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# A Study on the Current State of Contaminants of Concern Research, with a Focus on Biosolids and Regulations

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A Study on the Current State of  
Contaminants of Emerging Concern Research,  
With a Focus on Biosolids and Regulations

by

Maren Mariah Fulton

A research project report submitted in partial fulfillment  
of the requirement for the degree of

MASTER OF SCIENCE  
IN  
CIVIL AND ENVIRONMENTAL ENGINEERING

Project Advisor:  
Dr. Gwynn Johnson

Portland State University  
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Author,  
Maren Fulton

## Abstract

### A Study on the Current State of Contaminants of Emerging Concern Research, With a Focus on Biosolids and Regulations

Maren Mariah Fulton

Chair of the Supervisory Committee:

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Wastewater treatment plants are a major source of contaminants of emerging concern, as these facilities are the main receptors of these products via household, commercial, and industrial drains, and transport via stormwater runoff. Biosolids are composed of numerous constituents, with a number of environmentally persistent and potentially toxic contaminants of emerging concern identified as present in large concentrations. Research is needed to understand the transport and fate mechanisms of these compounds in biosolids. Additionally, this research is needed to determine a new priority framework to regulate CECs, both on the national level and regional levels. Wastewater treatment plant influent and effluent treatment regulations and practices may be improved upon as more knowledge accrues regarding contaminants of emerging concern behavior in the environment.

The United States environmental regulatory process is a constant work in progress. Inherited from decades-old public health traditions, environmental regulatory programs arose to address the issues of public health as water and air quality issues surfaced. The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601), enacted in 1976, provided the EPA regulatory authority to protect the environment and consumers' health against risks posed by chemicals in commerce. TSCA only retroactively addressed chemical hazards, after they had been deemed unsafe and previously unrestricted in the public. A bill to overhaul TSCA, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act

(House Amendment to the Senate Amendment to H.R. 2576, TSCA Modernization Act of 2015), was passed by the Senate on June 7, 2016 and sent on for President Obama's signature. The amended law will give the EPA new authority to evaluate the safety of a new chemical before it enters the marketplace. It will also allow EPA to evaluate the safety of chemicals already known to be risks, including chemicals found to persist in the human body and in the environment.

The Columbia River is presented as a case study as an example of a significant waterbody with research and regulatory gaps concerning CECs. The Columbia River waterbody was chosen as it represents an important natural resource for which data gaps exist on CEC sources and pathways into the waterbody, and which also does not receive adequate protective regulations under the national regulatory framework.

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## List of Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
BPA	bisphenol A
CEC	contaminants of emerging concern
CFR	Code of Federal Regulations
cfs	cubic feet per second
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CRTRWG	Columbia River Toxics Reduction Work Group
CWA	Clean Water Act
DBP	drinking water disinfection byproducts
DDT	dichlorodiphenyltrichloroethane
ECHA	European Chemicals Agency
EPA	United States Environmental Protection Agency
EU	European Union
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act of 1972
FWPCA	Federal Water Pollution Control Act of 1948
FWPCA	Federal Water Pollution Control Act of 1972
FWQA	Federal Water Quality Administration
ITC	Interagency Testing Committee
kg/yr	kilogram per year
LCREP	Lower Columbia River Estuary Program
MS4	municipal separate storm and sewer systems
NAS	National Academy of Science
NEP	National Estuary Program
NEPA	National Environmental Policy Act
NOAA	National Oceanic and Atmospheric Administration
NOM	natural organic matter
NP	nanoparticles
NPDES	National Pollutant Discharge Elimination System
NPL	National Priority List
NRC	National Research Council
NSSS	National Sewage Sludge Survey
OPA	Oil Pollution Act of 1990
OTs	organotins
PAHs	polycyclic aromatic hydrocarbons
PBDEs	polybrominated diphenyl ethers
PCA	polychlorinated alkanes
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzo-furans
PCNs	polychlorinated naphthalenes
PFC	perfluorinated compounds
PFOA	perfluorooctanoic acid
PFOS	perfluorooctanesulfonic acid

PHS	United States Public Health Service
P.L.	Public Law
POP	Persistent Organic Pollutants
POTW	publicly owned treatment works
QAC	quaternary ammonium compounds
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
TCA	1,1,1-trichloroethane
TCC	triclocarban
TCS	triclosan
TSCA	Toxic Substances Control Act
TMDL	Total Maximum Daily Load
USCG	United States Coast Guard
USDA	United States Department of Agriculture
USGS	United States Geological Survey
USACE	United States Army Corps of Engineers
UV	ultraviolet
WDOE	Washington State Department of Ecology
WQA	Water Quality Act
WRDA	Water Resources Development Act
WWTP	wastewater treatment plant



## Chapter 1

### 1. Introduction

Over the past few decades, research has documented with increasing frequency the effects and occurrence of a class of environmental pollutants now commonly called contaminants of emerging concern (CECs). CECs include all classes of pollutants for which the environmental risks are previously unknown, unrecognized, or unsuspected. A contaminant of ‘emerging concern’ refers to a compound that is not currently regulated (e.g., not designated as a Priority Pollutant in the United States (U.S.)), is commonly detected at low levels in the environment, and may present a threat to environmental and human health.

The designation, ‘emerging concern,’ represents a shift in perspective of what is traditionally considered to be an environmental contaminant. Despite being found at low concentrations, due to their ubiquitous nature, CECs are now being more widely detected in far-ranging and diverse locations in the environment, from surface and groundwaters (Vulliet, 2011) to household dust (Ali, 2011), and from plants (Divan Jr., 2009) and animals (Sun, 2012) to arctic ice (De Laender, 2011; Hermanson, 2010). Most of these chemicals have not been adequately examined for toxicological or environmental impacts, and screening methods and regulatory restrictions are still under development (EPA, 2016). Research into the occurrence and risk of exposure to these compounds has been rapidly expanding, and legislation to regulate sources and discharges of CECs to the environment has been evolving to keep up with these scientific findings.

Many CECs are industrially produced, yet are dispersed to the environment often via common domestic, commercial, and industrial uses. CECs include many pharmaceuticals, personal care products (such as shampoos, deodorants, and fragrances), commercial and household chemicals, some pesticides, nanomaterials, and hormones. It has been estimated that over 100,000 chemicals are currently in commerce, with up to 1,000 new compounds added to current-use each year. Of these thousands of chemicals,

more than 40,000 organic chemicals have been identified as CECs, and that estimate fails to include or consider the associated degradation by-products of those chemicals in environmental systems (Diamond, 2011). Many of these chemicals make their way to wastewater treatment plants (WWTPs), where they may be released to the environment via treated effluent and land application of treated sewage sludge (biosolids).

The land application of biosolids is considered to be a relatively positive reuse option of WWTP sludge, both nationally and internationally. Researchers have shown that biosolids contribute nutrients and beneficial soil amendments such as nitrogen and phosphorus (National Resource Council (NRC) 2002). A significant volume of research has been conducted on the presence of persistent organic pollutants (POPs) in biosolids such as polychlorinated dibenzo-p-dioxins/dibenzo-furans (PCDD/PCDFs), polychlorinated biphenyls (PCBs) and polycyclic aromatic hydrocarbons (PAHs) (e.g., Wild et al., 1991; Alcock et al., 1996; Stevens et al., 2001), and concentrations of these 'traditional' POPs in biosolids have declined due to effective source control (Wild et al., 1990; Clarke et al., 2008, 2010). However, analytical results have indicated the presence of large concentrations of a number of CECs, identified as environmentally persistent and potentially toxic, as being present in large concentrations in biosolids (NRC 2002; Davis et al., 2012; LaGuardia, 2004). Research on the transport, fate, and potential ecological effects of CECs once biosolids are applied to agricultural fields, garden plots, and landscaped plants and shrubs is still emerging (Clarke, 2011).

Finally, the Columbia River Basin is presented in this paper as a study of a significant waterbody with threatened water quality. The Columbia River discharges an average volume of 265,000 cubic feet per second (cfs), and is the fourth largest river by volume in the U.S. following the Mississippi, the St Lawrence, and the Ohio Rivers, respectively. The Columbia River waterbody was chosen as it represents an important natural resource for which data gaps exist on CEC sources and pathways into the waterbody, and which also does not receive adequate protective regulations under the national regulatory framework.

## 1.1 Objectives and Scope

Research regarding the transport and fate, and potential ecological effects of CECs sourced from land-applied biosolids is ongoing in both the U.S. and internationally. The purpose of this paper is to present an overview of the current state of CEC research, with a focus on CECs in biosolids. This paper also aims to present a review on the current state of legislation governing regulations of monitoring requirements and acceptable use of land-applied biosolids. The literature review included over 25 articles, spanning from 1990 to 2016, and numerous reports and documents that referenced CEC research, from which a subset was selected based on relevance of studies of CECs and water quality, and biased towards recent and current research. A case study on the Columbia River watershed is also presented to provide a topical perspective on the relevance of regulatory and CEC issues.

## 1.2 Problem Statement and Relevance

Approximately 5.6 million dry tons of biosolids are used or disposed of annually in the United States, of which approximately 60% are land-applied as soil amendments. EPA estimates that biosolids are applied to approximately 0.1% of available agricultural land in the United States on an annual basis (NRC, 2002). Biosolids are composed of numerous constituents, with a number of environmentally persistent and potentially toxic CECs identified as present in large concentrations (NRC, 2002; Davis et al., 2012; LaGuardia, 2004), which may be released to the environment via land application.

