A Practical Understanding of the Polymer Exemption

INTRODUCTION

The polymer exemption at 40 C.F.R. § 723.250 exempts qualifying polymers from the premanufacture notification requirements of section 5 of the Toxic Substances Control Act (TSCA), (40 C.F.R. § 720). To implement the exemption persons need only internally and in writing certify compliance with the exemption as of the date of first manufacture or import under the exemption, notify the Environmental Protection Agency (EPA) before January 31 as to the number of polymers (if any) commenced under the exemption in the preceding calendar year, and keep certain records. The exemption is based on the premise that certain new, relatively large, stable, inert molecules can be exempted from premanufacture notice (PMN) review before they are manufactured or imported.

The first TSCA “exemption” for polymers, finalized in 1984, required submission and EPA review based on an abbreviated form of a PMN that was referred to as a polymer exemption notice (PEN). If approved, polymers subsequently reported to be manufactured or imported for commercial purposes were listed, with restrictions, on the TSCA Chemical Substance Inventory (Inventory). While the current polymer exemption is significantly more complicated than the original exemption, a much larger percentage of polymers are likely to be eligible, more than offsetting its increased complexities. Its most exceptional feature is that one can manufacture or import an eligible new polymer virtually without delay. One also does not have to satisfy many of the other requirements of the PMN process: filing a detailed submission, paying a user fee, and obtaining a Chemical Abstracts Index Name for the polymer. Not having to undergo EPA review not only saves time and money, it also eliminates the possibility of an adverse determination upon review.

Unfortunately, determining whether a given polymer will qualify for the exemption is not always simple. Because EPA does not make a contemporaneous, independent review, it is essential that businesses correctly interpret the exemption and carefully apply its provisions.

A potential user of the TSCA polymer exemption should begin by definitively establishing the chemical identity and relevant characteristics of the subject polymer. Polymers whose identities and relevant characteristics cannot be sufficiently defined should be presumed to be ineligible for the exemption. This includes polymers that have precursors or key properties that are not completely known. Professional assistance should be sought regarding polymer characterization and for polymers whose chemical identities are complex, inconsistent, incomplete, or otherwise difficult to establish.

EPA requires a one-time report for each polymer manufactured or imported under the exemption. Manufacturers and importers of the exempt polymers must report the number of polymers that have been commercialized. EPA must receive this report by January 31 of the year following the calendar year in which an exempt polymer was first manufactured in or imported into the U.S. under the exemption.

Preparing an accurate report is impossible unless one can validly distinguish one polymer from another. This task can be difficult because manufacturers can create polymers with vastly different properties that EPA considers the
same polymer under TSCA. Conversely, manufacturers can produce polymers that are differentiated under TSCA even though they consist of essentially the same molecules. The problems of polymer discrimination and identification can be more difficult when polymers are manufactured from other polymers. One must therefore: (1) establish the chemical identity of the polymer; and (2) confirm that the identity of the polymer is unique compared to any other polymer identities for which the exemption has previously been invoked.

In March 2006, EPA published a Federal Register notice proposing to amend the polymer exemption to address Agency concerns about polymers that contain certain perfluoroalkyl groups.[1] In January 2010, EPA promulgated the final rule, which eliminated eligibility for new polymers and revoked eligibility for existing polymers under the exemption if the polymers incorporate specific types of perfluoroalkyl groups.[2]

As a final introductory comment, in our experience the lure of self-determined eligibility under the polymer exemption may be its greatest potential liability. Because the exemption allows immediate manufacture of an eligible polymer, internal review may be rushed or inadequate and lead to non-compliance. We hope that the guidance provided below will materially assist you in avoiding errors the first and every time that you invoke this exemption.

I. POLYMER EXEMPTION REQUIREMENTS The polymer exemption has three types of requirements: (1) a polymer definition, (2) exclusions, and (3) conditions. Because the conditions are most likely to limit the availability of the exemption, we address the conditions first.

A. Paragraph (e) Conditions

Paragraphs (e)(1), (e)(2), and (e)(3) of 40 C.F.R. § 723.250 provide three alternative conditions. Basically, paragraphs (e)(1) and (e)(2) apply to two non-overlapping ranges of molecular weight. Paragraph (e)(3) applies to certain polyesters and has no explicit molecular weight requirement. Because it is the simplest of the three and, if applicable, eliminates the need to satisfy more onerous requirements, its applicability is preferable and should be considered first. Due to its simplicity, (e)(3) is also easy to use or eliminate. If the candidate substance contains no ester linkages, or its precursors contain any atomic elements other than carbon, hydrogen, oxygen, silicon, or chlorine, then one should move on to (e)(1) and (e)(2).

