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THE TOXIC SUBSTANCES CONTROL ACT
FREQUENTLY ASKED QUESTIONS

1. What is a chemical substance for purposes of regulation under TSCA?

The Toxic Substances Control Act (TSCA) defines the term "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including -- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical." The Environmental Protection Agency (EPA) states: "TSCA defines 'chemical substance' broadly and in terms which cover microorganisms as well as traditional chemicals."

2. Are there any exemptions from the definition of a "chemical substance"?

TSCA specifically exempts from the definition of "chemical substance" (1) mixtures; (2) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticides; (3) tobacco and tobacco products; (4) certain materials regulated under the Atomic Energy Act; (5) firearms and ammunition; and (6) foods, food additives, drugs, cosmetics, and devices regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition to those substances specifically excluded from TSCA, EPA has exempted other categories of substances from certain TSCA requirements. For example, certain chemical substances -- including impurities and byproducts -- are excluded from TSCA Section 5 requirements because "[a]lthough 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." EPA also exempts "articles" from various TSCA requirements.

3. What are "articles" under TSCA?

TSCA defines "article" as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) depending in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of an article, and that results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles." Fluids and particles are not considered articles, however, regardless of shape or design. Articles that contain chemical substances which are not intended to be removed and have no separate commercial purpose are generally exempt from TSCA. Articles that contain chemical substances designed to be used or released (*i.e.*, ink in pens) are subject to TSCA requirements.

4. Who is subject to TSCA requirements?

TSCA may apply to any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance. A person is defined broadly as "any natural or juridicial person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government."

5. How does EPA keep track of the chemical substances subject to TSCA?

TSCA Section 8(b) directs EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." This list is known as the TSCA Chemical Substance Inventory (TSCA Inventory). EPA compiled the initial TSCA Inventory in 1977. The TSCA Inventory is continually updated by the addition of chemical substances for which a premanufacture notice (PMN) and subsequent notice of commencement (NOC) have been submitted. For those chemical substances whose identities are confidential, EPA maintains a confidential portion of the TSCA Inventory that only EPA can review.

6. How can a person search the confidential portion of the TSCA Inventory?

A manufacturer or importer can request that EPA search the TSCA Confidential Inventory by filing a *bona fide* intent request (BFI Request). A BFI Request is a letter submitted to EPA by a manufacturer or importer asking EPA to search the TSCA Confidential Inventory. A manufacturer or importer may submit a BFI Request only if it meets the requirements established by EPA at 40 C.F.R. Section 720.25.

7. What chemical substances are subject to PMN requirements?

Chemical substances manufactured in or imported into the United States that are not listed on the TSCA Inventory and that are not otherwise exempt from TSCA Inventory listing are considered "new" chemical substances subject to TSCA Section 5 PMN requirements.

8. What are the exemptions from PMN requirements?

Some chemical substances that are not listed on the TSCA Inventory may be exempt from PMN and related TSCA Section 5 requirements. Several exemptions from PMN requirements are considered "self-executing" because they do not require EPA approval. Instead, once a manufacturer or importer determines that one of the self-executing exemptions applies, the new chemical substance may be manufactured or imported without first submitting a

PMN, so long as the company complies with any recordkeeping or other requirements for the particular exemption. The self-executing exemptions are exemptions for chemical substances having no "separate commercial purpose"; polymers meeting specified requirements; and research and development (R&D) substances meeting specified requirements. Other exemptions from PMN requirements require EPA approval. In these instances, a manufacturer or importer must submit, and EPA must approve, an exemption application before a company may authorize the manufacture or import of the new chemical substance. In addition, each manufacturer or importer must comply with any recordkeeping or other requirements for the particular exemption approved by EPA. These exemptions are: low volume exemptions (LVE); low release and exposure exemptions (LoREX); and test marketing exemptions (TME).

9. What information does EPA initially seek in a PMN?

The PMN form seeks information on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate. TSCA does not require a submitter to test new chemical substances before submitting a PMN. Health and safety data relating to a new chemical substance's health or environmental effects that are in a submitter's possession or control, however, must be submitted with the PMN. The submitter must provide this information to "the extent it is known to or reasonably ascertainable by the submitter." EPA has developed a PMN review process to estimate the risk attributable to a new chemical substance and to determine whether an unreasonable risk of injury to health or the environment may occur if the chemical substance is distributed in commerce. EPA may request additional information from a submitter during its review of a PMN application.