The presence of priority pollutants such as heavy metals and polychlorinated biphenyls (PCBs) in land-applied biosolids has been extensively studied, including the effects on human health and the environment, and environmental behavior (NRC, 2002). However, data gaps exist in information regarding risks to human and environmental health, occurrence, persistence, transport and fate, and the transformation of emerging contaminants (Chase et al., 2012; Calderon-Preciado, 2011a). Consumption of

unregulated chemicals is constantly increasing, along with increasing detection rates of significant concentrations of these chemicals in biosolids. Research is needed to understand the transport and fate mechanisms of these unregulated compounds in biosolids. Additionally, this research is needed to determine a new priority framework to regulate CECs, both on the national level and regional levels, including the Columbia River Basin. Advancement in the body of CEC research can also provide guidance on improving regulatory oversight, such as implementing appropriate risk evaluation procedures of new chemicals prior to commercial release, and potentially decrease the frequency of one banned chemical being replaced by a new and unevaluated alternative chemical, such as flame-resistant polybrominated diphenyl ethers (PBDEs) and their replacement congeners (Davis et al., 2012). Understanding the concentrations and environmental behavior of CECs in land-applied biosolids is key to determining the significance and implications of these emerging pollutants on human health and the environment.

## Chapter 2

### 2. Introduction to CECs and Relevant Regulations

This section provides an introduction to CECs and environmental concerns regarding CECs, as well as a brief history of relevant environmental regulations. The summary of environmental regulations includes a description of Federal regulatory agencies and regulations, as well as international environmental regulations.

#### 2.1 Introduction to CECs

CECs include all classes of pollutants for which the environmental risks are previously unknown, unrecognized, or unsuspected. CECs are commonly dispersed to the environment via domestic, commercial, and industrial uses. Sources of CECs include agriculture, landfills, residential household drains and WWTPs, and pesticide use in landscaping applications. CECs include many pharmaceuticals, personal care products, commercial and household chemicals, some pesticides, nanomaterials, and hormones. Classes of CECs identified as problem or priority chemicals include perfluorinated chemicals (e.g., PFOS, PFOA); polychlorinated alkanes (PCAs); polychlorinated naphthalenes (PCNs); organotins (OTs); unregulated congeners of polybrominated diphenyl ethers (PBDEs); triclosan (TCS); triclocarban (TCC); benzothiazoles; antibiotics and pharmaceuticals; synthetic musks; bisphenol A (BPA); quaternary ammonium compounds (QACs), steroids; personal care products; unregulated pesticides; and a wide range of industrial chemicals and nanomaterials.

One of the primary reasons for the increase in awareness of CECs in the environment has been due to recent improvements in the sensitivity of analytical techniques, allowing the detection of previously undetectable low-concentration contaminants. Studies on the risks posed by these pollutants to human and environmental health and safety, and research on the sources, transport, fate, and behavior of CECs are now at the forefront of environmental research. The topic has even gained exposure in media with published

articles concerning these compounds. One reason that CECs attract popular attention is because the major source of these contaminants is from the general population, via everyday use of products that contain the very compounds that pose environmental risks.

The Athens, Georgia, EPA National Exposure Research Laboratory conducted a 2010-2011 biennial review to identify particular CECs as major trends in research or as new emerging contaminants (Richardson, 2011a). The EPA acknowledged that many new environmental CECs were identified in this biennial review due to improved analytical techniques that have allowed detection levels at previously undetectable limits in the low ng/L concentrations. This is significant, as prior analytical techniques did not allow for such low detection levels, resulting in many chemicals occurring undetected in the environment. The CECs identified in this biennial review are summarized below.

Perfluorinated compounds (PFCs) were identified as a major trend of research in the biennial review conducted by the Georgia EPA research laboratory. PFCs have been in production for more than 50 years, and are used in the production of stain repellents, paints, adhesives, waxes, polishes, metals, electronics, fire-fighting foams, caulks, and food packaging such as microwave popcorn bags and French fry boxes. PFCs are persistent and environmentally mobile, due to their unique chemistry of being composed of one of the strongest chemical bonds of carbon-flourine, and their hydrophobic and lipophilic behavior. Between 2000 and 2002, an estimated 5 million kg/yr of PFCs were produced worldwide, with 40% of this in North America alone (Richardson, 2011a).

Brominated flame retardants have been used for many years, and were updated in manufacturing use by polybrominated diphenyl ethers (PBDEs) since the polybrominated biphenyls were banned about 30 years ago. While penta- and octa-PBDEs were banned in various states, replacement fire retardant chemicals have been produced to keep pace with legislative regulations.

Perchlorate is now recognized as a worldwide environmental issue, and has been found in environmental waters across the United States and in other parts of the world. It has been

detected in food products in the US, in Europe, and the Far East. Perchlorate is very water-soluble and environmentally stable, and can accumulate in plants which can lead to exposure in humans and animals. Natural sources of perchlorate include naturally sourced nitrate fertilizer. Ammonium perchlorate is used as an oxidizer in solid propellants for rockets, fireworks, and highway flares. Perchlorate can also be a contaminant from the drinking water treatment chemical sodium hypochlorite, and is not removed by conventional water treatment processes, leading to potential for human exposure to occur through drinking water.

Additional CECs include nanomaterials, which are 1 to 100 nm in size and can have unique properties, including high strength, thermal stability, low permeability, and high conductivity. The chemical structures of nanomaterials are highly varied, including fullerenes, nanotubes, quantum dots, metal oxanes, TiO<sub>2</sub> nanoparticles (NPs), nanosilver, nanogold, and zerovalent iron NPs (Richardson, 2011a).

Pharmaceuticals and hormones have been detected in environmental waters. Concerns regarding pharmaceuticals and hormones include potential threats to drinking water, and possible estrogenic and other effects to wildlife and humans. An additional issue of the release of pharmaceuticals to the environment includes the development of bacterial resistance. These CECs are transported to the environment most commonly via effluent from WWTPs due to incomplete removal in wastewater treatment, and also through livestock farm discharges (Richardson, 2011a). An estimated 3200 different substances are used as pharmaceutical ingredients, including painkillers, antibiotics, antidiabetics, betablockers, contraceptives, lipid regulators, antidepressants, chemotherapy drugs, and impotence drugs, and only a very small subset of these compounds has been investigated in environmental studies.

Drinking Water disinfection byproducts (DBPs) were also identified as CECs, and are formed by the reaction of disinfectants (chlorine, chloramines, ozone, chlorine dioxide, etc.) with natural organic matter (NOM) and bromide or iodide in source waters.

Nitrosamines, discovered as DBPs in 2002, are probable human carcinogens. Additional

new CECs include UV filters, used in sunscreens, cosmetics, and other personal care products. UV filters have potential for endocrine disruption and developmental toxicity. Environmental levels of UV filters were detected at levels close to the doses that cause toxic effects in animals (Richardson, 2011a).

1,4-Dioxane has been detected in environmental waters, has also been found in drinking water, and is a probable human carcinogen. Dioxane is a high production chemical used as a solvent stabilizer for the production of textiles including paper and cotton, and also in automotive coolants, cosmetics, and shampoos, as well as a stabilizer in 1,1,1-trichloroethane (TCA). In 2002 alone, an excess of 500 tons of dioxane were produced or imported in the United States.

Reports of benzotriazoles as an environmental contaminant have only been detected since approximately 2004, and studies indicate that they are likely ubiquitous environmental contaminants. Benzotriazoles are complexing agents widely used as anticorrosives. The two common forms, benzotriazole (1H-benzotriazole) and tolyltriazole (a mixture of 4- and 5-methyl-1H-benzotriazole), are water-soluble, resistant to biodegradation, and only partially removed in wastewater treatment.

Siloxanes have become a relatively new area of research of CECs, with concerns about potential toxicity and transport into the environment due to reportable quantities in wastewater, river water, and landfill biogases (Richardson, 2011b). Siloxanes are used in the production of a number of personal care products and common utensils and household products such as cosmetics, deodorants, soaps, hair conditioners, hair dyes, car waxes, baby pacifiers, cookware, cleaners, furniture polishes, and water-repellent windshield coatings.

Synthetic musk compounds are also a growing area of research of CECs, as they have been widely detected in wildlife and humans. Musks are highly lipophilic, and tend to accumulate in sediments, sludges, and biota. Musks are commonly used as fragrance



additives in many consumer products, including perfumes, lotions, sunscreens, deodorants, and laundry detergents.

Finally, microorganisms and algal toxins (mostly cyanobacterial toxins produced from blue-green algae) have also been reported as CECs. An unusual CEC identified in this review was sucralose, identified as a persistent (half-life up to several years) contaminant found in surface water, groundwater, and coastal waters (Richardson, 2011b). The research paper by Soh et al. (2011) stated that sucralose is one of very few contaminants that are highly persistent but do not bioaccumulate, and have little or no reported toxicity at environmentally relevant concentrations. Their paper raised an important question:

“Is persistence reason enough for concern or regulation?” (Soh et al., 2011)

### **2.1.1 Wastewater Treatment Plants as Sources of CECs**

WWTPs are a major source of CECs, as these facilities are the main receptors of these products via disposal down household, commercial, and industrial drains, and transport via stormwater runoff (e.g., from areas treated with land-applied biosolids). CECs subsequently get introduced to the environment via wastewater effluent that drains to major waterbodies, via leachate after disposal of WWTP sludge in landfills, or transported with treated biosolids and applied to agricultural and other lands as a soil amendment. Approximately 5.6 million dry tons of biosolids are used or disposed of annually in the United States, of which approximately 60% is used for land application. EPA estimates that biosolids are applied to approximately 0.1% of available agricultural land in the United States on an annual basis. All biosolids are treated to achieve contaminant concentration limits, as established by the EPA under the 40 CFR Part 503 Standards for the Use or Disposal of Sewage Sludge. Based on the extent of treatment, biosolids may be land-applied under restricted and regulated conditions, as determined by the Part 503 Rule.

## **2.2 Relevant Environmental Regulatory Agencies and Environmental Regulations**

Potential conflict of interests can arise between public health goals and commerce and industry regulations, as is often evident in the evolution of environmental legislation. Regulatory targets are complicated by the myriad factors and stakeholders that hold influence.

