

TerranearPMC Safety Share

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A major environmental regulation, known as the Toxic Substances Control Act or TSCA.....pronounced TOSCA, has been jokingly misconstrued for the opera of the same name, written by Giacomo Puccini; considered to be one of the most lethal operas of all time as all the main characters - heroes and villains – do not make it to the end of the story alive. It may be stretching a point a little bit, but nevertheless amusing, that the environmental regulation, TSCA, centers on the lethality of manufactured chemicals and to protect persons, so that unlike the opera, we all maintain a long and healthful life.

TSCA was passed by the United States Congress and signed into law by President Gerald Ford on October 11, 1976, after many years of negotiation between different factions of the government and chemical producers. TSCA, as authorized by the EPA, regulates new and existing chemicals. This law was a response to Congress' growing concerns about the unreasonable risks that chemical products pose to human health and the environment. Its three main objectives are to: 1) assess and regulate new commercial chemicals before they enter the market, 2) to regulate chemicals already existing (in 1976) that posed an "unreasonable risk to health or to the environment" and, 3) to regulate these chemicals' distribution and use. Some specific responsibilities for which TSCA has jurisdiction include the manufacture, processing, commercial distribution, use, and disposal of polychlorinated biphenyls (PCBs), asbestos, and lead-based paint.

Unlike other environmental regulations, such as the Clean Water Act (CAA), the Resource, Conservation and Recovery Act (RCRA –also established in 1976), TSCA does not address pollutant releases or wastes produced as byproducts of manufacturing. Instead, TSCA was designed as an attempt to exert direct government control over manufactured chemicals. For example, the use of chlorofluorocarbons is now strictly prohibited in all manufacturing processes in the United States, even if no chlorofluorocarbons are released into the atmosphere as a result.

The types of chemicals regulated by the act fall into two broad categories: existing and new. New chemicals were defined as "any chemical substance which is not included in the chemical substance list compiled and published under TSCA section 8(b)." This list includes all of chemical substances manufactured or imported into the United States prior to December 1979. At that time, this list covered 99% of the EPA's mandate and includes some 8,800 chemicals imported or produced at quantities above 10,000 pounds. Existing chemicals include any chemical currently listed under section 8(b). The distinction between existing and new chemicals is necessary as the act regulates each category of chemicals in different ways.

TSCA does not separate chemicals into categories of toxic and non-toxic. Rather it prohibits the manufacture or importation of chemicals that are not on the TSCA Inventory or subject to one of many exemptions. TSCA regulation defines the term "chemical substance" as "any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical".



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When TSCA was first promulgated, the chemical inventory contained approximately 53,000 listed substances, which has grown to over 80,000 substances. Of these, about 75,000 are found in the public portion of the inventory (listed by the Chemical Abstract Services – CAS) while the remainder are held as *Confidential Business Information* (CBI). Only substances listed on the inventory (or mixtures comprised of listed substances) can be sold in the United States.

TSCA regulations can be found in Title 40 of the Code of Federal Regulations (40 CFR), under subchapter R, which includes sections 700 – 799. As a general rule, manufacturers must submit pre-manufacturing notification (PMN) to the EPA prior to manufacturing or importing new chemicals for commerce. Exceptions include foods, food additives, drugs, cosmetics or devices regulated under the Federal Food, Drug, and Cosmetic Act, pesticides regulated by the Federal Insecticide, Fungicide, and Rodenticide Act, tobacco and tobacco products regulated by the Bureau of Alcohol, Tobacco, Firearms and Explosives, substances used only in small quantities for research and development (listed in the TSCA Regulation under Section 5(h)(3)), and radioactive materials and wastes regulated by the Nuclear Regulatory Commission. The EPA has only 90 days from receipt of a PMN to act before the new chemical may be legally marketed and included in products. In consequence, only 40 percent of acute toxicity and mutagenicity testing is ever completed; even less data on long-term effects or specific endpoints (including sub chronic, neuro toxicological, developmental, reproductive, and chronic) is ever generated.

The EPA reviews new chemical notifications and if it finds an "unreasonable risk to human health or the environment," it may regulate the substance from limiting uses or production volume to outright banning it. In 2013, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was proposed as the first major overhaul in many years, which requires EPA to designate certain substances as either active or inactive in U.S. commerce. The Agency has posted an updated list of chemical substances that reflects the Notices of Activity (NOAs) reported to EPA through January 5, 2018. EPA intends to update this list approximately once per month.

TSCA has a low volume exemption for commercially producing or importing a new chemical. The PMN process must still be met; however there is only a 30-day EPA review (and no filing fee); while such new substances are limited to less than 10,000 kg of annual production.

Penalties resulting from an EPA TSCA violation can be significant. For a PMN violation, a company can be fined up \$32,500 for each day that a batch of non-listed material (a substance that is not on the TSCA inventory) is produced. Criminal penalties for knowing and willful violations may involve monetary fines as well as imprisonment for up to one year for each violation,

I cannot remember the books I've read any more than the meals I have eaten; even so, they have made me - Ralph Waldo Emerson