10. When must a NOC be submitted?

Within 30 days of the first commercial manufacture (date of completion of production lot) or import (date new chemical substance clears U.S. Customs) of a chemical substance for which EPA has approved a PMN, the manufacturer or importer must prepare a draft NOC using EPA's Form 7710-56. The NOC seeks information on the submitter's identity, the chemical substance's identity, and the date of commencement of manufacture or import. Upon receipt of the NOC, EPA places the PMN chemical substance on the TSCA Inventory.

11. Can EPA require persons to test chemical substances subject to TSCA?

Yes. Under TSCA Section 4, EPA has authority to promulgate rules requiring manufacturers, importers, and processors to test chemical substances or mixtures for their effects on human health and the environment. To require testing, EPA must first find that "there are insufficient data and experience upon which the effects of the manufacture, distribution in

commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted," and "testing of such substance or mixture with respect to such effects is necessary to develop such data." EPA must also find that the chemical substance or mixture presents "an unreasonable risk" to human health or the environment, or is produced in substantial quantities that could result in substantial or significant human exposure or environmental release.

12. Who is subject to testing requirements under TSCA Section 4?

TSCA Section 4 imposes testing requirements on manufacturers (including importers), as well as processors of chemical substances subject to a test rule. Manufacturers, however, are primarily responsible for testing. Under EPA's regulations, manufacturers will be responsible for testing where testing is necessary to assess risks that arise primarily from manufacturing, from both processing and manufacturing, or from distribution, use, and/or disposal activities. Testing obligations will be imposed on processors where the testing is being conducted to evaluate the risks associated with processing of the chemical, or where no manufacturer submits a notice of intent to conduct testing.

13. What is the High Production Volume (HPV) Challenge Program?

EPA, in cooperation with the Environmental Defense Fund and the American Chemistry Council (formerly the Chemical Manufacturers Association), established the HPV Challenge Program to encourage chemical manufacturers and importers to conduct testing of chemicals on EPA's list of HPV chemicals, which was compiled based on the 1990 Inventory Update Rule (IUR). HPV chemicals are defined as those manufactured or imported in quantities exceeding one million pounds. HPV testing is designed to generate basic toxicity information as defined by the Screening Information Data Set (SIDS) program, developed by the Organization for Economic Cooperation and Development (OECD). The SIDS program requires information on basic physical/chemical properties and approximately 13 studies in the areas of ecotoxicity, environmental fate, and mammalian toxicity. All data produced under the HPV program will be made available to the public. EPA will establish and maintain an electronic database designed to present the data and information in a meaningful and accurate way. For chemicals that are not sponsored under the HPV Challenge Program, EPA will use its Section 4 rulemaking authority to compel testing.

14. When can EPA issue an administrative order controlling new chemical substances?

TSCA Section 5(e) grants to EPA the authority to issue administrative orders controlling new chemical substances where it finds (1) there is insufficient information to evaluate the risk

reasonably, and (2) either the chemical may present an unreasonable risk to health or the environment, or it will be produced in substantial quantities that will enter the environment or to which there will be substantial or significant human exposure. In its order, EPA can ban or limit the manufacture, distribution, use, or disposal of the chemical.

15. What is a significant use for a new chemical substance?

Section 5(a) requires manufacturers, importers, and processors of existing chemicals to provide notice to EPA of any use of a substance that EPA has determined is "a significant new use." A determination that a use is significant and new must be made by rule, known as a Significant New Use Rule (SNUR). TSCA does not establish standards or criteria for establishing when a new use is deemed "significant," but requires EPA to consider "all relevant factors" before promulgating a SNUR, including (a) the projected volume of manufacturing and processing of a chemical substance, (b) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (c) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (d) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

16. Can EPA seize a chemical substance if EPA determines it presents an unreasonable risk to human health or the environment?

Yes. EPA may commence a civil action in an appropriate United States district court to seize chemical substances or mixtures that EPA determines are imminently hazardous chemical substances or mixtures that will present an unreasonable risk of serious and widespread injury to health and the environment. EPA may commence such action notwithstanding the existence of a final rule under TSCA Section 4, 5, or 6.

17. What information does EPA seek when it issues a Preliminary Assessment Information Rule (PAIR)?

Each PAIR requires certain manufacturers and importers of certain chemical substances listed on the TSCA Inventory to submit a one-time report by the date established in the *Federal Register* announcing the PAIR. The report addresses: (1) the quantities of chemical substances manufactured, imported, used as a reactant, used in industry and consumer products, or lost to the environment; and (2) worker exposure. Manufacturers and importers must submit such information to the extent it is "readily obtainable by management and supervisory employees responsible for manufacturing, processing, distributing, technical services, and marketing." "Extensive" file searches are "not required."

