



## Use of the Chemical Name in Managing New Chemical Polymers under the Amended Toxic Substances Control Act<sup>1</sup>

May 31, 2017

### 1.0 Background

#### 1.1 Identification of Polymers on the TSCA Inventory

Polymers make up about 30%<sup>2</sup> of the chemical substances included in the original Inventory created under the old Toxic Substances Control Act (TSCA, Pub. L. No. 94-469). “Chemical substance” is defined in TSCA Section 3(2)(A) to mean “any organic or inorganic substance of a particular molecular identity.” EPA’s guidance on polymers states that “[an] Inventory listing for each polymer describes a *category* of possible chemicals that would fit that substance name, instead of just representing a single molecular structure”<sup>3</sup> and can vary within that listing in molecular weight (MW) and composition (*e.g.*, the ratios or the order of reaction of the starting monomers). Most polymers on the Inventory are identified (or “named”) in terms of the monomers used in their manufacture (“manufacture” also includes import) as well as other reactants (*e.g.*, free-radical initiators, cross-linking agents) that become chemically incorporated into the polymer structure, subject to the two percent rule (see below). Other polymers are identified using Structural Repeating Unit representation. The two percent rule states that the description of the polymer must include monomers and chemically incorporated reactants used at

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<sup>1</sup> This proposal was developed by three former officials in the U.S. Environmental Protection Agency’s (EPA) Office of Pollution Prevention and Toxics (OPPT), all of whom now work at Bergeson & Campbell, PC (B&C<sup>®</sup>): Charles M. Auer, Senior Regulatory and Policy Advisor, who both worked in and managed the new chemicals program in OPPT and was the OPPT Office Director when he retired in 2009 after 32 years at EPA; Richard E. Engler, Ph.D., Senior Chemist, who worked as an expert Toxic Substances Control Act (TSCA) chemist in OPPT’s Industrial Chemistry Branch for 17 years where he participated in the review of thousands of new chemical notices; and Oscar Hernandez, Ph.D., Senior Regulatory Chemist, who worked as a risk assessor and manager in the Risk Assessment Division in OPPT for over 30 years and participated in the review of tens of thousands of new chemicals over his 30 year career in OPPT until his retirement as the Director of the Risk Assessment Division.

<sup>2</sup> EPA, Overview: Office of Pollution Prevention and Toxics Laws and Programs (2008) (OPPT 101), available at [http://archive.epa.gov/oppt/pubs/oppt101\\_tscalaw\\_programs\\_2008.pdf](http://archive.epa.gov/oppt/pubs/oppt101_tscalaw_programs_2008.pdf).

<sup>3</sup> EPA, Toxic Substances Control Act Inventory Representation for Polymeric Substances (1995) (emphasis added), available at <https://www.epa.gov/tsca-inventory/polymeric-substances-tsca-inventory>.

greater than two percent by weight, although monomers and reactants used at less than two percent may be included in the name.

## 1.2 Experience with New Chemical Polymers under Old TSCA

Approximately 60 percent of the new chemicals submitted to EPA as premanufacture notifications (PMN) under Section 5 of old TSCA were polymers.<sup>4</sup> While some new chemical polymers were identified as a concern by EPA<sup>5</sup> (examples include acrylate/methacrylate, polyanionic, and polycationic polymers), as discussed below, most new chemical polymers were generally considered by EPA to present low hazards, especially those that have high MW such that absorption by people or environmental organisms was limited and, as such, under old TSCA most PMN polymers were not regulated. In fact, OPPT developed an approach to “drop” low concern polymers based on initial review by its chemists that applied criteria, discussed below, developed over time by the new chemicals program based on its experience with new chemical polymers. Subsequently, these considerations and criteria served as the starting point for the TSCA Section 5(h)(4) polymer exemption under which certain polymers could be exempted from PMN requirements (codified at 40 C.F.R. § 723.250).

The best available description of the polymer drop criteria used by OPPT is found in EPA’s Chemistry Assistance Manual for Premanufacture Notification Submitters issued in 1997:<sup>6</sup>

Based on its experience during the review of thousands of new chemical substances, EPA has identified a group of polymers (see below) that it believes poses no unreasonable risk of harm to human health or the environment. When a PMN substance in initial chemistry review falls within this group, the [OPPT’s

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<sup>4</sup> OPPT 101.

