Safe Chemicals Act of 2011, as amended, Section-by-Section

This fact sheet covers some of the most important sections of the Safe Chemicals Act of 2011, as amended, introduced by Sen. Frank R. Lautenberg (D-N.J.). For more than 15 years, EWG has supported and worked tirelessly for a new chemical regulatory regime that determines which chemicals are safe for the marketplace, especially for the most vulnerable among us.

Sec. 5. Minimum Information Sets (MIS) and Testing of Chemical Substances

Establishes a series of different minimum information sets to provide the Environmental Protection Agency with sufficient data to make categorization, prioritization and safety determinations. Submission of a MIS is not required for all existing chemicals but is required for ones where EPA needs additional data to make these determinations. Industry must submit the appropriate minimum information set as part of a pre-manufacture notice for new chemicals.

EPA's authority is broadened to require additional testing to obtain data on chemicals and samples of chemical substances. Among the information the agency can request is whether the chemical is present in blood, bodily fluids or tissue. In general the EPA may require the use of biomonitoring to determine the presence of a chemical in the body. One company can conduct toxicity testing on behalf of other companies; the MIS may be tailored to specific chemicals or category of chemicals.

Since 2000 EWG has conducted biomonitoring tests of more than 200 people, including tests of 20 samples of umbilical cord blood (http://www.ewg.org/sites/humantoxome/). These studies have driven the debate about the hundreds of chemicals to which Americans are exposed, even in the womb. In our most recent cord blood biomonitoring, which took samples from 10 newborns from ethnic and racial minorities, we found up to 232 toxic chemicals, including flame retardants and bisphenol A. (http://www.ewg.org/minoritycordblood/home).

EWG President Ken Cook has traveled the country telling the story of our umbilical cord blood research in his *10 Americans* talk:
https://www.youtube.com/watch?v=jh2p2RFAanE&feature=related

Sec. 6. New Chemical Substances and New Uses of Chemical Substances

Maintains the current pre-manufacture notice (PMN) process, which requires EPA to categorize a new chemical substance within 90 days of a PMN submission. New chemicals that EPA determines are likely to meet the safety standard are allowed onto the market and then placed in the queue for safety determination. New chemicals that are unlikely to meet the safety standard or about which there is insufficient information are not allowed onto the market.

New uses of an existing chemical that has not undergone a safety determination require a PMN and submission of the required MIS. New uses of an existing chemical that has already undergone a safety determination require a PMN, updating of the MIS and an EPA determination

that the safety standard will still be met.

EWG has long supported a more robust review of new chemicals than the current scheme, which allows most chemicals to be placed on the market with little or no safety review.

Sec. 7. Batching, Categorization, Prioritization, Safety Standard Determination, and Risk Management

Establishes a process for assessing the safety of all existing chemicals in the EPA's inventory. The burden is on chemical companies to prove a chemical is safe. EPA is required to categorize existing chemicals and identify those that need safety assessment or risk management. The agency may grant exemptions for uses vital to the American economy or national security. EPA must consider both existing data and information submitted by manufacturers.

The process for batching, categorizing, prioritizing, assessing, and approving or restricting chemicals operates as follows:

Batching of Chemical Substances. EPA is directed to establish an initial batch of 6,000 chemical substances for review, based on the chemical data reporting (CDR) rule for evaluation within 5 years. Following the initial batch, EPA is required to establish similarly sized batches every five years until all existing chemicals on the inventory have been evaluated.

Categorization of Chemical Substances. After a batch is established EPA must categorize the chemicals as substances of:
1) very high concern, defined as highly hazardous and having widespread exposure and are moved into expedited risk assessment
2) very low concern, deemed to meet the safety standard, barring any significant new uses or information
3) needs a safety determination and should go into the prioritization process; or
4) insufficient information, which requires the company to submit a MIS.

Prioritization of Chemical Substances**.** After chemicals are categorized, EPA must prioritize those that require a safety determination into 3 priority classes:
1) Priority Class I chemicals have the highest need for safety determination and those determinations must be completed within 5 years.
2) Priority Class II and III chemicals are required to submit a MIS. Based on that data, EPA either reprioritizes the substance as higher or low priority.