1. Condition (e)(3)

Paragraph (e)(3) applies to polyesters. To be eligible under (e)(3), polymers must satisfy a minimal polyester definition. The other (e)(3) requirement is that polyesters must be manufactured from a list of acceptable reactants. If a candidate substance contains no ester linkages, or is manufactured from a precursor which is not listed as an acceptable reactant, (e)(3) is not acceptable.

The list of acceptable reactants is provided in the table at 40 C.F.R. § 723.250(e)(3). With one exception, all of the reactants on the list contain only the atomic elements carbon, hydrogen, oxygen, and silicon. Because one listed precursor consists of the hydrolysis products of reactants that include the element chlorine, chlorine might remain in this single precursor and in the polyesters created from it. Without consulting the list, one knows that a precursor that contains nitrogen, fluorine, phosphorus, or sulfur obviates the (e)(3) condition because no listed precursor contains these atomic elements.
2. Condition (e)(1)

Paragraph (e)(1) covers polymers with number-average molecular weights (NAMWs) of at least 1000 but less than 10,000. Polymers in this molecular weight range also always must have a molecular weight distribution such that there are less than 25 weight percent oligomers with molecular weights below 1000 and less than 10 weight percent oligomers with molecular weights below 500. All of the criteria must be met simultaneously for the condition to apply.

In addition, polymers that meet the molecular weight criteria of the (e)(1) condition must also satisfy an important limitation for certain reactive functional groups (RFGs). Because this RFG limitation functions more like an exclusion, it is discussed below with other exclusions.

3. Condition (e)(2)

Paragraph (e)(2) covers polymers with molecular weights of 10,000 or greater. The concomitant requirements for molecular weight distribution are oligomer contents of less than five weight percent with molecular weights less than 1000 and less than two weight percent with molecular weights less than 500.

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<tr>
<th>Condition</th>
<th>MW min</th>
<th>MW max</th>
<th>% &lt;500 max</th>
<th>% &lt;1000 max</th>
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<tr>
<td>(e)(2)</td>
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<td>none</td>
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Comparing the criteria in paragraphs (e)(1) and (e)(2) above reveals an unintended gap: certain polymers that should be eligible under the exemption may not satisfy either provision. Consider a polymer with a NAMW of 10,100 and a molecular weight distribution that includes three weight percent of polymer molecules with less than 500 molecular weight. If such a polymer is eligible under this exemption at all, it would have to qualify under (e)(3). A polymer with a NAMW of 9900, could be eligible even if its oligomer content with molecular weights below 500 were nine percent, three times higher than the oligomer content of the polymer above that has a higher NAMW! [3]

Polymers that qualify under (e)(2) also are subject to a (d)(5) limitation regarding water-absorbing ability. Although this limitation is an exclusion that in principle applies to any polymer that qualifies under any of the three conditions, it cannot apply to (e)(1). Due to its unlikely application to (e)(3), its function is primarily that of an (e)(2) limitation. Because it is ambiguous and is an exclusion under paragraph (d), this limitation is discussed with the other exclusions below.

B. Exclusions

Paragraph (d) of the 1995 polymer exemption provided five exclusions. The 2010 amendments added a sixth exclusion. The first three exclusions under paragraph (d) are revamped versions of exclusions from the original
exemption rule. The fourth and fifth exclusions concern the regulatory status of precursors and the capacity of a polymer to absorb water. As was noted above, the water-absorption exclusion applies primarily to condition (e)(2). The new, sixth exclusion concerns the presence of certain perfluoroalkyl groups.

As was noted earlier, there are two other exclusions that are not explicitly listed as exclusions but function as such and are discussed in this section of this document. One such exclusion is the reactive functional group exclusion that is tied to condition (e)(1). The second additional exclusion is the implicit molecular weight floor of 1000 under the (e)(1) condition. Both additional exclusions are discussed below. Due to its preemptive effect, we begin with the fourth exclusion under paragraph (d).

1. (d)(4); Unreviewed Reactants

This exclusion prohibits a manufacturer or importer commercializing a polymer under the polymer exemption if any one or more of the reactants used or incorporated at two weight percent or more are not listed on the TSCA Inventory or manufactured under an applicable exclusion to section 5 of TSCA. Used and incorporated have special meanings that are discussed below under the heading, Two-Percent Rule.

The (d)(4) exclusion for polymer precursors that have not been reviewed or “grandfathered” as existing chemicals in the U.S. is a problem primarily for polymer importers. A manufacturer or importer of a polymer is not in a position to file a bona fide intent to manufacture or import notice (bona fide inquiry) under 40 C.F.R. § 720.25 requesting EPA to determine the Inventory status of a reactant used to manufacture the polymer unless the importer or manufacturer of the polymer intends to manufacture or import the reactant itself for a commercial purpose. It may need to overcome the (d)(4) exclusion by filing a PMN for the reactant and, at least once, importing the reactant. Alternatively, an importer could file a PMN for the polymer without qualifying the reactant. Either remedy involves additional time and money.

