



ENVIRONMENTAL UPDATE

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Waxman TSCA “Reform” Bill Would Radically Expand Chemical Regulation and Impose New Safety and Reporting Requirements

On July 22, Rep. Henry Waxman (D-CA) introduced [H.R. 5820, the “Toxic Chemicals Safety Act of 2010.”](#) A major step in the Toxic Substances Control Act (“TSCA”) “reform” initiative, H.R. 5820 would impose significant new burdens on industry, increase TSCA obligations on companies that have historically avoided this statute, and far exceed EU’s Registration, Evaluation and Authorization of Chemicals (“REACH”) chemical requirements. A hearing is currently scheduled for July 29. Some key features of H.R. 5820 include:

- **Burden of Proof:** Companies bear the burden of proving that chemicals and mixtures are safe for intended uses. REACH does not require companies to prove that their chemicals are safe (except for chemicals specially designated for the “authorization” process).
- **Safety Standard:** Companies must show, and EPA must determine, that there is a “reasonable certainty that no harm will result” from all intended uses over the life cycle of a chemical, taking into account aggregate exposure (including exposure to pesticides, foods, drugs, cosmetics and medical devices), available information on cumulative exposure, and vulnerable populations (including children and individuals with pre-existing medical conditions). REACH does not establish a generally applicable safety standard.
- **Scope — Companies:** Processors, as well as manufacturers (which include importers), would become subject to the premanufacture review (“PMN”) and safety determination requirements. Since under current law, only chemical manufacturers are subject to the PMN requirements, the new bill would capture a broad swath of companies that process chemicals and mixtures to make products.

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- **Scope — Chemicals:** New chemical mixtures and significant new uses of mixtures apparently would be subject to the PMN and safety determination requirements unless EPA, at its discretion, concludes that particular mixtures are similar enough to not require separate review. EPA may also designate existing mixtures already on the market for data submission and safety determination requirements. This is a major expansion of TSCA jurisdiction, which currently focuses on individual substances. REACH does not require the separate registration of mixtures (called “preparations” in REACH).
- **Scope – Food, Food Additives, Drugs, Medical Devices and Pesticides:** The bill removes the current exclusion of these substances from the definition of “chemical substance” under TSCA, instead only excluding from TSCA jurisdiction manufacturing and processing activities “solely” involving these categories of products. This means, for example, that where EPA is authorized to impose risk management controls on “commercial uses” of chemicals, it could be interpreted to give EPA authority under TSCA to impose requirements on food, food additive, drug, medical device and pesticidal uses.
- **Safety Reviews:** Beginning with a short list of chemicals contained in the bill, and following with a 300-chemical list created and regularly refreshed by EPA, safety determinations will be made on existing chemicals. EPA may also add mixtures to this list. The aggressive review schedule requires the safety determinations to be completed within 30 months of listing (18 months for the statutory short list).
- **Minimum Data Sets:** Over a five-year period, “minimum data sets” for existing chemicals must be submitted to EPA by manufacturers and processors for all chemicals (and any mixtures designated by EPA) currently in commerce in the U.S. New chemical submissions must also include the minimum data set. The minimum data set includes toxicity and exposure data, taking into account all stages of the life cycle and intended uses. This schedule is approximately twice as fast as the REACH deadlines for submitting “dossiers,” and does not include REACH’s general exemption for chemicals manufactured in volumes of < 1 ton/year (per company).
- **Declarations:** Within one year of enactment, each manufacturer and processor of an existing chemical must submit a declaration containing a broad and detailed set of manufacturing/processing, exposure, health, safety and toxicity data. New chemical submissions must also include these declarations. EPA, at its discretion, may also require such declarations for mixtures. This is significantly more burdensome than REACH’s “pre-registration” requirement, both in terms of content and timing. This information must be updated every 3 years, and “immediately” if there is “significant new information” indicating a new “potential adverse effect,” suggesting an adverse effect at a lower dose than previously demonstrated, or “otherwise reasonably relevant” to an analysis of whether the chemical or mixture meets the safety standard.
- **Persistent, Bioaccumulative and Toxic Chemicals (“PBTs”):** EPA must identify and publish a list of PBTs, and then impose risk management conditions on the listed PBTs “necessary to achieve the greatest practicable reduction in exposure.” These conditions do not have to be justified based on risk.
- **Risk Management:** If EPA determines that a chemical or mixture does not meet the safety standard, EPA may impose a wide range of risk management controls, or may prohibit the manufacture, processing or distribution in commerce of the not only the chemical or the mixture, but of the articles or products manufactured from the chemicals. EPA may also establish requirements “regulating any manner or method” of the “commercial use” of a substance or mixture. This essentially puts EPA in the product regulation business. Further, the risk management

provisions authorize EPA to impose controls to reduce occupational exposures, thus expanding EPA's jurisdiction into that of OSHA.

- **Constraints on Business:** Changes in intended uses or significant changes in volume for chemicals or mixtures will be considered “new uses” that trigger EPA review and pre-approval (including a demonstration that the safety standard is met). The increased volume trigger is analogous to new source review provisions under the Clean Air Act.
 - **Certifications:** The data submissions and declarations required of manufacturers and processors of chemicals and mixtures must be accompanied by certifications by a responsible official that the submission is “accurate and reliable” and that it “includes all material facts known to, in the possession or control of or reasonably ascertainable by the manufacturer or processor.”
 - **Disclosure to Commercial Purchasers:** Manufacturers and processors of chemical and mixtures shall provide to all known commercial purchasers a disclosure that includes chemical identity and the identity of all of the ingredients of mixtures, detailed toxicological information, and all health and safety studies and records of significant adverse reactions submitted to EPA. Requiring the “downstream” disclosure of the ingredients of mixtures may raise confidential business information issues.
 - **Preemption:** State laws regulating chemicals are preempted only if such state laws render compliance with TSCA impossible. This allows state laws, such as California’s “Green Chemistry” initiative, to impose different or more stringent requirements than TSCA.
- **Enforcement:** Criminal penalties are increased to \$50,000/day and five years of imprisonment, and a new category of criminal violation is created: a person who knowingly or willfully violates TSCA and who knows that such violation may result in imminent danger of death or serious bodily injury shall be subject to a fine of not more than \$250,000 (\$1 million for companies) or imprisonment of not more than 15 years. In addition, those who incorrectly (as determined by EPA) designate information as confidential business information (“CBI”) are subject to civil penalties, and those who submit information as CBI knowing that it does not meet the CBI criteria shall be guilty of a misdemeanor and fined not more than \$5,000, or imprisonment for not more than one year, or both.

There are many other significant provisions, including sections on children’s health, animal testing, promoting “green chemistry,” and tightening chemical import/export requirements.

While the future of this specific bill is uncertain, given other high profile agenda items and the November mid-term elections, it is a shot across the bow that sets the terms of the debate on key issues such as the burden of proof, the relevant safety standard, the applicability of TSCA to the economic sectors that process chemicals into products, the regulation of mixtures, and the competitive impact of TSCA “reform” that would leapfrog the already challenging burdens of REACH.

If you have questions about any of these items, please contact Christopher Bell (1.202.736.8118 or cbell@sidley.com) or your regular Sidley Austin LLP contact.

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