This section provides a brief history of relevant environmental regulatory agencies and environmental regulations and an overview of agencies providing regulatory oversight for environmental protection, including the regulation of CECs. Between 2012 and 2016, during which time this literature review was conducted, an effort was made to focus on the most current and relevant papers available at the time on CEC research. At the time of the 2012 research, the Toxic Substances Control Act (TSCA) reform was under consideration, and pending legislation. By the time of the 2016 research period, TSCA reform legislation had been passed by the Senate and signed by President Obama on June 22, 2016. TSCA reform is covered under Section 2.2.2.2. Additionally, a brief summary of international regulations is included for perspective, as well as reference for future direction of regulations.

### **2.2.1 United States Federal Environmental Agencies**

This section provides a summary of the evolution and creation of U.S. Federal agencies providing regulatory oversight for environmental protection. The modern climate of the United States environmental regulatory process was inherited from decades-old public health traditions, from which environmental regulatory programs arose to address issues of public health as threatened by water and air quality issues. In addition, maritime navigation protection regulations arose to protect and promote commerce and industry related to harbors, ports, and otherwise navigable waters.

The U.S. Public Health Service (PHS) originally began in 1798 as the U.S. Marine Hospital Service. Congress changed the name to the “U.S. Public Health and Marine Service” in 1902, expanding its functions to deal with the broad issues of public health, and in 1912 to the PHS. Environmental authorities founded under the PHS included the National Air Pollution Control Administration, originally a research body founded in 1955, and the Federal Water Quality Administration (FWQA), authorized in 1965 by the Water Quality Act (WQA). The FWQA was authorized to issue federal water quality standards for interstate waters, where states failed to do so. The FWQA left the PHS in 1966 to become part of the Department of the Interior, and later was absorbed under the EPA.

The U.S. Environmental Protection Agency (EPA) was established in December 1970, effectively integrating the administration of a variety of federal research, monitoring, standard-setting and enforcement activities, to ensure environmental protection under the umbrella of a single agency. The founding of the EPA was the result of a hybrid of regulations and policy standards originally enacted under agencies such as the PHS and USACE, and many duties were transferred to the EPA from other Federal Agencies. The EPA was assembled from parcels of three federal Departments, three Bureaus, three Administrations, two Councils, one Commission, one Service, and many diverse offices (EPA, 1992).

### **2.2.2 United States Federal Environmental Regulations**

This section provides a chronological history of environmental regulations, with a focus on regulations that pertain to water quality, or potential sources of water quality contamination. This background is referenced from the Congressional Research Service Report RL30798, Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency (Bearden et al., 2013).

The Rivers and Harbors Appropriation Act of 1899 is the oldest environmental law in the United States, and is administered by the U.S. Army Corps of Engineers (USACE).

Section 9 of the Act, applying to bridges and causeways within navigable waters, was re-delegated to the U.S. Coast Guard (USCG) under the provisions of the Department of Transportation Act of 1966, based on the conflict of interest of both ownership and regulation by USACE of many bridges. Actions regulated under section 10 of the Act include excavation, fill, or alteration of any port, harbor or channel, including damming of navigable streams for the purposes of hydroelectric generation or other navigable purposes. Section 13 of the Act controls discharge of refuse of any kind into navigable waters of the United States without a permit, otherwise known as the Refuse Act. Additional environmental enforcement authority under the USCG includes jurisdiction of certain aspects of the Clean Water Act (CWA), such as enforcement of the Oil Pollution Act of 1990 (OPA).

The Federal Water Pollution Control Act (FWPCA) of 1948 was the first comprehensive federal clean water program, passed under Public Law (P.L.) 80-845 (Act of June 30, 1948), and administered under the PHS. At this time, water pollution was viewed as a state and local problem, and there were no federally required goals or guidelines. Federal enforcement and involvement was limited to issues over interstate waters, and only with the consent of the state from which the pollution originated. The FWPCA of 1948 specifically provided state and local government with technical assistance funding to address water pollution problems, including research grants.

In the latter half of the 1950s into the 1960s, water pollution control programs were modified by four laws amending the 1948 FWPCA statute, extending the federal role and federal jurisdiction to include navigable, as well as interstate waters. The four laws were:

- Water Pollution Control Act of 1956 (P.L. 84-660 (Act of July 9, 1956))
- 1961 Federal Water Pollution Control Act Amendments (P.L. 87-88)
- Water Quality Act of 1965 (P.L. 89-234)
- 1966 Clean Water Restoration Act (P.L. 89-753)

Water quality standards became a feature of the law under the 1965 Water Quality Act, and required states to set standards for interstate waters to be used to determine actual pollution levels.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was originally passed in 1947 to address shortcomings of the 1910 Federal Insecticide Act, and regulatory authority was assigned to the United States Department of Agriculture (USDA). FIFRA was revised in 1972 by the Federal Environmental Pesticide Control Act (FEPCA), which transferred authority to the EPA. The revised Act emphasized protection of the environment and human health, and shifted the burden of proof of environmental compliance of pesticide products to the chemical manufacturer (EPA, 1996a).

Other notable statutes transferred to the EPA at its inception included certain functions of the National Environmental Policy Act (NEPA) that pertain to ecological systems, and the Federal Water Pollution Control Act (FWPCA) of 1972, better known as the Clean Water Act (CWA).

#### **2.2.2.1 Clean Water Act**

The Federal Water Pollution Control Act Amendments of 1972 (P.L. 92-500), referred to as the Clean Water Act (CWA), totally revised the original 1948 FWPCA. The CWA is the primary federal law that governs water pollution, and established the basic structure for regulating the discharge of pollutants into the waters of the United States. This represented a fundamental change in Federal policy, as the CWA shifted the regulatory focus from water quality standards to effluent standards as the foundation for the strategy to control pollution from point sources, primarily industrial dischargers and publicly owned treatment works (POTWs), henceforth referred to as wastewater treatment plants (WWTPs) in this paper. Point sources are defined as discharges from a “discrete conveyance” (or outfall) by industrial facilities (including mining, manufacturing, oil and gas extraction, etc.), municipal governments and other government facilities (such as military bases), and some agricultural facilities (such as animal feed lots).

The Clean Water Act of 1972 transferred administration of the FWPCA to the EPA, in coordination with state governments. The 1972 law gave the EPA authority to develop pollution control programs such as setting wastewater and industry effluent standards, thereby establishing effluent limitations for the amounts of specific pollutants that may be discharged by municipal sewage plants and industrial facilities. Congress created a major public works financing program for bringing WWTPs up to treatment standards, authorized and funded under Title II.

The CWA also authorized the setting of water quality standards for all contaminants in surface waters. Title IV of the CWA made it unlawful to discharge any pollutant from a point source into navigable waters, unless a permit was obtained under the newly introduced National Pollutant Discharge Elimination System (NPDES), established under section 402. The NPDES program is the primary mechanism under the permit program for regulating point sources of pollution. Initially, the NPDES program focused on WWTPs and industrial wastewater. Nonpoint source pollution was not specifically addressed until the Water Quality Act (WQA) of 1987. A nonpoint source is defined as a diffuse source of pollution that does not have a point of origin. They include stormwater runoff from industrial sources, municipal storm drains, and agricultural stormwater discharges and irrigation return flows.

Additional major changes to the FWPCA have been introduced via additional amendments, including the Clean Water Act of 1977, the Water Quality Act of 1987, and the 1990 Oil Pollution Act. The WQA of 1987 expanded the NPDES program under CWA section 402. The updated program addressed certain nonpoint sources not subject under the 1972 CWA, in particular stormwater runoff, requiring separation of sewer and stormwater systems. Under the Stormwater Phase II Final Rule MS4 Program, operators of regulated small municipal separate storm and sewer systems are required to capture stormwater and provide stormwater treatment at the WWTP, instead of allowing direct discharge of nonpoint stormwater runoff to surface waterbodies. The permit exemption for agricultural discharges continued, but Congress created a grant program at EPA to

expand research of nonpoint controls and management practices. Additionally, the 1987 WQA created a program for management of biosolids generated by WWTPs.

The CWA was amended again in 1992 to set site-specific allowable pollutant levels for individual water bodies and to create an antidegradation policy to maintain and protect existing uses and high quality waters. Water bodies that do not meet applicable water quality standards are placed on the section 303(d) list, requiring development of a Total Maximum Daily Load (TMDL) of contaminant(s) specific for that water body. A TMDL establishes water quality-based limitations of the maximum amount of a pollutant that a water body can receive and still meet water quality standards. Once a TMDL is issued for a water body, appropriate modification of NPDES permits must be implemented to reflect the TMDL requirements.

#### **2.2.2.2 Toxic Substances Control Act**

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601), enacted in 1976, provided the EPA regulatory authority to protect the environment and consumers' health against risks posed by chemicals in commerce. Chemicals in current-use are subject under TSCA, with the exception of chemicals regulated under other federal laws, such as those laws concerning food, drugs, cosmetics, firearms, ammunition, pesticides, tobacco, or mixtures. EPA is required by Section 8 of TSCA to develop and maintain an inventory of all chemicals, or categories of chemicals, manufactured or processed in the United States. EPA reviews approximately 700 new chemical manufacturing notices annually.

The TSCA inventory in 1979 identified approximately 55,000 chemicals in commerce. While this Act authorized EPA to passively screen new and existing chemicals used in U.S. manufacturing and commerce to identify potentially dangerous products or uses that should be subject to federal regulation, to require chemical manufacturers to conduct reporting and record-keeping, and require testing for chemical products, TSCA did not give EPA authority to independently evaluate the safety of a chemical before it went to marketplace. Based on these evaluations of new and existing chemicals and their

environmental risks, the EPA could only place restrictions relating to chemical substances and/or mixtures.