Independent of polymer exemption issues, no substance can be manufactured, imported, processed, or used, unless the substance is included on the TSCA Inventory or manufactured or imported under an applicable exclusion. To legally manufacture any substance for a non-exempt commercial purpose under TSCA in the U.S., all its reactants must be manufactured or imported in compliance with section 5 of TSCA, i.e., be existing substances or subject to an exclusion from reporting under section 5 of TSCA. If the reactants used are subject to a section 5 exclusion, the requirements of the polymer exemption still must be met. Outside of the U.S., reactants are available that are not included on the Inventory or covered under an applicable exclusion. However, the polymer exemption does not necessarily disqualify as polymer precursors non-Inventory-listed reactants that are used or incorporated at two weight percent or less in a polymer.

2. (d)(1); Positively Charged Polymers

This provision eliminates cationic or some potentially cationic polymers from the exemption unless the polymer has a sufficiently low charge density or it is a non-dispersible, non-soluble solid. Cationic polymers are those that include molecules that contain a positive charge. Polymers that are associated with non-polymeric, positive counterions are not cationic polymers.

Polymers are potentially cationic if they are reasonably anticipated to become cationic in a natural aquatic
environment (e.g., polymers that bear one or more amino groups or isocyanate groups [4] that can hydrolyze to amino groups). A polymer is ineligible for the exemption if the equivalent weight of all cationic groups is less than 5000 [5] unless the polymer is a solid that is neither soluble nor dispersible in water and will only be used as a solid.[6] A threshold of 5000 equivalent weight means that the mass of the substance that constitutes one molar unit of positive charge is 5000 grams or greater.

The (d)(1) exclusion applies solely to cationic groups; while the presence of potentially cationic groups might trigger this exclusion, such polymers still could be eligible for the polymer exemption if the actual charge in the natural aquatic environment is below the threshold concentration.[7] The simultaneous incorporation of negative charge does not cancel positive charge for the purpose of this exclusion.

Equivalent weight is not necessarily related to molecular weight. The molecular weight may be high or low for the same equivalent weight and vice versa. The equivalent weight of a substructure is only related to molecular weight when the mean number of substructures per molecule is accurately known.

3. (d)(2); Atomic Element Limitations

This exclusion limits the identities of the atomic elements that constitute an eligible polymer. All eligible polymers must contain as an integral part of their composition two or more of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur. In the original polymer exemption this kind of requirement was accompanied by a requirement for a minimum level of carbon. This carbon floor is not part of the current polymer exemption.

The specific monatomic counter ions, Na+, Mg+2, Al+3, K+, Ca+2 are permitted. Chlorine, bromine, and iodine are permitted whether they are covalently bound to carbon or as the specific monatomic counter ions, Cl-, Br-, and I-. Covalently-bound fluorine is permitted, but only if it is not incorporated as one or more trifluoromethyl groups that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.[8] Fluorine is never permitted as any ion. Either alone or in any combination, the atomic elements, lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, or zirconium are permitted at less than 0.20 weight percent total.

No other atomic elements are permitted. Unusual oxidation states of the permitted counterions, and excess combinations of elements such as phosphorus and boron also are excluded under this limitation. This limitation is not relevant to impurities. Impurities are not considered an “integral part of the polymer’s composition.”

4. (d)(3); Instability

Polymers cannot be manufactured or imported under the polymer exemption if they substantially degrade, decompose, or depolymerize. Under the original exemption, EPA generally limited its consideration of degradation, decomposition, and depolymerization issues to the use of the polymer and not its eventual disposal. Under the current exemption, this limitation applies if the polymer substantially degrades, decomposes, or depolymerizes — or is designed (or can be reasonably anticipated) to substantially degrade, decompose, or depolymerize — prior to, during, or after use.

Although EPA maintains that the exclusion in the final rule is substantively the same as in the original rule, the
difference in emphasis is potentially significant. On one hand, the exclusion seems to reward the absence of degradation data, assuming susceptibility to degradation is not apparent. On the other hand, alkyd resins and other polymers might be ineligible because they could be “reasonably anticipated to substantially degrade, decompose, or depolymerize ... after use, even though they are not actually intended to do so.” Many polymers were judged to be eligible under the original exemption because they were not designed nor reasonably anticipated to substantially degrade, decompose, or depolymerize in use. Now substantial degradation in a wastewater treatment plant might be reasonably anticipated for those same polymers.

Although biopolymers no longer are explicitly excluded from the polymer exemption, to be eligible, biopolymers must not substantially degrade, decompose, or depolymerize. Most biopolymers can be reasonably anticipated to substantially degrade, decompose, or depolymerize — prior to, during, or after use.