<sup>5</sup> EPA, TSCA New Chemicals Program Chemical Categories (2010), available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new>.

<sup>6</sup> EPA, Chemistry Assistance Manual for Premanufacture Notification Submitters (1997), available at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemistry-assistance-manual>.

Industrial Chemistry Branch] chemist labels the case a "[CRSS<sup>7</sup> drop]" and the Agency performs no further review.

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For a polymer to be considered a [CRSS drop], it must satisfy all six of the following criteria:

- (1) It must belong to one of twelve (12) acceptable polymer classes: polyesters, polyamides and polyimides, polyacrylates, polyurethanes and polyureas, polyolefins, aromatic polysulfones, polyethers, polysiloxanes, polyketones, aromatic polythioethers, polymeric hydrocarbons, and phenolformaldehyde copolymers;
- (2) The levels of oligomer present in the polymer must be less than or equal to (a) 10 weight percent of polymer molecules with molecular weight less than 500 daltons and (b) 25 weight percent of polymer molecules molecular weight less than 1,000 daltons;
- (3) It must have no more than the level of ionic character permitted by the polymer exemption rule (generally a functional group equivalent weight for ionic groups greater than or to 5,000);
- (4) It must have (a) no reactive functional groups, (b) only reactive functional groups specifically excluded based on OPPT's risk assessment experience (e.g., blocked isocyanates), or (c) a reactive functional group equivalent weight no less than a defined threshold (e.g., for pendant methacrylates, the equivalent weight threshold is 5,000);
- (5) The lowest number-average molecular weight of the polymer must be less than 65,000 daltons but greater than 1,000 daltons; and
- (6) the polymer must not swell in water.

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<sup>7</sup> CRSS is the Chemical Review and Search Strategy meeting held early in EPA's initial review of Section 5 notices.

These criteria have been developed for use by EPA, although they can be useful to submitters interested in developing low risk polymers. These criteria should not be confused with the criteria stated in the Polymer Exemption Rule ([40 C.F.R. § 723.250]), which specifically exempt certain polymers from PMN submission. (The above criteria were used, however, in the development of the Polymer Exemption Rule).

It has been the Agency's experience that polymers meeting these criteria have a low risk for causing adverse environmental and human health effects. Both the group of acceptable polymer classes and the reactive functional group are being updated and expanded as OPPT's experience in risk identification and assessment continues to grow. The actual figure varies from time to time, but, in general, many of the PMNs for polymers meet these criteria and are dropped from further review. (Many of these polymers also qualify for exemption and need not be reported at all.)

The CRSS drop criteria applied by OPPT may have changed since this description from 20 years ago, however. At a minimum, the criteria have been changed to reflect modifications made in the polymer exemption to exclude certain perfluorinated polymers (40 C.F.R. § 723.250).

Other examples of efforts to assess low concern polymers include the information developed by EPA for the Sustainable Futures program<sup>8</sup> and an Organization for Economic Cooperation and Development (OECD) expert meeting considering criteria for identifying polymers of low concern.<sup>9</sup> Both can provide additional insights that could be helpful in identifying and refining criteria for low concern polymers.

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<sup>8</sup> EPA, Sustainable Futures Interpretative Assistance Document (2013), available at [https://www.epa.gov/sites/production/files/2015-05/documents/06-iad\\_polymers\\_june2013.pdf](https://www.epa.gov/sites/production/files/2015-05/documents/06-iad_polymers_june2013.pdf).

<sup>9</sup> OECD, Data Analysis of the Identification of Correlations between Polymer Characteristics and Potential for Health or Ecotoxicological Concern (2009), available at <https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf>.

## 2.0 Dealing with Polymers under Amended TSCA

Under new TSCA (Pub. L. No. 114-182), EPA is required to assess and make a determination on each PMN chemical that is submitted. The Section 5(a)(3) determinations include:

- (A) Presents an unreasonable risk;
- (B)(i) Information available is insufficient to permit a reasoned evaluation of the hazards;
- (ii)(I) May present an unreasonable risk;
- (ii)(II) Produced in substantial quantities and has substantial or significant exposure; and
- (C) Not likely to present an unreasonable risk.