TSCA only retroactively addressed chemical hazards, after they had been deemed unsafe and previously unrestricted in the public. Title I, enacted in 1976, addressed two chemical substances, PCBs and elemental mercury. Specifically, Section 6(e) originally regulated PCBs and banned most uses, and with 2008 amendments restricting sales of elemental mercury (P.L. 110-414). In addition, five titles have been added to address the following specific chemical concerns:

- asbestos in 1986 (Title II, P.L. 99-519)
- radon in 1988 (Title III, P.L. 100- 551)
- lead in 1992 (Title IV, P.L. 102-550)
- environmental issues in schools in 2007 (Title V, P.L. 110-140)
- formaldehyde in 2010 (Title VI, P.L. 111-199)

TSCA was formed with the intention to conduct and report test data by producers (i.e., manufacturers, importers, and processors) of chemicals in commerce, however the law did not give the EPA the ability to control substances on the market. A bill to overhaul TSCA, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (House Amendment to the Senate Amendment to H.R. 2576, TSCA Modernization Act of 2015), was passed by the Senate on June 7, 2016, and sent on for President Obama's signature. President Obama signed the Act into Law on June 22, 2016.

### **TSCA Limitations and TSCA Reform**

Many chemicals, even some in widespread use, are not well characterized in terms of their potential health and environmental effects, and many of these are potential or existing CECs. TSCA is one of the first lines of defense in regulating new and existing CECs, but has been considered ineffective and out of date (Schierow, 2009), and incapable of assessing the safety of all chemicals in use today.



The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act will amend TSCA to give the EPA new authority to evaluate the safety of a new chemical before it enters the marketplace. It will also allow EPA to evaluate the safety of chemicals already known to be risks, including chemicals found to persist in the human body and in the environment. The bill also limits companies' ability to claim product information as confidential, allowing regulators, health professionals and the general public access to previously restricted information about the chemical components in chemical products. The TSCA Modernization Act of 2015 is presented in full in Appendix A.

The first version of the TSCA inventory in 1979 identified approximately 55,000 chemicals in commerce. Due to the overwhelming number of chemicals, Section 4(e) of TSCA established the Interagency Testing Committee (ITC) as an independent advisory committee to the Administrator of the EPA. The ITC was created to make recommendations on prioritizing and selecting chemicals for testing or information reporting to meet the data needs among government agencies. These chemicals are then added to the "Priority Testing List".

Chemicals were assigned a higher priority if known or suspected to cause or contribute to cancer, gene mutations, or birth defects. Section 4(a) of TSCA directed the EPA to require test data to be reported on existing chemicals when certain conditions prevail, including:

- *the manufacture, processing, distribution, use, or disposal of the chemical "may present an unreasonable risk;" (Sec. 4(a)(1)(A)(i)*
- *the chemical is produced in very large volume and there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure. (Sec. 4(a)(1)(B)(i)*

If either condition existed, EPA shall by rule require that testing be conducted if:

- (ii) existing data are insufficient to resolve the question of safety, and*
- (iii) testing is necessary to develop the data*

Section 5 and Section 6 of TSCA Title I directed EPA to require manufacturers and processors to conduct testing for existing chemicals in order to:

- prevent future risks through pre-manufacture screening and regulatory tracking of new chemical products (Section 5);
- control unreasonable risks already known, or as they are discovered for existing chemicals (Section 6).

TSCA also required EPA to be given a short notice of 90 days when there were plans to produce, process, or use an existing chemical in a way that differs from previously permitted uses, if the Administrator determined by rule that new uses of the chemical may produce significant changes in human and environmental exposures and therefore require notification. Although the legislative history of TSCA included a presumption that testing of new products would take place before they were widely used, either as the chemical was developed, or as its markets grew, TSCA forbade promulgation of blanket testing requirements for all new chemicals. This reflected a concern that uniform testing requirements could stifle innovation in the chemical industry. The purpose of the screening procedure was to identify potential hazards, and control them before use of a chemical becomes widespread; however, the ability of EPA to direct regulation of new chemical products was limited by the original TSCA language. Thus, EPA was restricted to determining only which chemicals, or which categories of chemicals, warrant the costs of premarket testing, and was required by TSCA to regulate only “to the extent necessary to protect adequately” against a risk, and to use the “least burdensome” regulatory approach, even in controlling unreasonable risks.

The TSCA Modernization Act of 2015 updates TSCA Section 6 – Prioritization , Risk Evaluation, and Regulation of Chemical Substance and Mixtures, subsection (a), by striking the language “to protect adequately against such risk using the least burdensome requirements,” and inserts, “so that the chemical substance or mixture no longer presents such risk.” Additionally, the TSCA Modernization Act of 2015 requires the Administrator to establish a risk-based screening process, including criteria for

designating substances as high-priority or low-priority for risk evaluations. The Act further clarifies that:

*The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.*

The TSCA Modernization Act of 2015 also gives the EPA greater time periods for evaluating new chemicals, expands the authority of EPA to determine the risk-based screening process required by a manufacturer, and grants the authority to EPA to independently designate a chemical as high-risk. Chemical manufacturers will be required to make a safety finding to get a product on market, which gets away from the passive system as TSCA originally existed. Instead of requiring that EPA had to document that a chemical posed a risk before it could ask the manufacturer to conduct toxicity or exposure tests, EPA will be able to determine that chemicals in furniture, clothing, cleaning products and other common household items are safe before such products are allowed into commerce.

However, the Act still allows for some regulatory leeway in interpretation, as language in the legislation states EPA must consider the “cost-effectiveness” of any proposed rule, which may be considered restating the previously mentioned “least-burdensome requirements” on industry.

### 2.2.2.3 Additional Environmental Protection Acts

The Safe Drinking Water Act (1974), Title XIV of the Public Health Service Act, protects the public water supplies from harmful contaminants. The law focuses on all waters actually or potentially designed for drinking use, whether from above-ground or underground sources.

The Resource Conservation and Recovery Act (RCRA), passed in 1976, created authority for the EPA to control hazardous waste from “cradle to grave.” This includes the generation, transportation, treatment, storage and disposal of hazardous waste. This law also set a framework for the management of non-hazardous waste.

The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), enacted in 1980, provides for a federally funded “Superfund” to clean up uncontrolled or abandoned hazardous waste sites as well as accidents, spills and other releases of pollutants into the environment. To prioritize cleanup action, CERCLA directed EPA to create a National Priorities List (NPL) of the most contaminated sites which present the greatest risks to human health and the environment. The NPL includes both non-federal sites and federal facilities deemed to present a sufficient level of risk to warrant listing. The law gives the U.S. EPA the authority to locate the parties responsible for any release and assure their cooperation in the cleanup. Additionally, Section 104(i) of CERCLA established the Agency for Toxic Substances and Disease Registry (ATSDR) mainly to assess potential health risks at NPL sites. The ATSDR assesses individual sites based on the likelihood of human exposure to contamination through the air, soil, surface water, groundwater, and other pathways such as consumption of contaminated food sources. These assessments serve two purposes: to inform the public of potential health hazards at a contaminated site and to aid decision-makers in evaluating what cleanup actions may be warranted to prevent potentially harmful exposure.

The Pollution Prevention Act (1990) focuses industry, government and public attention on reducing pollution through cost-effective changes in production, operation and raw

material use. Pollution prevention also includes other practices such as source reduction, recycling and sustainable agriculture that increase efficiency in the use of energy, water and other natural resources.

#### **2.2.2.4 Wastewater Treatment Plant and Land-Applied Biosolids Regulatory Requirements**

Wastewater treatment produces two end products: effluent and sewage sludge. Biosolids are the treated component of sewage sludge. Approximately 75% of the United States population contributes to wastewater directly through a sewerage system to over 16,000 wastewater treatment plants (DHS, 2016).

Wastewater pretreatment regulations were established through 40 CFR Part 403 (as of June 26, 1978). These regulations addressed industrial facilities contributing to the influent stream, and aimed to prevent introduction of pollutants into the WWTPs that would interfere with the operation of a plant, including interference with disposal of municipal biosolids due to contamination. These regulations under Part 403 dramatically reduced concentrations of selected pollutants (e.g., pollutants which create a fire hazard, oil and grease, and corrosive pollutants, among other hazardous wastes) discharged to WWTPs and therefore reduced the concentrations of pollutants in treated biosolids.

Section 402 of the CWA (the NPDES permit program), and 40 CFR Part 503 (*Standards for Use or Disposal of Sewage Sludge*), allows regulation of land-applied biosolids from the consideration of a point-source discharge to groundwater. The 1993 Code of Federal Regulations, 40 CFR Part 503, under Section 405 of the 1987 WQA, created a program for general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of sewage sludge produced during treatment of domestic sewage in WWTPs. Contaminants considered under this rule were selected based in part on analytical results from the 1988 National Sewage Sludge Survey (NSSS), which analyzed sewage sludge for 411 possible contaminants from 176 WWTPs within the U.S.

The Part 503 rule established management practices for usage and disposal of biosolids, including land-application of biosolids, concentration limits, and loading rates for chemicals occurring in biosolids, and treatment and use requirements designed to control and reduce pathogens (EPA, 1993). The chemical land-application standards in the Part 503 rule were determined by EPA through risk assessments aimed at identifying the chemical constituents in biosolids judged likely to pose the greatest hazard. Likely exposure scenarios and calculated concentration limits and loading rates were also identified. The regulations to guide the management practices and operational standards are as follows:

- (1) Identify uses for sewage sludge, including disposal;
- (2) Specify factors to be taken into account in determining the measures and practices applicable to each such use or disposal (including publication of information on costs); and
- (3) Identify concentrations of pollutants which interfere with each such use or disposal.

Under Part 503, the first primary regulated contaminants in biosolids were ten inorganic chemicals: arsenic, cadmium, chromium (limits later deleted under 60 FR 54764), copper, lead, mercury, molybdenum, nickel, selenium, and zinc.

Different land application rules apply to different classes of biosolids, and the following quality control regulations were established under the Part 503 regulation:

Two levels of sewage sludge quality with respect to heavy metal concentrations:

- Pollutant ceiling concentrations
- Pollutant concentrations ("high quality" sewage sludge)

Two levels of quality with respect to pathogen densities:

- Class A
- Class B

Two types of approaches for meeting vector attraction reduction:

- Sewage sludge processing
- The use of physical barriers.