In the absence of explicit guidance, part of the previous exemption’s scope appears to be lost for polymers that could be substantially degraded during disposal. Rather than filing PMNs, polymer manufacturers and importers could seek determinations from EPA as to whether degradation will be considered substantial.

5. (d)(5); High Molecular Weight, Water-Absorbing Polymers

This provision excludes certain water-absorbing polymers from eligibility for the polymer exemption. It defines a water-absorbing polymer as one “that is capable of absorbing its own weight of water” and has a NAMW equal to or greater than 10,000.[9] In other words, a polymer that has a NAMW of 10,000 or more and that is capable of absorbing a mass of water that is equal to, or more than, the mass of the polymer may not be manufactured or imported under the exemption.

As discussed in the preamble of the 1995 polymer exemption rule,[10] the exclusion for water-absorbing polymers is intended primarily to address concerns for “super absorbent” polymers, also known as “super slurpers.” The exclusion responds to information received as a notification of substantial risk under section 8(e) of TSCA for a water-absorbing polyacrylate.

The exclusion for water-absorbing polymers is problematic primarily for polymers that might be eligible under paragraph (e)(2). Because the (d)(5) exclusion applies across the entire exemption, it only applies to polymers with NAMWs of 10,000 or greater. It does not apply to condition (e)(1). Polymers manufactured only from reactants that are listed under paragraph (e)(3) and that have molecular weights of 10,000 or more are not likely to meet the definition of water-absorbing. The permissible reactants for (e)(3) polyesters are not conducive to absorbing water after being incorporated into polymers.

Unlike some other aspects of polymers, the property of water absorption generally does not attach to a polymer’s chemical identity. Rather, the capability to absorb water can be characterized for a particular version of a given polymer. Conversely, if some version of a polymer manifests a prohibited degree of water absorption, the polymer is necessarily ineligible for the exemption.

Determining whether a given substance is a water-absorbing polymer might not be straightforward. The definition of a water-absorbing polymer as “a polymeric substance that is capable of absorbing its own weight of water” provides meager guidance. Polymers are often manufactured in association with solvents and other substances
(including residual precursors) that makes the assessment of the water-absorbing status of the polymer, per se, unclear or impractical.

The capacity of every polymer to absorb water need not always be determined to establish compliance with the polymer exemption. The subject polymer may be totally soluble in water or in a solvent that consists of water to a significant extent. Alternatively, as manufactured, the polymer may be dispersed in water or in a solution that contains a significant level of water. Formation of a polymer as a waterborne solution or dispersion does not necessarily mean that the polymer has absorbed its own weight in water. The polymer phase of the emulsion may be hydrophobic with little or no absorbed water, or it may be hydrophilic and pervaded with a great deal of absorbed water.

Moreover, the exclusion pertains to the capacity of a polymer to absorb water. Polymers that are manufactured as aqueous solutions or dispersions may escape the water-absorbing exclusion on the basis that they have absorbed as much water as possible and are not capable of absorbing any more.

At the other extreme, the polymer might not have sufficient affinity for water to be considered water-absorbing. Clearly, hydrophobic polymers that are not appreciably wet by water do not need to be evaluated for their non-water-absorbing capacity.

If a polymer is isolated from its solution or dispersion and cannot be dissolved or dispersed again in water, such a polymer should not be considered water-absorbing. However, if such a polymer will be processed in a manner that creates particles, and those particles are capable of absorbing their own weight of water without dissolving, the polymer should be considered excluded because the risks that EPA seeks to avoid with this exclusion for high molecular weight polymers might be expected to be realized.

If a particular polymer might absorb and retain enough water to be considered water-absorbing, we typically recommend use of the modified tea bag method to determine the absorptive capacity of the polymer. Originally developed by the Corn Refiners Association and subsequently disseminated by EPA on its website, the test protocol provides one approach to determining the swellability of high molecular weight polymers.

The sample of the polymer should be that version of the polymer that is intended to be commercialized that has the greatest capability for water absorption. The water-absorbing exclusion provided by paragraph (d)(5) applies to all production of the polymer for the exemption’s conditions under paragraph (e)(2) and all versions of polyesters that have a NAMW of 10,000 or greater under paragraph (e)(3). That a particular version of a polymer is not water-absorbing does not qualify any other version of the same polymer if it is water-absorbing. In short, the exclusion must never be violated by any version even if some versions satisfy this limitation.