If EPA makes any of the (A) or (B) determinations, it is required to regulate under Section 5(f) or (e), respectively, to the extent necessary to protect against an unreasonable risk. EPA is also required in making certain of the determinations and in regulating to consider the “conditions of use” of the new chemical, a term that as defined (TSCA Section 3(4)) includes “intended, known, or reasonably foreseen” circumstances for manufacture, processing, and use, among others. New chemical polymers as notified may be intended to be manufactured only at high MW but, because of the way they are named for the Inventory, as noted by EPA in its Polymer Guidance, a given polymer describes a category of possible chemicals that would fit that substance name and could vary in MW and composition. Thus, as a result of this polymer naming convention, although notified as a high MW polymer, other forms of the polymer could present particular issues when considering reasonably foreseen circumstances that include manufacture at a lower MW. Other reasonably foreseen aspects could include manufacture of forms of the new polymer within the category described by the name that are relatively more water soluble or reactive (such that the reactive functional group equivalent weight is lower). Such changes could present increased concerns relative to those for a high MW, insoluble, and less reactive form of the new polymer that is the subject of the PMN. Thus, while the PMN polymer when manufactured as intended could meet CRSS drop criteria (as described above) and be designated as “not likely” to present an unreasonable risk, other reasonably foreseen forms of the polymer could present concerns.

If EPA makes a (C) determination of “not likely to present an unreasonable risk,” the notifier can begin manufacture once the determination has been made and EPA is required by Section 5(g) to

publish a statement of its finding in the *Federal Register* (see, e.g., 82 Fed. Reg. 19044, (Apr. 25, 2017)). The *Federal Register* notice includes a link to the EPA determination for each such PMN (see, for example, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-39>).

EPA in its early efforts to implement new TSCA seems to be taking a precautionary approach to new polymers that likely results from the need to make a determination that can include consideration of reasonably foreseen conditions of use. This arguably requires EPA to consider the potential risks associated with reasonably foreseen forms of the polymer that differ from that intended by the notifier and, to the extent this results in EPA not being able to support a “not likely” determination, may force EPA to regulate under Section 5(e). Table 1 presents outcome statistics for PMNs under new TSCA. As can be seen, EPA has indicated its intention to regulate 21 percent of the PMNs under Section 5(e) on the basis of reasonably foreseen uses (an additional 46 percent of the PMNs are slated for regulation under Section 5(e) on the basis of intended and reasonably foreseen uses). Recognizing that about 60 percent of the PMNs submitted to EPA under old TSCA were polymers suggests that a significant portion of the cases represented by the 21 percent figure are polymers. It is likely that potential manufacture of the new polymer in a form other than as described in the PMN (e.g., as a lower MW form) is an important contributor to the reasonably foreseen circumstances that are triggering EPA’s intention to pursue regulatory action.

Typically, regulation of new chemical polymers takes the form of an order under Section 5(e) and/or a Significant New Use Rule (SNUR) under Section 5(a)(2). Although EPA has stated that it could not use a “non-5e SNUR” (using, for example, the procedures at 40 C.F.R. § 721.170) to accomplish the needed control, this reluctance may be changing. Among the options, a non-5e SNUR seems to present the least potential for delay although, if not implemented carefully, such a SNUR could present regulatory burdens (regulatory compliance and recordkeeping) to the submitter and downstream customers and, in the case of exports, result in the need for export notices under Section 12(b). Another similar option is to impose a boilerplate Section 5(e) consent order that obligates the submitter to the SNUR conditions without imposing testing; furthermore, the consent order could be written to expire upon publication of the final SNUR. Such a policy would reduce the often extensive negotiations related to developing consent orders.

As discussed at the outset, EPA has developed and applies an approach to naming polymers that in effect creates a category of possible polymers that can vary in MW, composition, properties, and so on. When manufactured as an existing chemical, the substance produced must be consistent with the name/identity (including the definition, if one is included) on the Inventory. This thus constitutes a legal requirement that the named monomers must be present, but imposes no other limitations on the make-up of the polymer product. Given the need for EPA to review

and make determinations on all PMN chemicals, and considering reasonably foreseen conditions of use that, based on a name that describes a category of polymers could result in production of polymers that differ in MW or in other important ways from the intended polymer described in the PMN, might there be approaches wherein EPA could develop a new way to identify substance categories (like polymers) such that the name itself provides a way of ensuring that such substance categories consist of a subcategory of polymers that are of low concern and could satisfy the “not likely” determination including consideration of reasonably foreseen conditions of use? The use of such a “subcategory” naming approach is explored in the next section.