Safety Determination and Risk Management. For the chemicals subject to a safety determination EPA makes the final decision based on the standard of reasonable certainty that no harm will result to human health to the environment from aggregate exposure to a chemical. This is the safety standard that EWG has advocated for since the first Kid-Safe Chemicals Act was drafted in 2005. It is the gold standard for protection of human health and is the same standard to which that pesticides are subjected.

Once the determination is made, the EPA may restrict uses or ban the chemical to ensure the chemical meets the safety standard. If EPA does not complete the determination within 5 years the companies must tell consumers that EPA has not determined the safety of the chemical.

The legislation requires EPA to identify asbestos as a chemical of very high concern and act within 1 year to reduce human exposure to asbestos as much as possible. Asbestos is the substance that demonstrated the weakness of TSCA. EPA failed to ban asbestos because it could not meet the high burden of proof under TSCA.

EWG has worked extensively on the dangers of asbestos over the years. In a study of asbestos deaths in Texas: http://www.ewg.org/reports/slowdeath, we took an extensive look at the asbestos epidemic, including industry's cover-up, lawsuits, and asbestos-related illnesses, including mesothelioma, asbestosis and lung cancer: http://www.ewg.org/sites/asbestos/facts/index.php This report includes a map of asbestos deaths from 1979 to 2001: http://www.ewg.org/sites/asbestos/maps/government_data.php

Sec. 9. Reporting and Retention of Information

This section resets EPA's toxics inventory to provide an accurate picture of the number and types of chemicals in commerce. It requires chemical manufacturers to declare a current, potential or no commercial interest in a chemical substance. EPA is required to establish a publicly accessible electronic database for information relating to the toxicity, use and chemical exposure.

EPA must have a complete picture of the number of chemicals that are subject to this law. This provision will allow everyone to have a better understanding of chemicals in commerce and will give the agency a better understanding of the resources it needs to comply with the law.

Sec 14. Disclosure of Data

Establishes the eligible recipients of CBI information, 3 categories of information eligible for protection, and requirements for certifying CBI claims. The 3 categories of eligible information are:
1) information that is always eligible for protection, that relating to marketing and sales, precise production and trade secrets,
2) information that may be eligible for protection, including chemical identity of new chemicals. This category establishes a maximum 5 year period of CBI protection, although additional protection can be granted by submitting a new CBI claim, and
3) information that is never eligible for protection, including general health and safety information, the identity of existing chemicals.

The section requires the EPA to review all chemical identity-related CBI claims and at least 25 percent of other claims. It requires companies to justify confidentiality claims.

As EWG documented in our Secret Chemicals report, the public had no access to more than 17,000 of the chemicals in the toxics inventory. Companies had claimed CBI protections for more than two-thirds of the 20,400 chemicals that came onto the market between 1976 and 2009. Due to CBI protections, a large number of the chemicals were in consumer products, including 10 specifically designed for children's products and manufactured in high volumes.

Flame retardants are a major issue. They are ubiquitous and present significant health risks, including cancer and neurological and reproductive system damage. As certain flame retardants are barred or phased out, we are concerned about the secrecy surrounding the chemicals introduced as replacements. The issue of safe substitutes is not unique to flame retardants. We are learning that some BPA alternatives may not be safe.

Over the last decade EWG has done extensive research on flame retardants:

Mother's Milk: EWG's 2003 study of chemical fire retardants in the breast milk of American women was the first of its kind. It found that the average level of bromine-based fire retardants in the milk of 20 first-time mothers was 75 times the average measured in recent European studies. Milk from two study participants contained the highest levels of fire retardants ever reported in the U.S. Milk from several other new mothers in the study scored among the highest levels of fire retardants detected in the U.S. up to that point.

Fire Retardants in Toddlers and Their Mothers : EWG's blood tests of toddlers and preschoolers found 11 different flame retardants in a group of children -- typically 3 times as much as their mothers.

Pollution in Minority Newborns: This 2009 study was a comprehensive analysis of pollutants detected in the cord blood of 10 newborns from racial and ethnic minorities. Flame retardants were found in 10 out of 10 samples. Bisphenol A, a synthetic estrogen that has been linked to cancer and impaired development of the reproductive system and other organs, was found in 9 of 10 samples.

Sec. 30. Children's Environmental Health Research Program.

Requires EPA to establish a research program focused on children's health to provide grants to independent researchers to advance scientists' understanding of children's vulnerability to industrial chemicals.