6. (d)(6); Certain Perfluoroalkyl Groups

The 2010 amendments added a sixth exclusion to the five exclusions of the 1995 polymer exemption. Under a new paragraph (d)(6), the perfluoroalkyl groups that are no longer permitted “as an integral part of” the composition of new polymers under the polymer exemption after February 26, 2010, include:

one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length: Perfluoroalkyl
sulfonates (PFAS), perfluoroalkyl (PFAC), fluorotelmomers, or perfluoroalkyl moieties that are covalently bond to
either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

The 2010 amendments stipulated that no new polymer could be manufactured or imported under the polymer
exemption after February 26, 2010, unless it complied with the exclusion at paragraph (d)(6). Polymers that were
validly manufactured or imported under the 1995 polymer exemption before February 27, 2010, that contain
(except as impurities) any of the newly-excluded perfluoroalkyl groups no longer could be manufactured under the

The perfluoroalkyl groups that are no longer permitted in new polymers under the TSCA polymer exemption after
February 26, 2010, could be more briefly described as one or more trifluoromethyl groups that are covalently
bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer
molecule. In a pendant perfluoroalkyl group of more than one carbon, a CF$_3$- group is covalently bound to a carbon
atom.

The 2010 amendments have no impact on most eligible polymers and do not necessarily affect all polymers that
contain covalently bound fluorine. While the (d)(6) exclusion excludes long-established perfluoroalkyl groups, EPA
did not attempt to exclude perfluororalkyl groups covalently bound to atoms other than carbon and sulfur.
Conversely, EPA apparently had no basis on which it could permit certain perfluoroalkyl groups of more than one

7. Reactive Functional Groups

The polymer exemption rule defines a reactive functional group (RFG) as an atom or associated group of atoms in a
chemical substance that is intended or can be reasonably anticipated to undergo further chemical reaction. This
provision is expressed in the regulation as a limitation to the (e)(1) condition, not as an exclusion. Although the
reactive functional group limitation it is not applicable to the (e)(2) and (e)(3) conditions, it might be better
understood as an exclusion, albeit one that only applies to (e)(1).

The original polymer exemption contained an RFG exclusion. In the 1995 exemption, the RFG exclusion, like the
entire exemption itself, is more complex compared to the original version. Nonetheless, it allows more polymers
to be exempt.

More polymers are potentially exempt due to both the exclusion’s sole applicability to the (e)(1) condition and
other complicating refinements. The refinements can be extremely complicated if one has different kinds of RFGs
present in the polymer's molecules. A “quick and clean” approach is to identify the equivalent weight for all RFGs
that will form an ionic or covalent linkage to an amino acid. If that equivalent weight is less than 5000 for all such
groups combined, the polymer is probably excluded by this provision, but there is hope that it is not excluded
unless the equivalent weight is less than 1000.

The (e)(1) limitation only applies when the polymer’s molecular weight is 1000 or more, but less than 10,000 and
the oligomer levels are less than 25 and 10 weight percent below 1000 and 500 molecular weight, respectively.
The RFG exclusion does not apply to polymers (a) whose molecular weight will always be 10,000 or more under
condition (e)(2), (b) whose oligomer levels are equal to or greater than 25 and 10 weight percent below 1000 and
500 molecular weight, respectively, or (c) that are polyesters under condition (e)(3).

In its 1997 guidance, EPA divided RFG’s into three tiers characterized as High, Moderate, and Low Concern. EPA’s guidance gives more examples, but the calculations shown are flawed. The RFG exclusion is complex and the following explanation should be considered to be abridged.

The RFG exclusion permits a polymer to be manufactured or imported under the polymer exemption for condition (e)(1) if it has a combined concentration of (High Concern) RFGs such that the equivalent weight of all RFGs combined is greater than 5000. RFGs that are not listed must be assumed to be in the most restricted (High Concern) group. Guidance as to what might be in this High Concern category is implicit in the list of Moderate Concern RFGs and from the preamble to the current and original regulations. For example, because “alkoxysilanes with greater than C2-alkoxysilanes” (i.e., propoxy- and higher alkoxysilanes) are Moderate Concern RFGs, methoxy- and ethoxysilanes are High Concern RFGs.

Moderate Concern RFGs are permitted at higher concentrations for polymers that otherwise satisfy the (e)(1) condition. For these RFGs of Moderate Concern, the equivalent weight can be as low as 1000. There is a list of Moderate Concern RFGs at 40 C.F.R. § 723.250 (e)(1)(ii)(B). Note that this list does not include amines nor ureas, per se; these groups are not included in the listings. What are included are methylolamines and methylolureas. Amines are considered High Concern, while ordinary ureas are not considered RFGs. A common reactive group in the Moderate Concern category is the epoxy group. Low Concern RFGs are permitted without restriction. This list is described in 40 C.F.R. § 723.250 (e)(1)(ii)(A). The status of some groups that are not listed may be unclear. If in doubt, assume the group is High Concern or seek clarification.

8. Molecular Weight Less Than 1000

While not explicitly stated in the polymer exemption, polymers with NAMWs less than 1000 are excluded from eligibility unless they are (e)(3) polyesters manufactured from the list of acceptable precursors. Except for the polyesters eligible under (e)(3), the 1000 molecular weight threshold reinforces the effect of the polymer definition.