Class A biosolids contain no detectible levels of pathogens, must meet strict vector attraction reduction requirements and low levels metals contents, and are permitted to ensure that these standards have been met. Class B biosolids are treated but still contain detectible levels of pathogens, and have buffer requirements to protect water quality, restricted public access, and crop harvesting restrictions for virtually all forms of Class B biosolids.

Under the Part 503 regulation, fewer restrictions are imposed on the use of higher quality sewage sludge. Class A biosolids may be applied in small quantities without restriction by the general public on public-contact sites, including parks, golf courses, lawns, and home gardens. When used in bulk, Class A biosolids are subject to buffers for water quality protection, but not to crop harvesting restrictions. Based on the extent of treatment, Class B biosolids may be applied where little exposure of the general public is expected to occur on the sites, such as on agricultural land, forests, and reclamation sites.

In 1995 EPA revisited the pollutants considered in Rule 503 under the so-called “Round Two” evaluation. However, a second comprehensive analytical survey of contaminants in biosolids was not conducted, and EPA instead focused largely on compounds previously considered during the original NSSS, with an emphasis on chlorinated dioxins, furans and co-planar PCBs (EPA, 1996b). In 2003, EPA concluded that these compounds did not present a significant risk to human health or the environment, and made the decision to not regulate levels of these compounds in biosolids (EPA Headquarters Press Release October 17, 2003).

As public health concerns regarding the use of biosolids increased, EPA in 1999 asked the National Academy of Science (NAS) to conduct an independent evaluation

reassessing the scientific basis of the Part 503 Rule. NAS produced the resulting report *Biosolids Applied to Lands: Advancing Practices and Standards* in 2002. The NAS committee stated in the 2002 report that the Part 503 Rule relied on an outdated biosolid contaminant characterization (NRC, 2002), and that the original NSSS did not address possible adverse changes in biosolids composition due to changes in treatment processes and chemical uses over the last decade. Suggested actions recommended by the committee included that a new national sewage sludge survey be conducted, to ensure that Part 503 Rule risk assessment assumptions are based on sound science (NRC 2002). At the 2003 Biosolids Research Summit, a research agenda was created to address research gaps identified by the NRC report. The top identified research gaps were to create a targeted characterization of pathogens, and to conduct a new national survey of CECs in biosolids. Both were ranked as the second and third highest research priorities, following only the development of a rapid incident response study aimed at examining whether a linkage existed between biosolids land application and reports of human health impacts (WERF, 2004).

### **2.2.3 International Environmental Regulatory Agencies and Environmental Regulations**

Europe has passed tough chemical regulations, including one of the world's most extensive chemical safety regulations, known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), passed on June 1, 2007. The European Chemicals Agency (ECHA) is the prime regulatory authority for REACH, and helps companies comply with the legislation, advances the safe use of chemicals, and provides information on chemicals and addresses chemicals of concern (ECHA REACH, 2016). The law requires companies that produce or sell chemicals in the European Union (EU) to register toxicity data on the compounds and to outline any new tests needed to clarify their biological effects and places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU.



The European Union Council Directive 86/278/EEC was adopted over 20 years ago to promote land application of biosolids in agriculture and to regulate its use, to prevent harmful effects on soil, vegetation, animals, and humans. The Directive was initiated June 12, 1986, with the intent of the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture. The Directive currently sets limit values for seven heavy metals that may be toxic to plants and humans: cadmium, chromium, copper, nickel, lead, zinc, and mercury. Since its adoption, several Member States have enacted and implemented stricter limit values for heavy metals and set requirements for other contaminants. Currently, the European Commission is assessing whether the current Directive should be reviewed, and to what extent (EC, 2016).

## Chapter 3

### 3. Case Study on Columbia River

The Columbia River is presented as a case study as an example of a significant waterbody with research and regulatory gaps concerning CECs.

#### 3.1 Introduction/Problem Statement

The Columbia River is important to the entire Pacific Northwest region as a food and water source, for transportation and shipping, for recreation, and also as a cultural resource for the many tribes within the Columbia River watershed. The Columbia spans three states and two nations, which makes for complex oversight authority.

The Columbia River is a receptor of numerous point-sources of pollution throughout its length, including urban stormwater runoff, wastewater treatment plant and industrial manufacturing effluent, as well as non-point source pollution such as overland flow from agricultural and industrial fields and air deposition of contaminants. Currently, the Columbia River is extensively monitored for known contaminants (mercury, PCBs, DDT, PBDEs) while limited resources are dedicated to identifying and monitoring emerging contaminants in the Columbia River. Additionally, the Columbia River Basin is a prime candidate for targeted studies on the effects land-applied biosolids within the watershed.

The purpose of this case study is to present an in-depth compilation of current research on emerging contaminants and to identify potential new monitoring methods and programs. This case study also provides an overview of the current Columbia River Monitoring Plan and describes current actions being undertaken by monitoring agencies and resource management agencies to monitor and control emerging contaminants.

### 3.2 Relevant Agencies and Programs that Affect the Columbia River

This section provides a summary of regional agencies and watershed protection groups providing regulatory oversight for environmental protection of the Columbia River basin.

#### **National Estuary Program and LCREP**

Between 1989 and 1995, a six-year study was conducted by the Bi-State Water Quality Program on the lower Columbia River between the Bonneville Dam and the Pacific Ocean. Research studies collected water quality data and toxic contaminant data within the lower Columbia River and estuary, generating a large dataset on the threats to the health of the river and river organisms.

The findings of the six-year study highlighted four problems in the lower Columbia River estuary:

- Toxics in sediment and fish tissue that can affect the health of humans, fish, and wildlife
- Habitat loss/modification that can affect fish and wildlife resources
- Water quality problems that affect beneficial uses in portions of the estuary
- Overall decline in anadromous fish runs that has resulted in threatened and endangered species listings (WDOE, 1997)

Based on the results of this research, the lower Columbia River was nominated by the governors of Washington and Oregon states for the EPA National Estuary Program (NEP) in July 1995. The NEP is a non-regulatory program established by Congress via amendments to the Clean Water Act in 1987, and is a place-based program established to protect and restore “water quality and ecological integrity of estuaries of national significance” (EPA NEP Overview 2016). The NEP provides support for the development of management plans for the Nation’s most significant estuaries that are threatened by degradation caused by human activity. Currently, 28 estuaries are

designated as significant, and the program provides resources to help manage these estuaries of national, regional, and local significance.

The EPA accepted the lower Columbia River into the NEP, and established the Lower Columbia Estuary Partnership (LCREP). LCREP is supported by the US Environmental Protection Agency, the states of Oregon and Washington, and numerous other public and private entities. LCREP advocates for long-term monitoring, to address issues about the sources, distribution, and persistence of toxics in the lower river.

### **Columbia River Toxics Reduction Work Group**

As part of the NEP, a long-term monitoring plan was developed for the lower Columbia River and estuary to address many of the issues that face the lower Columbia River Basin. The Columbia River Toxics Reduction Work Group (CRTRWG) was formed in 2005 as a collaborative workgroup among EPA and federal, state, tribal, local, industry, and nonprofit partners to focus on toxics in the Columbia River, with the goal to reduce toxics in the Columbia River Basin and prevent further contamination. This group was modeled on EPA collaborative efforts underway throughout the U.S. including the Chesapeake Bay and the National Estuary Program (EPA and CRTRWG, 2010). In 2009, the EPA produced *The Columbia River Basin State of the River Report for Toxics* with the support and guidance of CRTRWG.

The *State of the River Report for Toxics* determined that four contaminants were above risk action levels: mercury, dichlorodiphenyltrichloroethane (DDT) and associated breakdown products, polychlorinated biphenyls (PCBs), and polybrominated diphenyl ether (PBDE) flame retardants. Additional contaminants are found in the Basin, including arsenic, dioxins, radionuclides, lead, pesticides, industrial chemicals, and CECs including pharmaceuticals found in wastewater.

EPA and the CRTRWG released the Columbia River Toxics Reduction Action Plan (Action Plan) in September 2010. The Action Plan included five general initiatives and

actions to be accomplished through 2015, to better understand and reduce toxic contamination in the Columbia River Basin:

- Increase public understanding and political commitment to toxics reduction in the Basin
- Increase toxic reduction actions
- Conduct monitoring to identify sources and then work to reduce toxic contamination
- Develop a regional, multi-agency research program
- Develop a data management system that will allow sharing of information on toxics in the Basin

The work with the CRTRWG is currently conducted via coordination and partnerships without any designated funding sources, with the exception of work done in the estuary through LCREP. The CRTRWG states that:

“To a great extent, success in reducing toxics in the Basin will depend on a commitment by all levels of government, in both the United States and Canada, tribal governments, nongovernmental organizations, industry groups, and the public to work together. The problems are too large, widespread, and complex to be solved by only one organization or country.”

### **3.3 Gaps in Columbia River Research and Restoration Funding**

The CRTRWG identified a number of priorities for state and local governments to address to reduce toxics in the Columbia Basin. The workgroup believes that a focus on enhancing programs in these areas will help advance the prevention and reduction of toxics in the Columbia River Basin. The Priority Initiatives of the Columbia River Toxics Reduction Working Group, January 2013, are summarized below:

- **Sustainable Purchasing:** Develop a list of sustainable products and a list of chemicals of concern that could be used by all entities in the Basin for greening their operations
- **Green Chemistry:** Initiate a Regional Green Chemistry Center to advance the discussion on how to develop chemical processes that provide less toxic materials
- **Chemicals of Emerging Concern:** Develop monitoring programs and toxicity information to inform actions to address chemicals of emerging concern that are currently unregulated
- **Pesticide Stewardship Partnerships:** Enhance and expand the successful Pesticide Stewardship Partnership model used by the State of Oregon to encourage voluntary changes in pesticide use and practices that lead to measurable environmental improvements
- **Stormwater:** Expand stormwater technical assistance programs to small and medium businesses, providing much-needed pollution prevention expertise at the local level

Contaminants such as DDTs have been determined to persist in the Columbia River despite being banned decades ago, while CECs, including flame retardants (PBDEs) and personal care products, pose new threats to human health and fish and wildlife. However, the Columbia River Basin is the only major EPA-designated ‘large aquatic ecosystem’ to receive zero funding pursuant to the NEP designation. Additionally, the Columbia River Monitoring Plan does not address CECs in biosolids.

