The Toxic Substances Control Act: Exclusions and Exemptions

The Toxic Substances Control Act (TSCA) covers much more than toxic substances - unless everything is toxic. Yet, there are substances that are not subject to TSCA at all (with a notable exception to that exclusion). There also are several exclusions from the premanufacture notice requirements of section 5 of TSCA including some limited exemptions. By example, this presentation addresses substances not subject to TSCA, chemical substances not subject to premanufacture notification, and chemical substances that might be exempt from premanufacture notification. In this short presentation, the examples I am going to discuss are the exclusion from TSCA for pesticides, the (h)(7) premanufacture exclusion, and the polymer exemption from premanufacture notification.

Exemptions and exclusions from premanufacture notification are listed in the Code of Federal Regulations at 40 C.F.R. § 720.30. More detailed discussions of TSCA issues are available on Keller and Heckman's website: www.khlaw.com. The Environmental Protection Agency (EPA) has published a draft Q & A document that covers, among other things, 24 enumerated exclusions including five exemptions. The EPA has sought comments on this draft through March 15, 2004. Substances Excluded From TSCA Altogether

Chemical substance is defined in TSCA to exclude substances such as pesticides, tobacco products, firearms, foods, drugs, and cosmetics, when they are manufactured, processed, or distributed in commerce for use as pesticides, tobacco products, firearms, foods, drugs, or cosmetics. These substances are covered by other federal laws. For example, consider pesticides.

A pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is defined in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant." FIFRA § 2(u). It is worth noting that chemical intermediates to pesticides that are not themselves pesticides are subject to TSCA. In addition, substances that are inert ingredients of pesticides are not subject to FIFRA until they are components of a pesticide. It also is important to note in general that if a chemical substance has a single commercial application that falls under TSCA's jurisdiction, its manufacture or importation for that application is subject to TSCA's premanufacture notification requirements regardless of the quantities that might be used in TSCA-exempt or PMN-exempt applications.

There is an exception to the general exclusion for substances that are not chemical substances under TSCA. For imported substances that are not chemical substances under TSCA, section 13 of TSCA requires a certification that they are not subject to TSCA! One might well reason that substances that are not subject to TSCA are not subject to its regulations. In this case, the authority under TSCA for this requirement is granted to the Department of the Treasury, and regulations promulgated by U.S. Customs require this so-called negative certification. 19 C.F.R. § 12.118 through 12.127 and 127.28 (amended).

Physicochemical Modification or the (h)(7) Exemption

Perhaps the least understood premanufacture notification exemption is the one at 40 C.F.R. § 720.30(h)(7),
known, among other things, as the (h)(7) or physicochemical effect exemption. In certain circumstances, this exemption allows a manufacturer to use other substances or energy to modify the physicochemical characteristics of an existing substance without reporting any incidental reaction products. *Physicochemical characteristics* is understood to include such properties as water solubility, crystalline morphology, viscosity, and pH. This provision relieves manufacturers from the burden of analyzing certain products for the presence of incidental reaction products, which, because they are “intentionally” present, may not be classified as *byproducts*.

At the outset, one should understand that (h)(7) is a subtle exclusion, and it does not afford general relief from premanufacture notification or relief from other regulatory requirements under TSCA. Under the (h)(7) exclusion, a reaction product is not subject to premanufacture notification, even if formed for an immediate or eventual commercial advantage, so long as the chemical substance is not itself intended to be distributed in commerce and has no commercial purpose separate from the combination of substances, mixture, article, or formulation of which it is a component.

Several definitions prove helpful in determining if certain chemical reaction products might be exempt from notification under this exclusion. Please note that many of the words and phrases used in the regulations and clarifications may be used in ways that are inconsistent with their ordinary meanings. (The special words and phrases in this section of this paper are set in italics.)