In practice, polymers that qualify for the 1995 exemption typically will have NAMWs somewhat higher than 1000. This is a consequence of the 1000 threshold being tied to oligomer contents. Few eligible polymers will have NAMWs very near 1000 because of the concomitant requirement that no more than 25 weight percent of the components of such polymers can have NAMWs below 1000.

C. Polymer Definition

The current definition of polymer is a modified version of the definition provided by the original polymer exemption. Both the original and current polymer exemption seek to draw a line between polymers and non-polymers and not exclude any conventional, synthetic polymers.

Under the polymer exemption, a polymer is defined as a chemical substance that consists of not less than 50.0 weight percent (a simple majority) of polymer molecules and less than 50.0 weight percent of molecules with the same molecular weight. The polymer molecules must be distributed over a range of molecular weights and the
differences among polymer molecules are primarily due to differences in the number of internal monomer units. This definition depends on a multitude of defined terms.

A monomer unit is the reacted form of a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction. It is an atom or a group of atoms chemically derived from a corresponding monomer, i.e., -(Ma´) derived from Ma. For example, a phthalate monomer unit, C8H4O3, corresponds to a phthalate monomer such as phthalic anhydride, phthalic acid, a half-acid ester of phthalic acid, or any other phthalate subunit precursor that has functioned as a monomer. Internal monomer units are monomer units that have been derived from monomers that have functioned as monomers, i.e., they are covalently bonded to at least two other molecules and generally are incorporated into the same polymer molecule more than once.

A polymer molecule contains a sequence of at least three monomer units that are covalently bound to each other and to at least one other monomer unit or other reactant. Sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string uninterrupted by units other than monomer units within the polymer molecule. The monomer units need not be identical. It is important to realize that a substructure that is covalently bonded to two or more other substructures might not be considered a monomer unit. A substructure is never a monomer unit if it is derived from a reactant that does not polymerize under the conditions of the relevant polymer-forming reaction.[16] Such a non-monomer substructure is considered to interrupt the sequence of monomer units. This interpretation is closely linked to the term, other reactant.

An other reactant “means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.”[17] Other reactants are those that, under the relevant reaction conditions, have not or cannot become a repeating unit in the polymer’s structure. A chemical substance that is linked to a molecule through only one covalent bond is an other reactant even if there are many such substructures in the same molecule.

The polymer definition acts as an entry gate to the polymer exemption. If the degree of polymerization is insufficient, or if the distribution of molecular weights is too narrow, the substance is not eligible for the exemption. The requirement that the minimum average molecular weight be 1000 under the criteria for paragraph (e)(1) also generally provides a minimum degree to which polymerization must be carried out for both criteria (e)(1) and (2). A NAMW of 1000 is often a surrogate for the polymer definition for reaction products whose reactants have the capability to polymerize, and will meet the criteria for (e)(1) but are not eligible under the criteria for (e)(3). If the criteria for the (e)(2) condition are met, it would be extremely difficult not to satisfy the polymer definition.[18] For the (e)(2) condition, the polymer definition is essentially redundant. The principal impact of the polymer definition is to ensure a minimal degree of polymerization for polyesters under (e)(3).

II. THE TWO-PERCENT RULE

The “two-percent rule” is a provision for reporting the chemical identity of polymers.[19] It initially appeared in the rule that established Initial Inventory Reporting under TSCA. Subsequently, the “two-percent rule” was incorporated into the TSCA premanufacture notification rule at subparagraph (iii) of 40 C.F.R. § 720.45(a)(2) as amended:
(2) For a polymer, the submitter must report the following...

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of the monomer or other reactant actually charged to the reaction vessel, or (B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.[20]

In the context of the two-percent rule, the percent used means the weight percent calculated from the mass of the precursor charged divided by the mass of the product formed (both on a 100-percent active basis). The calculation is independent of the degree of chemical incorporation of the polymer, so long as there is some chemical incorporation.

The percent incorporated in the two-percent rule means the weight percent calculated from the minimum mass of the precursor that theoretically could account for the mass or portion of the mass of the precursor that is chemically incorporated divided by the mass of the product formed (both on a 100-percent active basis). Where the percent incorporated is accessible and can be supported, it can lead to a lower percentage for decision making instead of the percent used. This can mean that polymers that used greater than two weight percent of a reactant and were denied eligibility solely on that basis now could be eligible if the degree of incorporation can be shown to be two weight percent or less. The percent incorporation is not the percentage of the mass of the reactant incorporated.

Analytical data or appropriate theoretical calculations must be maintained at the site of manufacture or import to support the incorporation level. Theoretical calculations are permitted if it can be documented that analytical measurement is not feasible or necessary to support the determination of how much of a reactant is chemically incorporated.