In May 2015, U.S Senator Jeff Merkley (D-OR) and Congressman Earl Blumenauer (D-OR), reintroduced the Columbia River Basin Restoration Act. On September 15, 2016, the U.S. Senate passed the Act as part of the Water Resources Development Act (WRDA) of 2016 (LCREP September 16, 2016). This bill addresses critical fish and wildlife habitat, water quality, and infrastructure needs in a total of 18 states and would authorize Congress to appropriate funds for a voluntary grant program to expand and add to monitoring efforts and provide the resources for sustained action to reduce

contaminants and evaluate them throughout the Columbia River system. If the Act becomes law, which has not yet been passed as of the time of this report, the status of the Columbia River would be elevated to that of other Large Aquatic Ecosystems, and it would authorize Congress to appropriate funds through the EPA to implement its Columbia Basin Toxics Reduction Plan and the Estuary Partnership Management Plan.

## Chapter 4

### 4. Conclusions

With over 100,000 chemicals in current use and new chemicals added each year, the environmental risks and behavior of these chemicals need to be properly evaluated and regulated. Ideally, problematic chemicals should be identified prior to their release into the environment and controlled accordingly. TSCA is one of the first lines of defense in regulating new and existing CECs, and is an important regulatory tool to assess the safety of chemicals in use today. Additionally, WWTPs are a destination for environmental contaminants sourced from residential and industrial sewer and storm drains, and many of these contaminants end up partitioning onto the treated sewage sludge. This sewage sludge that turns into treated biosolids then becomes a vector for environmental contamination as it is dispersed as land-applied biosolids.

#### 4.1 Research Gaps

Data gaps exist for CECs in understanding their occurrence, persistence, transport and fate, their transformation products, the characterization of CECs in biosolids, their risks to human and environmental health, and research on prioritizing CECs for regulatory purposes. Data gaps exist on national and regional scales for impacts from CECs released from biosolids to environments such as the Columbia River Basin. Additional concerns regarding CECs in environment include unknown exposure duration and mixture effects, or unknown synergistic and cumulative effects of CECs in the environment.

Questions raised by this research include:

- How do you decide which pollutants to permit? Toxicologists defer to EPA, and human-health revisions are based on EPA reference doses, etc.
- Toxicity data is needed to reach conclusions on regulating compounds
- Standards are needed for methods to perform monitoring requirements



This literature review also concluded that many new CECs were identified due to improved analytical techniques that have allowed detection levels at previously undetectable limits in the low ng/L concentrations. This is significant, as prior analytical techniques did not allow for such low detection levels, and many chemicals went undetected in the environment, their presence unknown previous to the new low-detection analytical techniques.

## 4.2 Legislative Gaps

The reformed TSCA law still allows for some regulatory leeway in interpretation and regulatory enforcement. The regulatory language states EPA must consider the “cost-effectiveness” of any proposed rule, which may be considered restating the previously mentioned “least-burdensome requirements” on industry. Strong legislation is needed to predict and prevent chemicals from being unnecessarily released to the environment. Additionally, wastewater pretreatment regulations and wastewater treatment methods can be improved to reduce CECs from both WWTP influent streams and effluent products.

The extent of environmental protection afforded by the current evaluation approaches for risk-based assessment does not consider the cumulative risk of the mixture of all CECs present. A multifaceted approach is needed to address these challenges, including a set of tools to characterize CEC exposure at the suborganism, organism, and population levels, to identify potential or actual effects of CECs on aquatic communities. Possible approaches include incorporating existing approaches used by the various water agencies to assess the risk of individual chemicals. However, addressing the extent of the potential effects of mixtures of the chemicals in combination with more common pollutants and other environmental stressors is complex.

There is a need to characterize and better understand the environmental and biological fate, transport, and transformation of CECs. This knowledge gap becomes more important as water supplies become more limited and water re-use practices change.

More than 40,000 organic chemicals have been identified as CECs, which does not include the associated breakdown products in the environment. However, agencies responsible for monitoring efforts, such as the National Oceanic and Atmospheric Administration (NOAA), the U.S. Geological Survey (USGS), and the U.S. Environmental Protection Agency (U.S. EPA), have widely different definitions as to what a CEC actually is (Diamond, 2011). For example, some researchers consider an already regulated chemical to be a CEC if there are additional, unregulated effects, such as endocrine disruption. Others broadly define a CEC as a chemical that is currently unregulated. With no consensus on the definition of a CEC, each agency monitors its own subjective list of chemicals.

### 4.3 Summary

Biosolids are composed of numerous constituents, with a number of environmentally persistent and potentially toxic CECs identified as present in large concentrations. The presence of priority pollutants such as heavy metals and polychlorinated biphenyls (PCBs) in land-applied biosolids has been extensively studied, including the effects on human health and the environment, and environmental behavior. However, with the constantly increasing consumption of unregulated chemicals and the detection of significant concentrations of these chemicals in biosolids, research is needed to understand the transport and fate mechanisms of these compounds in biosolids. Additionally, this research is needed to determine a new priority framework to regulate CECs, both on the national level and regional levels. WWTP influent and effluent treatment regulations and practices may be improved upon as more knowledge accrues regarding CEC behavior in the environment. Understanding the concentrations and environmental behavior of CECs in land-applied biosolids is key to determining the significance and implications of these emerging pollutants on human health and the environment.

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## **Appendix A – TSCA Modernization Act of 2015**





MAY 20, 2016

**RULES COMMITTEE PRINT 114-54**  
**TEXT OF HOUSE AMENDMENT TO THE SENATE**  
**AMENDMENT TO H.R. 2576, TSCA MOD-**  
**ERNIZATION ACT OF 2015**

**[Showing the text of the Frank R. Lautenberg Chemical  
Safety for the 21st Century Act.]**

**1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

**2** (a) **SHORT TITLE.**—This Act may be cited as the  
**3** “Frank R. Lautenberg Chemical Safety for the 21st Cen-  
**4** tury Act”.

**5** (b) **TABLE OF CONTENTS.**—The table of contents of  
**6** this Act is as follows:

Sec. 1. Short title; table of contents.

**TITLE I—CHEMICAL SAFETY**

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Manufacturing and processing notices.

Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances  
and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Exports of elemental mercury.

Sec. 11. Confidential information.

Sec. 12. Penalties.

Sec. 13. State-Federal relationship.

Sec. 14. Judicial review.

Sec. 15. Citizens’ civil actions.

Sec. 16. Studies.

Sec. 17. Administration of the Act.

Sec. 18. State programs.

Sec. 19. Conforming amendments.

Sec. 20. No retroactivity.

Sec. 21. Trevor’s Law.

TITLE II—RURAL HEALTHCARE CONNECTIVITY

Sec. 201. Short title.

Sec. 202. Telecommunications services for skilled nursing facilities.

1       **TITLE I—CHEMICAL SAFETY**

2       **SEC. 2. FINDINGS, POLICY, AND INTENT.**

3           Section 2(c) of the Toxic Substances Control Act (15  
4 U.S.C. 2601(c)) is amended by striking “proposes to  
5 take” and inserting “proposes as provided”.

6       **SEC. 3. DEFINITIONS.**

7           Section 3 of the Toxic Substances Control Act (15  
8 U.S.C. 2602) is amended—

9                   (1) by redesignating paragraphs (4) through  
10                   (14) as paragraphs (5), (6), (8), (9), (10), (11),  
11                   (13), (14), (15), (16), and (17), respectively;

12                   (2) by inserting after paragraph (3) the fol-  
13                   lowing:

14                   “(4) The term ‘conditions of use’ means the cir-  
15                   cumstances, as determined by the Administrator, under  
16                   which a chemical substance is intended, known, or reason-  
17                   ably foreseen to be manufactured, processed, distributed  
18                   in commerce, used, or disposed of.”;

19                   (3) by inserting after paragraph (6), as so re-  
20                   designated, the following:

21                   “(7) The term ‘guidance’ means any significant writ-  
22                   ten guidance of general applicability prepared by the Ad-  
23                   ministrators.”; and

1 (4) by inserting after paragraph (11), as so re-  
2 designated, the following:

3 “(12) The term ‘potentially exposed or susceptible  
4 subpopulation’ means a group of individuals within the  
5 general population identified by the Administrator who,  
6 due to either greater susceptibility or greater exposure,  
7 may be at greater risk than the general population of ad-  
8 verse health effects from exposure to a chemical substance  
9 or mixture, such as infants, children, pregnant women,  
10 workers, or the elderly.”.