18. How often must manufacturers submit reports under the IUR?

After 2006, the IUR requires certain manufacturers and importers of certain chemical substances listed on the TSCA Inventory and produced above threshold volumes to report, every five years, data on production volume, plant site, and site-limited status of those chemical substances. At the higher threshold of 300,000 pounds, additional downstream processing and use information is required.

19. What is a "significant adverse reaction"?

TSCA regulations define "significant adverse reactions" as "reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment." Examples of "significant adverse reactions" that must be reported are provided at 40 C.F.R. Section 717.12. They include, but are not limited to, long-lasting or irreversible health effects such as cancer and neurological effects; impairment of normal activities experienced by a number of people exposed to the same event or by one person each time he or she is exposed; long-lasting or irreversible damage to biological species, such as fish-kills or reduction in the ability of a species to survive; and long-lasting or irreversible effects on environmental media, such as groundwater contamination.

20. How must companies record significant adverse reactions?

EPA has not created a specific form to use to record TSCA Section 8(c) allegations. TSCA Section 8(c) allegation records must contain, however, the following information concerning each recordable allegation: (1) the name and address of the site that received the allegation; (2) the date the allegation was received; (3) the identity of the chemical substance or mixture; (4) a description of the person making the allegation (*i.e.*, employee, customer, plant neighbor); (5) a description of the alleged reaction(s); and (6) the gender and birth year of any person alleged to have experienced a health effect. The original allegation must be attached to the TSCA Section 8(c) allegation form.

21. Can EPA require companies to submit to EPA their records of significant adverse reactions?

Yes. EPA may issue a letter or *Federal Register* notice requiring the submission of TSCA Section 8(c) allegation records to EPA. The *Federal Register* notice will specify which records or portion of records must be submitted, and whether allegations relating to mixtures must be reported.

22. What is a "health and safety study" under TSCA Section 8(d)?

TSCA defines a "health and safety study" as "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other studies of a chemical substance or mixture, and any test performed under TSCA." Under TSCA Section 8(d), manufacturers, importers, and processors who fall within the North American Industrial Classification System (NAICS) Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refineries) must submit, for certain chemical substances and mixtures, unpublished health and safety studies that are in their possession, lists of all unpublished health and safety studies on those chemical substances and mixtures known to them but not in their possession, and lists of all unpublished health and safety studies being conducted or initiated on those chemical substances and mixtures.

23. Are there any requirements to report to EPA adverse information concerning a chemical substance?

Yes. Pursuant to TSCA Section 8(e), any person who manufactures, imports, processes, or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the chemical substance or mixture poses a "substantial risk of injury" to human beings or the environment must provide the information to EPA immediately. EPA provides that "immediately" means "not later than the 30th calendar day after the date the person obtained such information." Exceptions include information about emergency incidents of environmental contamination, which must be reported immediately, and non-emergency incidents of environmental contamination, which must be reported to EPA within 90 days of obtaining the information unless reported within 90 days to another EPA office, federal or state regulatory agency.

24. Does EPA provide guidance on what is a "substantial risk of injury"?

EPA has emphasized that "substantial risk" information "need not and most typically does not establish conclusively that a substantial risk exists." EPA has also said that in deciding whether information is "substantial risk" information, one must consider "(a) the seriousness of the effect . . . and (b) the fact or probability of [the effect's] occurrence." According to EPA, the two criteria should be weighed differently depending on the seriousness of the effect or the extent of the exposure (the more serious the effect, the less heavily one should weigh exposure, and vice versa).

25. Are there exemptions from reporting a substantial risk of injury under TSCA Section 8(e)?

Yes. Information otherwise subject to the reporting requirements of TSCA Section 8(e) need not be submitted if the information: (1) is contained in an EPA study or report; (2) is published in the open scientific literature or major U.S. news publication; (3) has been reported to EPA under mandatory reporting requirements of TSCA or other authority administered by EPA; (4) is contained in a formal publication, report, or statement made available to the public by another federal agency; (5) is corroborative of a well-established adverse effect (and does not newly identify any serious adverse effects or confirm a previously suspected serious adverse effect); or (6) is information for which EPA has waived compliance in accordance with TSCA Section 22.

26. Can a company claim information submitted to EPA as confidential?

Yes. TSCA Section 14(a) prohibits EPA, except in certain limited circumstances, from disclosing to the public "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Confidential information can be disclosed (1) to any officer or employee of the United States "(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or (B) for specific law enforcement purposes"; (2) to contractors with the United States if "disclosure is necessary for the satisfactory performance by the contractor"; (3) if the Administrator "determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment"; or (4) when "relevant in any proceeding under [TSCA]."