Simply stated, the two-percent rule means (a) that precursors of a polymer that are either used or incorporated at no more than two weight percent may be included in the description of a polymer manufactured from those precursors while (b) precursors used or incorporated (whichever is less) at more than two weight percent must be included in the chemical description reported and ordinarily will be reflected in the name of the polymer.[21]

The two-percent rule does not mean that a precursor reflected in the description of a polymer must be used or incorporated at more than two weight percent. Conversely, a precursor reflected in the description of a polymer generally must not be omitted or reduced to only a probability of being chemically incorporated.

Under EPA’s current (1997) polymer exemption guidance, the two-percent rule is not intended to operate the same way as it does outside of the polymer exemption. Under the current polymer exemption, EPA interprets the two-percent rule to mean that if a precursor is used or incorporated at less than or equal to two weight percent,[22] the manufacturer or importer cannot include that precursor in the determination of the chemical identity of the polymer. If a manufacturer or importer uses or incorporates a certain monomer or reactant in an exempt polymer at less than or equal to two weight percent, the manufacturer or importer may not later use or incorporate that monomer or reactant at greater than two weight percent under the exemption for the same
polymer. In other words, there is no option by which a monomer or other reactant may be included in the identity of the exempt polymer if its initial concentration is less than or equal to two weight percent. One part of the reporting provision is unchanged: if a reactant or monomer is used at greater than two weight percent in an exempt polymer, the reactant or monomer must not be eliminated completely from the polymer.

Another application of EPA’s guidance is not certain. Is a polymer that was initially manufactured under the polymer exemption with a given monomer or reactant used or incorporated at greater than two weight percent, the same polymer under the exemption if the same monomer or reactant is subsequently used or incorporated at a concentration that is equal to or less than two weight percent but greater than zero weight percent? Based on EPA’s guidance, it would appear that the subsequent version of the polymer as just described, would be the same polymer under the exemption as the initial polymer. Ordinarily, any precursor that is reflected in the description of a polymer may be used at any concentration greater than zero (so long as the concentration does not offend some requirement). The same understanding should apply under the polymer exemption. We have sought confirmation of this aspect of the application of the two-percent rule from EPA, but EPA has neither agreed nor disagreed with this position.

EPA’s guidance concerning the two-percent rule under the polymer exemption can create a problem. If precursors are to be used or incorporated both at less than or equal to two weight percent and at greater than two weight percent, one has more than one polymer to report. If there are n precursors used or incorporated both at less than or equal to two weight percent and at greater than two weight percent, there are 2n potential polymers. In each pair, one polymer must include the given precursor at greater than two percent and the other polymer may omit the precursor or use it at no more than two weight percent. Under the ordinary two-percent rule, the manufacturer or importer can designate whether the precursor used or incorporated at less than or equal to two weight percent is to be included in or omitted from the polymer’s chemical identity.

If a polymer will be manufactured or imported with any of its precursors at greater than two weight percent, that polymer may have the same chemical identity if any of the same precursors are subsequently used or incorporated at two weight percent or less so long as they are not eliminated. If that polymer also will be initially manufactured or imported such that any of its precursors that were at two weight percent or less, become manufactured or imported where they become more than two weight percent, separate chemical identities must be established and separate records, certifications, and notices must be provided if the guidance is followed.

III. REPORTING AND RECORDKEEPING

A. Reports

Reports postmarked no later than January 31 must be submitted by each manufacturer or importer after any calendar year in which a polymer was first manufactured or imported under the polymer exemption. The report must state merely the number of polymers manufactured or imported for the first time under the terms of the exemption in the calendar year preceding the notice. Each polymer under the exemption generally is reported only once for each manufacturer or importer. If no polymers were manufactured or imported under the terms of the exemption, no report is required. There is no requirement to give the identity or any other information concerning the polymers, per se. The only other information required in the year-end report is the name and address of the manufacturer or importer and the name and phone number of a technical contact. See 40 C.F.R. §
723.250(f). Any or all portions of the year-end report may be claimed as confidential business information.

B. Records

The manufacturer or importer must identify and maintain records, pursuant to 40 C.F.R. § 723.250(g), which include the following information:

1. a specific chemical name and CASRN (or EPA-assigned Accession Number) for each reactant. At this point in the regulations (subparagraph (g)(1)), EPA notes that reactants that introduce chemical or physical properties (including reactive functional groups) or atomic elements that render the polymer ineligible for the exemption are not allowed at any level. The phrase “at any level” does not seem to be intended to be taken literally. A reasonable interpretation is that EPA is simply intending to caution that a polymer must qualify for the exemption. There is no exception if the reactant that contributes an impermissible property may be used or incorporated at less than two percent. In other words, one would violate one or more terms of the exemption if one used an explicitly offending reactant – even if it were used (or incorporated) at less than two weight percent. For example, use of any level of a reactant that contains an impermissible atomic element according to the (d)(2) exclusion would violate the exemption. Use or incorporation of a reactant that contains a High Concern RFG might or might not cause the polymer to violate the exemption, depending on its level.