A *chemical substance*, as the term applies to substances regulated under TSCA, includes “any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical. . . .” 40 C.F.R. § 720.3(e). The term *chemical substance* does not include *mixtures* or any substance that is regulated under certain other chemical control laws insofar as those substances are manufactured, processed, or distributed solely for purposes that are not regulated under TSCA. *Id.*

A reaction product is a *mixture* of chemical substances if all of the chemical substances comprising the mixture are on the Inventory and if the *mixture* either is (1) an admixture or (2) could have been manufactured for commercial purposes without a chemical reaction at the time the determination is made. *Mixtures* are exempt from the PMN and Inventory Reporting requirements of TSCA. 40 C.F.R. §§ 720.30(b) and 710.4(d)(5). Components of *mixtures* must be individually listed on the Inventory, not subject to TSCA, or excluded from reporting.

The term *new chemical substance* is defined at section 3(9) of TSCA as a chemical substance which is not included in the compilation of chemical substances in U.S. commerce which is known as the TSCA Chemical Substance Inventory (Inventory). The Inventory implicitly includes *chemical substances* that exist in nature or are obtained from natural sources through certain processes if they substantially retain their natural state.

Pursuant to section 720.30(h)(7) of the premanufacture regulations, a manufacturer is not required to file a PMN for a *new chemical substance* when that *chemical substance* is not *manufactured for distribution in commerce* as a *chemical substance, per se*, and has no commercial purpose separate from the *substance, mixture, or article* of which it is a part. 40 C.F.R. § 720.30(h)(7). Put differently, the regulation excludes from premanufacture notification certain substances formed by chemical reactions intended to impart a physicochemical effect and which function as intended.
As used to discuss the (h)(7) exclusion, the word intend should be understood to mean reasonably ascertainable or reasonably anticipated. Known to or reasonably ascertainable by “means all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.” 40 C.F.R. § 720.3(p). Reasonably ascertainable information is that which a knowledgeable person could learn in a typical course of commercial activity. The EPA has also opined that in general, information in the current literature, information held by a company, or information held by a supplier to be reasonably ascertainable. The term, reasonably ascertained was used in connection with the intended use of a free-radical initiator. EPA requires substantiation of intent to include “adequate supporting information” and “will not accept mere assertion.” The term, reasonably anticipated, is defined in the polymer exemption at 40 C.F.R. § 723.250(b)(15). If the definition is modified to apply to all chemical substances, reasonably anticipated means “that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the substance, the type of reaction, the type of manufacturing process, the products produced in the reaction the intended uses of the substance, or associated use conditions.” This understanding of intent makes it clear that there must be some reasonable manifestation of the reasons that a chemical substance is formed, not merely an unsubstantiated assertion of intent.

The relevant portions of section 720.30, together with subsection (h) and paragraph (7), read as follows: § 720.30 Chemicals not subject to notification requirements. The following substances are not subject to the notification requirements of this part . . . .(h) The chemical substances described below: (Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part) . . .(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculent, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (ii) a chemical substance, which is intended solely to impart a specific physiochemical [sic] characteristic, functions as intended.

As noted, section (h) of § 720.30 is initially worded, “The chemical substances described below,” and that phrase is followed by a parenthetical sentence. This format seems to imply that the only substantive provisions of subsection (h) are the subordinate paragraphs. In actuality, subsection (h) says much more than may be apparent at first glance.

The parenthetical states that subsection (h) addresses chemical substances that are manufactured for commercial purposes under the Act. This refers to any amount of any organic or inorganic substance of a particular molecular identity that is manufactured or imported in the United States with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer. The substances included, among others, are substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture as well as impurities that remain in that substance or mixture. Impurities and byproducts without separate commercial value are nonetheless considered produced for the purpose of obtaining a commercial advantage, because they are part of the manufacture of a chemical substance for commercial purposes.
Moreover, the language of the parenthetical in section (h) draws a distinction between chemicals that are *manufactured for a commercial purpose* and *not* excluded - and those that are so *manufactured* and *are* excluded. Specifically, the language, "*not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part*" (emphasis added) means: (1) that the excluded substances are not sold, introduced, or delivered for introduction into commerce (or held after introduction into commerce); and (2) that the substances which are excluded from reporting are associated with other substances that do have commercial purpose.