27. When must exporters notify a country that it intends to export a chemical substance?

Chemical substances and mixtures subject to TSCA Section 12(b) export notification requirements are those for which EPA has taken one or more of the following actions: (1) data have been required under TSCA Section 4 or 5(b); (2) an order has been issued under TSCA Section 5; (3) a rule has been proposed or promulgated under TSCA Section 5 or 6; or (4) an action is pending or relief has been granted under TSCA Section 5 or 7.

28. What information must be provided in a TSCA Section 12(b) export notification?

If a TSCA Section 12(b) export notification is required for any chemical substance or mixture, the exporter must prepare a notice to EPA. Each notice must include the: (1) name of the chemical substance or mixture (if a confidential product is exported a generic name or

product name must be used); (2) Chemical Abstracts Service (CAS) Number (if readily available); (3) name and address of the exporter; (4) country or countries of import, which is defined as the "country where the goods are to be consumed, further processed, or manufactured, as known to the exporter at the time or exportation." If the exporter does not know the country of ultimate destination, the shipment is credited to the last country to which the exporter knows that the merchandise will be shipped"; (5) date(s) of export or intended export; and (6) TSCA section under which EPA has taken action (*i.e.*, TSCA Section 4, 5, 6, or 7).

29. Does TSCA regulate the importation of chemical substance?

Yes. Under TSCA Section 13, the Secretary of the Treasury (United States Customs Service or Customs) must refuse entry into the United States of any shipment containing any chemical substance -- including a chemical substance that is a component of a mixture and a chemical substance or mixture contained in an article that is designed to be used or released -- if that shipment fails to comply with TSCA. Under rules adopted by the United States Customs Service, importers must certify at the point of entry, for each shipment containing chemical substances, mixtures, or articles, that: (1) all chemical substances, mixtures, and articles being imported comply with all applicable rules and orders under TSCA Sections 5, 6, and 7, and are not offered for entry in violation of TSCA (positive certification); or (2) all chemical substances, mixtures, and articles being imported are not subject to TSCA (negative certification).

30. What document(s) must accompany shipments of chemical substances imported into the United States?

Import certificates must accompany each shipment containing chemical substances, mixtures, or articles that are not exempt from TSCA importation requirements. There are three types of Import Certificates: positive, negative, and blanket. One of these types of Import Certificates must accompany each applicable shipment. Import Certificates must be preprinted, typed, or stamped on the invoice for each shipment or attached to such invoice. Import Certificates may be signed by means of an authorized facsimile signature.

31. Does EPA have inspection authority under TSCA?

Yes. TSCA Section 11 grants to EPA broad authority to conduct inspections to enforce the Act. Under TSCA Section 11(a), EPA may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce, and any conveyance being used to transport chemical substances in connection with their distribution in commerce. Failure or refusal to

permit entry or inspection as required under Section 11 constitutes an unlawful act under TSCA Section 15, giving rise to civil penalties.

32. What activities are unlawful under TSCA?

Under TSCA Section 15, it is unlawful to (1) fail or refuse to comply with a Section 4 test rule or order, or any rule, order, or requirement issued under Section 5 or 6; (2) use for commercial purpose a chemical substance or mixture which the person knew or had reason to know was manufactured, processed, or distributed in violation of Section 5 or 6, or a rule or order issued under Section 5, 6, or 7; (3) fail or refuse to establish or maintain records, submit reports, notices or other information, or permit access to or copying of records required under TSCA; or (4) fail or refuse to permit entry or inspection as required by Section 11.

33. Are there criminal liabilities under TSCA?

TSCA Section 16(b) authorizes EPA to seek criminal penalties against any person who "knowingly or willfully" violates any provision of TSCA Section 15. EPA can seek criminal fines of up to $32,500 for each day the violation continues and/or imprisonment for up to one year. EPA can seek criminal penalties in lieu of, or in addition to, civil penalties.

34. What resources are available to learn more about TSCA?

The TSCA Hotline is an information service sponsored by EPA to answer questions about TSCA regulations and initiatives and request TSCA-related *Federal Register* notices, guidance documents, and other materials pertaining to the TSCA program. The hotline telephone number is (202) 554-1404. It is staffed Monday through Friday from 8:30 am to 5:00 p.m., Eastern Time. Information regarding TSCA can also be found on the Internet at EPA's website. EPA's address is http://www.epa.gov.

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