2. a representative structural diagram, if possible.

3. information to demonstrate that the polymer is not specifically excluded from the polymer exemption by any of the exclusions set forth at paragraph (d) of 40 C.F.R. § 723.250.

4. information to demonstrate that the polymer meets at least one of the three conditions of the polymer exemption set forth at paragraph (e) of 40 C.F.R. § 723.250.

5. the date of first commercialization under the polymer exemption.

6. production or importation records for the first three years of manufacture or importation from the date of first commercialization under the exemption.

7. analytical data or (if it can be documented that an analytical determination cannot be made or is unnecessary) theoretical calculations to support the molecular weight, oligomer concentrations, or reactant levels used at more than two weight percent but incorporated at two weight percent or less.

8. certification as of the date of first manufacture or import that (1) the polymer is manufactured or imported for a commercial purpose other than research and development, (2) all information in the certification is truthful, and (3) the polymer is eligible for the exemption.

The records must be retained for at least five years from the date of commencement of manufacture or import at the manufacturing or importing site. These records must be submitted to EPA within 15 working days of receiving a written request from EPA. In addition, access to or copying of these records must be permitted at all reasonable times upon EPA’s request.
IV. SUMMARY

Although the current polymer exemption is presented as (1) definition, (2) exclusions, and (3) conditions, it is more comprehensible in reverse order. Within the conditions, there are limitations that are more logically considered with the exclusions. Even among the exclusions, the order of presentation is not the order of likely importance. The determination of eligibility is more complex than apparent at first glance; record keeping and reporting appear simple but both pose several traps. With appropriate knowledge and experience, one can comply with the polymer exemption. We trust this guidance will provide useful insights and encourage use of the polymer exemption.


[3] It is our understanding that the 10,000 NAMW limitation in paragraph (e)(1) served an important purpose in a draft of the exemption. We note that if the phrase “and less than 10,000” were deleted from paragraph (e)(1), the anomaly described here would vanish. In other words, polymers that had NAMW’s at 10,000 and above should be able to qualify under the (e)(1) condition. It is unfortunate that polymers that could otherwise qualify for an exemption under (e)(1) become ineligible if their NAMW is too high! A technical correction to eliminate this unintended consequence would be appropriate.

[4] Amines and isocyanate groups are also reactive functional groups that are discussed later.


[7] This can sometimes be calculated based on ionization constants and pH.

[8] Prior to the 2010 amendments, the 1995 polymer exemption permitted fluorine, but only if it was covalently bound to carbon.

[9] Conventionally, the units of molecular masses or weights have not been stated explicitly. The units have been understood to be atomic mass units. Recently, EPA’s regulations have referred to atomic mass units as Daltons (Da), so named after John Dalton, an English chemist and physicist.


[12] Note that amines are potentially cationic under the (d)(1) exclusion.
[13] Certain chemically-recognized groups are not considered RFGs, so they are not specifically included in the list of Low Concern RFGs. Under the 1995 polymer exemption, Low Concern RFGs are treated the same as chemical groups that are non-reactive.


[15] See the definition of polyester at 40 C.F.R. § 723.250(b).

[16] This interpretation is important because in some circumstances it might cause the threshold for the degree of polymerization for polymer molecules to be much higher than for alternative interpretations.

[17] 40 C.F.R. § 723.250(b) (“other reactant”).

[18] For example, certain biopolymers such as enzymes potentially satisfy the (e)(2) condition but have too narrow a molecular weight distribution to satisfy the polymer definition. [19] 40 C.F.R. § 710.5(c) (now withdrawn).

[20] 40 C.F.R. § 720.45(a)(iii). The reference above in the quoted text to “as part of the polymer description on the Inventory” is the sole basis for inferring that the two-percent rule is applicable for interpreting Inventory listings. EPA has never published any rules directly bearing on the nomenclature used or interpretations that apply to the Inventory. The only formal rules have been in the context of reporting obligations for submitters.

[21] There are exceptions for certain situations such as oxidation and the involvement of water. Water is usually not listed as a reactant.

[22] There is no guidance if, depending on the method of calculation, the level of the precursor might be both above and below two percent.

[23] Using whichever available method (use or incorporation) gives the lower value.

[24] Note that a company might decide either to consolidate this reporting or report by plant site or importing site. If not done on a company-wide basis this could be a burden, especially for imported polymers and could result in duplicative reporting. With regard to the number of polymers reported per year, the requirement is company specific, not site specific, although the report can be made on a per-site basis. However, the other records that must be kept are site specific.