The rule also allows a domestic manufacturer to file a joint submission with a foreign supplier if the supplier claims the chemical identity of an imported ingredient to be confidential.

¹ Manufacturers of a current substance under a low volume, low exposure or polymer exemption will need to respond to the survey using Form A if the substance is on the public version of the current TSCA Inventory, or if it is “reasonably ascertainable” by the manufacturer or importer that the substance is on the confidential portion of the current TSCA Inventory. 82 Fed. Reg. 37528-37529.

Industry Wins

EPA made a number of important changes from the proposed version of the rule based on comments from CPMA and others:

Confidential Business Information: EPA will allow anyone to assert a CBI claim regarding chemical identity, regardless of who asserted it before. 82 Fed. Reg. 37527.

Look Back Reporting: EPA dropped its proposed requirement that survey respondents report the dates that they manufactured a substance since June 21, 2006. This is a significant win for industry, eliminating the burden of identifying specific dates between June 21, 2006 and June 21, 2016 that a company (or its predecessors in interest) made or imported a substance. 82 Fed. Reg. 37534.

Nomenclature: Based on longstanding concerns for the class 2, variable TSCA Inventory entries for complex inorganic color pigments, CPMA requested that EPA maintain the existing entries and nomenclature on the TSCA Inventory after the survey. The final rule indicates that EPA will continue to use the existing TSCA Inventory nomenclature. This is especially important for Class 2 substances and statutory mixtures.

Terminology: EPA is retaining specific defined terms that have been used for years in the administration of the TSCA Inventory, and is not inventing any new terminology for purposes of the final rule. Specifically, the definitions of “manufacture for commercial purposes” and “process for commercial purposes” are taken verbatim from the definition of “manufacture or import for commercial purposes” in the PMN rules (40 C.F.R. § 720.3(r)).

Type of Commercial Activity. In response to comments, EPA dropped its proposed requirement that survey respondents provide specific information about type of commercial activity (i.e., domestic manufacture or import). 82 Fed. Reg. 37525.

One and Done: Industry groups, including CPMA, advocated for a “one and done” survey process, in which a manufacturer would not have to submit a Form A if another person had already submitted a Form A for the same chemical. As a result, EPA dropped its proposed requirement that every manufacturer report its manufacture of a substance during the survey, even if other survey respondents also report the same chemical. Under the final rule, a manufacturer does not need to submit a Form A for a chemical if can obtain a CDX receipt of a Form A submitted by another manufacturer for the same chemical. This could save companies a significant amount of time and effort, depending on how easily they can obtain CDX receipts for chemicals previously submitted by others. 82 Fed. Reg. 37531.