The bill requires EPA to establish an advisory board with experts on children's health and toxic chemicals.

EWG has long focused on the impact of chemicals on children's health. The research program and advisory board would bring the latest scientific discoveries to bear on the dangers to children and other vulnerable people of chemicals found in food and consumer products

EWG has conducted extensive research on children's exposure to bisphenol A, which mimics estrogen in the body and can disrupt the hormone system. This chemical has been used for decades to harden polycarbonate plastic, used in baby bottles, drinking bottles and plastic cups, and epoxy resin, used to line the interiors of aluminum food cans. It leaches readily out of both types of plastic. Recently the federal Food and Drug Administration announced that BPA will no longer be permitted in baby bottles and sippy cups. The agency took is proceeding on a petition to bar BPA from infant formula cans, but hasn't taken action on cans of food marketed to children and other food packaging. EWG has helped raise the profile of BPA as one of the worst chemicals in commerce. Our 2007 study Toxic Plastics Chemical in Infant Formula demonstrated that this toxic chemical migrated from cans into formula. Our 2007 report Bisphenol A: Toxic Plastics Chemical in Canned Food found the chemical in more than half of 97 food cans purchased across the U.S. Our 2010 report on synthetic estrogen BPA coating cash register receipts found extensive use of BPA as a coating on paper store receipts.

Sec. 31. Reduction of Animal-Based Testing.

The EPA must minimize animal testing by encouraging the use of existing data, grouping of chemical substances for testing, formation of industry consortia to reduce redundancy, use of existing methods that eliminate or reduce the use of animals and the development and validation of emerging methods and models. EPA must establish an Interagency Science Advisory Board on Alternative Testing Methods and develop a strategic plan to promote alternative methods. Chemical companies could also request adaptation or a waiver of animal testing requirements.

EWG has long worked with animal welfare organizations to advance policies that minimize harm to animals and reduce the number of animals used in chemical safety testing.

Sec. 32. Safer Alternatives and Green Chemistry and Engineering.

Requires the development of market and other incentives for safer alternatives including expedited review for new chemicals that claim to be safer and recognition for safer alternatives through special marketing designations, awards and rewards.

EPA must also establish a green chemistry research network of at least 4 centers to support and provide research grants for the development and use of safer alternatives. It must establish a Green Chemistry Workforce Education and Training Program.

EWG fully supports the move to safer alternatives including through Green Chemistry. Successful reform of the Toxic Substances Control means answering the question: "Is this chemical safe?" If it is not, it must be removed from the market and a safer alternative found.

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Other Provisions

- Allows states and localities to pass stronger laws regulating chemicals and requires EPA to coordinate with states;

- Allows EPA to collect user fees from chemical companies for, among other things, submitting claims of secrecy on grounds of "confidential business information";
- EPA must act quickly to mitigate risk from chemicals of highest concern;
- Requires EPA to coordinate with the European Union and other international efforts to protect people from toxic chemicals;
- Allows EPA to take necessary steps to protect the public from chemicals that "may present an imminent and substantial endangerment to health or the environment";
- Strengthens EPA's ability to ask other agencies to reduce risk from chemicals;
- Strengthens EPA authority to conduct inspections of chemical company premises, gather information and issue warrants;
- Requires the government to bar importation of any chemical if it does not meet the standards in the law;
- Requires EPA to identify localities where people are disproportionately exposed to chemicals and take action to reduce their exposures.

EWG has long supported these provisions. EWG believes that chemical companies should pay fees for EPA reviews of secrecy claims and safety, much as pharmaceutical companies pay to support regulation of prescription drugs.

The European Union is ahead of the U.S. in its chemical regulatory scheme. EWG strongly advocates that the U.S. use data already given to the EU to cut down on costs, regulatory decision-making time and the number of animals tested. We support EPA's ability to act quickly on chemicals of very high concern, to protect Americans from imminent danger. We've long advocated that chemicals found in umbilical cord blood be considered chemicals of very high concern. We support the premise that the government should prohibit products that don't meet the safety standard from entering the country.

Some communities need environmental justice to redress air, water and soil contamination from nearby industries. EWG has worked in Anniston, Alabama, to help that community clean up PCB contamination, with the Louisiana Bucket Brigade and other communities beset by unjust pollution problems.