A review of paragraph (7) in the context of subsection (h), leads to the restatement that (h)(7) applies to any reaction product that results from a chemical reaction that occurs when a precursor chemical substance is treated with a different precursor chemical substance and (1) the treating precursor substance functions solely to impart a specific chemical or physical characteristic to the treated chemical substance and (2) one can reasonably ascertain or reasonably anticipate that neither the treated nor the treating precursor chemical substance functions predominantly as a chemical precursor (in a conventional manufacturing sense) to produce a primary reaction product, for its own value - given the circumstances under consideration.

At the outset, this exclusion was described as subtle. In most cases, (h)(7) is difficult to ascertain for a particular fact pattern. In some cases, there are other alternatives. The Polymer Exemption

The current polymer exemption is remarkable in that manufacturers and importers make their own determination of eligibility, keep records, and are only required to file an end-of-year report in connection with the use of the exemption. Overall, impediments to the commercialization of new polymers have been significantly reduced, which, in turn, greatly facilitates more rapid introduction of less risky polymers in commerce, and the EPA’s scarce resources are better utilized.

Unfortunately, it is not always simple to determine if a given polymer will qualify for the exemption. While it is clear not all polymers will qualify, many are thought to qualify that do not. Because the EPA will not make a contemporaneous, independent review, it is essential that businesses correctly interpret the exemption and apply its provisions assiduously. If you do not carry anything else away about the polymer exemption, this is essential: you must know that the polymer is eligible and the determination of eligibility is sound. We have information available describing our polymer exemption assurance services and an overview of the current polymer exemption including some controversial aspects in *A Practical Understanding of the Polymer Exemption*. Both are available on Keller and Heckman’s website: Polymer Exemption Assurance Service and *A Practical Understanding of the Amended Polymer Exemption*.

The EPA plans to propose amending the polymer exemption for the second time. This new proposed amendment will address concerns for polymers that contain perfluoroalkyl groups. Currently polymers that incorporate perfluoroalkyl groups can be eligible under the 1995 polymer exemption. In light of these concerns, I believe the EPA will seek to prevent the commercialization of such polymers under the polymer exemption in the near future. How will the EPA implement its concerns?

Will the EPA be careful with the current terms of the exemption? If not, the expedient approach will be to make polymers that contain carbon-fluorine bonds no longer eligible. The atomic element fluorine is now permitted if it is covalently bound to carbon. I predict that the EPA will not permit polymers that contain fluorine in any form to
be in commerce under the polymer exemption. If this is accurate, then the homopolymer of tetrafluoroethylene would not be eligible under the terms of the proposed exemption. Although the commerce of poly(tetrafluoroethylene) in the United States does not depend on the polymer exemption because it is an existing chemical substance, many polymers containing fluorine are in commerce due to the polymer exemption. I predict that some polymers commercialized under the 1995 exemption will not be permitted to continue to be commercialized indefinitely under the proposed amended polymer exemption. Premanufacture Notices (PMNs) or other exemptions will be needed to continue commercialization.

In the last, final polymer exemption rule, 60 Fed. Reg. 16316 (Mar. 29, 1995), the EPA withdrew proposed revocation provisions. The withdrawal was based on the likelihood being low that eligible polymers would pose an unreasonable risk. The Agency offered the rationale that the revocation provisions were not necessary to support the necessary statutory finding that polymers manufactured under terms of the exemption will not present an unreasonable risk of injury to human health or the environment. In this regard, the EPA said, *Should evidence be received by the Agency that casts reasonable doubt on the appropriateness of a criterion or set of criteria, the Agency has other regulatory options available, such as publication of a proposed amendment to the polymer exemption rule to either refine the criteria or impose new restrictions, similar to EPA’s treatment of water-absorbing high MW polymers in this rulemaking....* 60 Fed. Reg. at 16326 (emphasis added).

Expect that this language will soon be brought back to life and create issues for many polymers that have been commercialized under the polymer exemption since 1995.

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