### **3.0 Discussion of an Approach to Using Chemical Name/Identity to Create Subcategories of New Chemical Polymers as an Alternative to Reduce the Burdens and Complexity of Regulation under Section 5**

EPA has developed and applied criteria for identifying “polymers of low concern” in the polymer exemption and in the informal CRSS drop process described earlier. In the case of the polymer exemption, polymers made under the exemption must meet specific requirements consistent with the polymer subcategory represented by the exemption. In the case of CRSS drops under old TSCA, the polymer as notified, based on EPA’s review, was judged to meet the applicable criteria for such drops as developed by EPA. These criteria include certain limitations in the classes of polymers that are eligible, the MW of the new polymer, the presence of reactive functional groups over a certain threshold, and other properties and characteristics. Although it represents a departure from current practices for naming TSCA polymers, approaches to naming could be developed to take advantage of the fact that a polymer as named for the Inventory represents a category of possible substances and, by careful use of the chemical name, EPA can create a subcategory that distinguishes polymers that meet some specific requirements that would lead to low concern (*e.g.*, that meet the polymer exemption or CRSS drop criteria) from polymers that contain the same monomers, but need not meet these low concern criteria when manufactured. The approach is to divide the category of substances represented by the undifferentiated polymer name from the subcategories that meet the low hazard criteria. By taking this subcategory approach, EPA can justify making a “not likely” determination for such polymers and meet its statutory obligations without the need for costly and time-consuming regulatory action (*e.g.*, a consent order and SNUR). (It is recognized that there are instances where EPA can determine that a new chemical polymer named in the usual TSCA manner is not likely to present an unreasonable risk (*see*, for example, “determination-39” referenced above). The subcategory naming approach is not relevant in such cases.) Furthermore, the requirement under new TSCA that EPA, in making a “not likely” determination, must publish a statement of its findings can be used to make public EPA’s rationale for applying a subcategory approach to naming the polymer.



In the following examples, the capital letters indicate monomers or chemically incorporated reactants that would be used to name a TSCA polymer. The examples illustrate approaches that could be taken in naming/identifying new chemical polymers as subcategories, and it is recognized that there are other constructions that could be found useful.

- A, polymer with B, C, and D, E initiated, polymer exemption eligible.
  - Inventory guidance would be developed to make clear that the underlined, term when present in the name, requires that the polymer, as manufactured, is a subcategory that must meet the terms of the current polymer exemption.
  
- A, low concern polymer with B, C, and D, E initiated.
  - Inventory guidance would be developed to make clear that the underlined term, when present in the name, indicates that EPA has reviewed the polymer as a new chemical and determined that it is not likely to present an unreasonable risk. The guidance would also discuss and make clear that this term, when present in the name, requires that such polymers when manufactured must meet the relevant subcategory criteria (such as the polymer exemption or CRSS drop criteria) that would be elaborated and, as needed, kept current in the guidance.
  
- A, polymer with B, C, and D, E initiated, low concern.

Definition: Meets the definitions and criteria in 40 C.F.R. § 723.250(b), (d), and (e).

- Similar to the “polymer exemption eligible” option above, the Inventory listing for this subcategory would include a definition that cross-references the criteria necessary for EPA to find low concern. This example shows a reference to the polymer exemption and the approach suggested makes all of the flexibility present in the polymer exemption available to the PMN manufacturer. The definition could also reference the CRSS drop criteria as elaborated in Inventory guidance, or be specific for a particular PMN. Such criteria might include a limitation on the MW or the content of a functional group of concern. The *Federal*



*Register* reference to EPA's not likely determination on the PMN could also be noted in the definition.