11 **SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-**  
12 **TURES.**

13 Section 4 of the Toxic Substances Control Act (15  
14 U.S.C. 2603) is amended—

15 (1) by striking “standards” each place it ap-  
16 pears and inserting “protocols and methodologies”;

17 (2) in subsection (a)—

18 (A) by striking “If the Administrator  
19 finds” and inserting “(1) If the Administrator  
20 finds”;

21 (B) in paragraph (1), as so designated—

22 (i) by striking “(1)(A)(i)” and insert-  
23 ing “(A)(i)(I)”;

24 (ii) by striking “(ii)” each place it ap-  
25 pears and inserting “(II)”;

1 (iii) by striking “are insufficient data”  
2 and inserting “is insufficient information”  
3 each place it appears;

4 (iv) by striking “(iii)” each place it  
5 appears and inserting “(III)”;

6 (v) by striking “such data” and in-  
7 serting “such information” each place it  
8 appears;

9 (vi) by striking “(B)(i)” and inserting  
10 “(ii)(I)”;

11 (vii) by striking “(I)” and inserting  
12 “(aa)”;

13 (viii) by striking “(II)” and inserting  
14 “(bb)”;

15 (ix) by striking “(2)” and inserting  
16 “(B)”;

17 (x) in the matter following subpara-  
18 graph (B), as so redesignated—

19 (I) by inserting “, or, in the case  
20 of a chemical substance or mixture  
21 described in subparagraph (A)(i), by  
22 rule, order, or consent agreement,”  
23 after “rule”;

1 (II) by striking “data” each place  
2 it appears and inserting “informa-  
3 tion”; and

4 (III) by striking “and which are  
5 relevant” and inserting “and which is  
6 relevant”; and

7 (C) by adding at the end the following:

8 “(2) ADDITIONAL TESTING AUTHORITY.—In  
9 addition to the authority provided under paragraph  
10 (1), the Administrator may, by rule, order, or con-  
11 sent agreement—

12 “(A) require the development of new infor-  
13 mation relating to a chemical substance or mix-  
14 ture if the Administrator determines that the  
15 information is necessary—

16 “(i) to review a notice under section 5  
17 or to perform a risk evaluation under sec-  
18 tion 6(b);

19 “(ii) to implement a requirement im-  
20 posed in a rule, order, or consent agree-  
21 ment under subsection (e) or (f) of section  
22 5 or in a rule promulgated under section  
23 6(a);

24 “(iii) at the request of a Federal im-  
25 plementing authority under another Fed-

1           eral law, to meet the regulatory testing  
2           needs of that authority with regard to tox-  
3           icity and exposure; or

4                   “(iv) pursuant to section 12(a)(2);  
5           and

6                   “(B) require the development of new infor-  
7           mation for the purposes of prioritizing a chem-  
8           ical substance under section 6(b) only if the Ad-  
9           ministrators determines that such information is  
10          necessary to establish the priority of the sub-  
11          stance, subject to the limitations that—

12                   “(i) not later than 90 days after the  
13          date of receipt of information regarding a  
14          chemical substance complying with a rule,  
15          order, or consent agreement under this  
16          subparagraph, the Administrator shall des-  
17          ignate the chemical substance as a high-  
18          priority substance or a low-priority sub-  
19          stance; and

20                   “(ii) information required by the Ad-  
21          ministrators under this subparagraph shall  
22          not be required for the purposes of estab-  
23          lishing or implementing a minimum infor-  
24          mation requirement of broader applica-  
25          bility.

1           “(3) STATEMENT OF NEED.—When requiring  
2           the development of new information relating to a  
3           chemical substance or mixture under paragraph (2),  
4           the Administrator shall identify the need for the new  
5           information, describe how information reasonably  
6           available to the Administrator was used to inform  
7           the decision to require new information, explain the  
8           basis for any decision that requires the use of  
9           vertebrate animals, and, as applicable, explain why  
10          issuance of an order is warranted instead of promul-  
11          gating a rule or entering into a consent agreement.

12          “(4) TIERED TESTING.—When requiring the  
13          development of new information under this sub-  
14          section, the Administrator shall employ a tiered  
15          screening and testing process, under which the re-  
16          sults of screening-level tests or assessments of avail-  
17          able information inform the decision as to whether  
18          1 or more additional tests are necessary, unless in-  
19          formation available to the Administrator justifies  
20          more advanced testing of potential health or environ-  
21          mental effects or potential exposure without first  
22          conducting screening-level testing.”;

23                   (3) in subsection (b)—

24                           (A) in paragraph (1)—

1 (i) in subparagraph (B), by striking  
2 “test data” and inserting “information”;

3 (ii) in subparagraph (C), by striking  
4 “data” and inserting “information”; and

5 (iii) in the matter following subpara-  
6 graph (C), by striking “data” and insert-  
7 ing “information”;

8 (B) in paragraph (2)—

9 (i) in subparagraph (A)—

10 (I) by striking “test data” and  
11 inserting “information”;

12 (II) by inserting “Protocols and  
13 methodologies for the development of  
14 information may also be prescribed  
15 for the assessment of exposure or ex-  
16 posure potential to humans or the en-  
17 vironment.” after the first sentence;  
18 and

19 (III) by striking “hierarchical  
20 tests” and inserting “tiered testing”;  
21 and

22 (ii) in subparagraph (B), by striking  
23 “data” and inserting “information”;

24 (C) in paragraph (3)—



1 (i) by striking “data” each place it  
2 appears and inserting “information”;

3 (ii) in subparagraph (A), by inserting  
4 “or (C), as applicable,” after “subpara-  
5 graph (B)”;

6 (iii) by striking “(a)(1)(A)(ii) or  
7 (a)(1)(B)(ii)” each place it appears in sub-  
8 paragraph (B) and inserting  
9 “(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)”;

10 (iv) in subparagraph (B), in the mat-  
11 ter before clause (i), by striking “sub-  
12 section (a)” and inserting “subsection  
13 (a)(1)”;

14 (v) by adding at the end the following:  
15 “(C) A rule or order under paragraph (1) or (2) of  
16 subsection (a) may require the development of information  
17 by any person who manufactures or processes, or intends  
18 to manufacture or process, a chemical substance or mix-  
19 ture subject to the rule or order.”;

20 (D) in paragraph (4)—

21 (i) by striking “of data” each place it  
22 appears and inserting “of information”;  
23 and

1 (ii) by striking “test data” each place

2 it appears and inserting “information”;

3 and

4 (E) by striking paragraph (5);

5 (4) in subsection (c)—

6 (A) in paragraph (1), by striking “data”

7 and inserting “information”;

8 (B) in paragraph (2), by striking “data”

9 each place it appears and inserting “informa-

10 tion”;

11 (C) in paragraph (3)—

12 (i) by striking “test data” each place

13 it appears and inserting “information”;

14 and

15 (ii) by striking “such data” each place

16 it appears and inserting “such informa-

17 tion”; and

18 (D) in paragraph (4) by striking “test

19 data” each place it appears and inserting “in-

20 formation”;

21 (5) in subsection (d)—

22 (A) by striking “test data” each place it

23 appears and inserting “information”;

24 (B) by striking “such data” each place it

25 appears and inserting “such information”; and

1 (C) by striking “for which data have” and  
2 inserting “for which information has”;

3 (6) in subsection (e)—

4 (A) in paragraph (1)—

5 (i) in subparagraph (A)—

6 (I) by striking “promulgation of  
7 a rule” and inserting “development of  
8 information”; and

9 (II) by striking “data” each place  
10 it appears and inserting “informa-  
11 tion”; and

12 (ii) in subparagraph (B), by striking  
13 “either initiate a rulemaking proceeding  
14 under subsection (a) or if such a pro-  
15 ceeding is not initiated within such period,  
16 publish in the Federal Register the Admin-  
17 istrator’s reason for not initiating such a  
18 proceeding” and insert “issue an order,  
19 enter into a consent agreement, or initiate  
20 a rulemaking proceeding under subsection  
21 (a), or, if such an order or consent agree-  
22 ment is not issued or such a proceeding is  
23 not initiated within such period, publish in  
24 the Federal Register the Administrator’s  
25 reason for not issuing such an order, en-

1           tering into such a consent agreement, or  
2           initiating such a proceeding”; and

3           (B) in paragraph (2)(A)—

4                 (i) by striking “eight members” and  
5                 inserting “ten members”; and

6                 (ii) by adding at the end the fol-  
7                 lowing:

8                 “(ix) One member appointed by the Chairman  
9                 of the Consumer Product Safety Commission from  
10                 Commissioners or employees of the Commission.

11                 “(x) One member appointed by the Commis-  
12                 sioner of Food and Drugs from employees of the  
13                 Food and Drug Administration.”;

14           (7) in subsection (f)—

15                 (A) in paragraph (1), by striking “test  
16                 data” and inserting “information”; and

17                 (B) in the matter following paragraph  
18                 (2)—

19                 (i) by striking “from cancer, gene  
20                 mutations, or birth defects”;

21                 (ii) by striking “data or”;

22                 (iii) by striking “appropriate” and in-  
23                 serting “applicable”; and

24                 (iv) by inserting “, made without con-  
25                 sideration of costs or other nonrisk fac-

1                   tors,” after “publish in the Federal Reg-  
2                   ister a finding”;

3                   (8) in subsection (g)—

4                   (A) by amending the subsection heading to  
5                   read as follows:“PETITION FOR PROTOCOLS  
6                   AND METHODOLOGIES FOR THE DEVELOPMENT  
7                   OF INFORMATION”;

8                   (B) by striking “test data” each place it  
9                   appears and inserting “information”; and

10                   (C) by striking “submit data” and insert-  
11                   ing “submit information”; and

12                   (9) by adding at the end the following:

13                   “(h) REDUCTION OF TESTING ON VERTEBRATES.—

14                   “(1) IN GENERAL.—The Administrator shall re-  
15                   duce and replace, to the extent practicable, scientif-  
16                   ically justified, and consistent with the policies of  
17                   this title, the use of vertebrate animals in the testing  
18                   of chemical substances or mixtures under this title  
19                   by—

20                   “(A) prior to making a request or adopting  
21                   a requirement for testing using vertebrate ani-  
22                   mals, and in accordance with subsection (a)(3),  
23                   taking into consideration, as appropriate and to  
24                   the extent practicable and scientifically justi-

1           fied, reasonably available existing information,  
2           including—

3                   “(i) toxicity information;

4                   “(ii) computational toxicology and  
5                   bioinformatics; and

6                   “(iii) high-throughput screening meth-  
7                   ods and the prediction models of those  
8                   methods; and

9                   “(B) encouraging and facilitating—

10                   “(i) the use of scientifically valid test  
11                   methods and strategies that reduce or re-  
12                   place the use of vertebrate animals while  
13                   providing information of equivalent or bet-  
14                   ter scientific quality and relevance that will  
15                   support regulatory decisions under this  
16                   title;

17                   “(ii) the grouping of 2 or more chem-  
18                   ical substances into scientifically appro-  
19                   priate categories in cases in which testing  
20                   of a chemical substance would provide sci-  
21                   entifically valid and useful information on  
22                   other chemical substances in the category;  
23                   and

24                   “(iii) the formation of industry con-  
25                   sortia to jointly conduct testing to avoid

1 unnecessary duplication of tests, provided  
2 that such consortia make all information  
3 from such testing available to the Adminis-  
4 trator.