EPA's current guidance on the role of a definition in the chemical name clarifies EPA intent with regard to the effect of a definition. For example:

- In its guidance document for UVCB substances (unknown or variable composition, complex reaction products and biological materials), EPA makes the following statement:<sup>10</sup>

These substances have supplemental definitions that are considered integral parts of the names for TSCA purposes. In general, the definitions serve to narrow the scope of the CA Names. Thus, any substance that matches a CA Name on the TSCA Inventory but is not covered by the corresponding substance definition is not considered to be covered by that Inventory name.

- In the guidance document for complex reaction products, EPA makes the following statement:<sup>11</sup>

[D]efinitions are often developed to supplement the chemical names if the name itself does not adequately define the characteristics and limitations of the substance category. The definition often describes the scope of composition by indicating such information as the typical or allowed carbon number ranges or physical property ranges, the types of atoms or substances that may be included, and the allowed raw material sources or processes of manufacture. For all substances that have a supplemental definition, that definition is considered to be part of that name for TSCA purposes.

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<sup>10</sup> EPA, Toxic Substances Control Act Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials: UVCB Substances (1995), available at <https://www.epa.gov/sites/production/files/2015-05/documents/uvcb.pdf>.

<sup>11</sup> EPA, Toxic Substances Control Act Inventory Representation for Combinations of Two or More Substances: Complex Reaction Products (1995), available at <https://www.epa.gov/sites/production/files/2015-05/documents/rxnprods.pdf>.

All three of these options will potentially lead to separate subcategory listings on the Inventory for polymers that are made from identical monomers. For example, one subcategory that is identified in a specified way (*e.g.*, meeting the polymer exemption criteria) and one that does not include such a specification. Although this could lead to a proliferation of entries on the Inventory, in practice, such an outcome is not likely. The approach would be used with notified new chemical polymers (ones for which EPA is required to make a determination) and such polymers would either present an opportunity to be named/identified as a subcategory meeting low concern criteria (such as those in the polymer exemption or CRSS drop), or not. If the polymer as notified presents concerns such that the “not likely” determination cannot be made, EPA would impose restrictions to protect against the identified unreasonable risk using a consent order and/or SNUR rather than seeking to apply a subcategory.

A system that uses the chemical identity to create subcategories that limit the forms of the polymer that can be manufactured under that name provides strong protection with minimal EPA resources and no consent order or SNUR is required to produce this outcome. This way, the delay in realizing the innovation benefits of such “safe” polymers would be minimized. Arguably EPA could make the “not likely” determination on such polymers early in the PMN review process, as was the case for CRSS drops under old TSCA; furthermore, under new TSCA, manufacture can commence once the determination was made. The time and expense associated with developing and issuing the consent order and SNUR would be saved, and the impacts of regulatory actions on the supply chain are minimized.

We acknowledge that the subcategory naming approach discussed above is a departure from the long-standing current system of identifying polymeric chemical substances under TSCA. However, as EPA states, polymer listings on the Inventory are categories of substances and EPA can certainly develop nomenclature methodology that permits dividing a particular category into subcategories. The statutory obligations under new TSCA impose significant new requirements on EPA, manufacturers, and others in the supply chain; a creative solution such as incorporating low concern criteria in a substance’s identity to create a low concern polymer subcategory will allow all parties to focus their limited resources managing substances that may present unreasonable risks, as opposed to subcategories of low hazard substances that are not likely to present such risks.

**Table 1. PMN Statistics under New TSCA** (<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/interim-status-section-5-notices>)

|   | <b>Cases Reviewed under Amended TSCA</b> |
|---|--|
| <b>PMNs Submitted</b>   | <b>513</b>                               |
| <b>Invalid</b>  | <b>39 (8%)</b>                           |
| <b>PMNs reviewed through March 13, 2017</b>   | <b>322</b>                               |
| <b>Determinations:</b>  |  |
| <b>5(e) regulation -- Insufficient information</b>  | <b>71 (21%)</b>                          |
| <b>5(e) regulation -- May present unreasonable risk for intended and reasonably foreseen uses</b> | <b>148 (46%)</b>                         |
| <b>5(e) regulation -- May present unreasonable risk for reasonably foreseen uses</b>              | <b>68 (21%)</b>                          |
| <b>5(e) regulation -- Exposure based</b>  | <b>0 (0%) (?)</b>                        |
| <b>Not likely to present an unreasonable risk</b>   | <b>35 (11%)</b>                          |