5 “(2) IMPLEMENTATION OF ALTERNATIVE TEST-  
6 ING METHODS.—To promote the development and  
7 timely incorporation of new scientifically valid test  
8 methods and strategies that are not based on  
9 vertebrate animals, the Administrator shall—

10 “(A) not later than 2 years after the date  
11 of enactment of the Frank R. Lautenberg  
12 Chemical Safety for the 21st Century Act, de-  
13 velop a strategic plan to promote the develop-  
14 ment and implementation of alternative test  
15 methods and strategies to reduce, refine, or re-  
16 place vertebrate animal testing and provide in-  
17 formation of equivalent or better scientific qual-  
18 ity and relevance for assessing risks of injury to  
19 health or the environment of chemical sub-  
20 stances or mixtures through, for example—

21 “(i) computational toxicology and  
22 bioinformatics;

23 “(ii) high-throughput screening meth-  
24 ods;

1 “(iii) testing of categories of chemical  
2 substances;

3 “(iv) tiered testing methods;

4 “(v) in vitro studies;

5 “(vi) systems biology;

6 “(vii) new or revised methods identi-  
7 fied by validation bodies such as the Inter-  
8 agency Coordinating Committee on the  
9 Validation of Alternative Methods or the  
10 Organization for Economic Co-operation  
11 and Development; or

12 “(viii) industry consortia that develop  
13 information submitted under this title;

14 “(B) as practicable, ensure that the stra-  
15 tegic plan developed under subparagraph (A) is  
16 reflected in the development of requirements for  
17 testing under this section;

18 “(C) include in the strategic plan devel-  
19 oped under subparagraph (A) a list, which the  
20 Administrator shall update on a regular basis,  
21 of particular alternative test methods or strate-  
22 gies the Administrator has identified that do  
23 not require new vertebrate animal testing and  
24 are scientifically reliable, relevant, and capable  
25 of providing information of equivalent or better



1 scientific reliability and quality to that which  
2 would be obtained from vertebrate animal test-  
3 ing;

4 “(D) provide an opportunity for public no-  
5 tice and comment on the contents of the plan  
6 developed under subparagraph (A), including  
7 the criteria for considering scientific reliability  
8 and relevance of the test methods and strate-  
9 gies that may be identified pursuant to sub-  
10 paragraph (C);

11 “(E) beginning on the date that is 5 years  
12 after the date of enactment of the Frank R.  
13 Lautenberg Chemical Safety for the 21st Cen-  
14 tury Act, and every 5 years thereafter, submit  
15 to Congress a report that describes the progress  
16 made in implementing the plan developed under  
17 subparagraph (A) and goals for future alter-  
18 native test methods and strategies implementa-  
19 tion; and

20 “(F) prioritize and, to the extent con-  
21 sistent with available resources and the Admin-  
22 istrator’s other responsibilities under this title,  
23 carry out performance assessment, validation,  
24 and translational studies to accelerate the devel-  
25 opment of scientifically valid test methods and

1 strategies that reduce, refine, or replace the use  
2 of vertebrate animals, including minimizing du-  
3 plication, in any testing under this title.

4 “(3) VOLUNTARY TESTING.—

5 “(A) IN GENERAL.—Any person developing  
6 information for submission under this title on a  
7 voluntary basis and not pursuant to any request  
8 or requirement by the Administrator shall first  
9 attempt to develop the information by means of  
10 an alternative test method or strategy identified  
11 by the Administrator pursuant to paragraph  
12 (2)(C), if the Administrator has identified such  
13 a test method or strategy for the development  
14 of such information, before conducting new  
15 vertebrate animal testing.

16 “(B) EFFECT OF PARAGRAPH.—Nothing  
17 in this paragraph shall, under any cir-  
18 cumstance, limit or restrict the submission of  
19 any existing information to the Administrator.

20 “(C) RELATIONSHIP TO OTHER LAW.—A  
21 violation of this paragraph shall not be a pro-  
22 hibited act under section 15.

23 “(D) REVIEW OF MEANS.—This paragraph  
24 authorizes, but does not require, the Adminis-  
25 trator to review the means by which a person

1           conducted testing described in subparagraph  
2           (A).”.

3 **SEC. 5. MANUFACTURING AND PROCESSING NOTICES.**

4           Section 5 of the Toxic Substances Control Act (15  
5 U.S.C. 2604) is amended—

6           (1) in subsection (a)—

7           (A) in paragraph (1)—

8           (i) by striking “Except as provided  
9           in” and inserting “(A) Except as provided  
10           in subparagraph (B) of this paragraph  
11           and”;

12           (ii) by redesignating subparagraphs  
13           (A) and (B) as clauses (i) and (ii), respec-  
14           tively;

15           (iii) by striking all that follows “sig-  
16           nificant new use” and inserting a period;  
17           and

18           (iv) by adding at the end the fol-  
19           lowing:

20           “(B) A person may take the actions described  
21           in subparagraph (A) if—

22           “(i) such person submits to the Adminis-  
23           trator, at least 90 days before such manufac-  
24           ture or processing, a notice, in accordance with  
25           subsection (d), of such person’s intention to

1 manufacture or process such substance and  
2 such person complies with any applicable re-  
3 quirement of, or imposed pursuant to, sub-  
4 section (b), (e), or (f); and

5 “(ii) the Administrator—

6 “(I) conducts a review of the notice;

7 and

8 “(II) makes a determination under  
9 subparagraph (A), (B), (C), or (D) of  
10 paragraph (3) and takes the actions re-  
11 quired in association with that determina-  
12 tion under such subparagraph within the  
13 applicable review period.”; and

14 (B) by adding at the end the following new  
15 paragraphs:

16 “(3) REVIEW AND DETERMINATION.—Within  
17 the applicable review period, subject to section 18,  
18 the Administrator shall review such notice and de-  
19 termine—

20 “(A) that the relevant chemical substance  
21 or significant new use presents or will present  
22 an unreasonable risk of injury to health or the  
23 environment, without consideration of costs or  
24 other nonrisk factors, including an unreason-  
25 able risk to a potentially exposed or susceptible

1           subpopulation identified as relevant by the Ad-  
2           ministrator under the conditions of use, in  
3           which case the Administrator shall take the ac-  
4           tions required under subsection (f);

5           “(B) that—

6                   “(i) the information available to the  
7                   Administrator is insufficient to permit a  
8                   reasoned evaluation of the health and envi-  
9                   ronmental effects of the relevant chemical  
10                  substance or significant new use; or

11                  “(ii)(I) in the absence of sufficient in-  
12                  formation to permit the Administrator to  
13                  make such an evaluation, the manufacture,  
14                  processing, distribution in commerce, use,  
15                  or disposal of such substance, or any com-  
16                  bination of such activities, may present an  
17                  unreasonable risk of injury to health or the  
18                  environment, without consideration of costs  
19                  or other nonrisk factors, including an un-  
20                  reasonable risk to a potentially exposed or  
21                  susceptible subpopulation identified as rel-  
22                  evant by the Administrator; or

23                  “(II) such substance is or will be pro-  
24                  duced in substantial quantities, and such  
25                  substance either enters or may reasonably

1           be anticipated to enter the environment in  
2           substantial quantities or there is or may be  
3           significant or substantial human exposure  
4           to the substance,

5           in which case the Administrator shall take the  
6           actions required under subsection (e);

7           “(C) that the relevant chemical substance  
8           or significant new use is likely not to present an  
9           unreasonable risk of injury to health or the en-  
10          vironment, without consideration of costs or  
11          other nonrisk factors, including an unreason-  
12          able risk to a potentially exposed or susceptible  
13          subpopulation identified as relevant by the Ad-  
14          ministrator under the conditions of use, in  
15          which case the submitter of the notice may  
16          commence manufacture of the chemical sub-  
17          stance or manufacture or processing for a sig-  
18          nificant new use; or

19          “(D) that the relevant chemical substance  
20          is a low-hazard substance, in which case the  
21          submitter of the notice may commence manu-  
22          facture of the chemical substance or manufac-  
23          ture or processing of the chemical substance for  
24          a significant new use.

25          “(4) FAILURE TO RENDER DETERMINATION.—

1           “(A) FAILURE TO RENDER DETERMINA-  
2           TION.—If the Administrator fails to make a de-  
3           termination on a notice under paragraph (3) by  
4           the end of the applicable review period and the  
5           notice has not been withdrawn by the sub-  
6           mitter, the Administrator shall refund to the  
7           submitter all applicable fees charged to the sub-  
8           mitter for review of the notice pursuant to sec-  
9           tion 26(b), and the Administrator shall not be  
10          relieved of any requirement to make such deter-  
11          mination.

12          “(B) LIMITATIONS.—(i) A refund of appli-  
13          cable fees under subparagraph (A) shall not be  
14          made if the Administrator certifies that the  
15          submitter has not provided information required  
16          under subsection (b) or has otherwise unduly  
17          delayed the process such that the Administrator  
18          is unable to render a determination within the  
19          applicable review period.

20          “(ii) A failure of the Administrator to  
21          render a decision shall not be deemed to con-  
22          stitute a withdrawal of the notice.

23          “(iii) Nothing in this paragraph shall be  
24          construed as relieving the Administrator or the

1 submitter of the notice from any requirement of  
2 this section.

3 “(5) ARTICLE CONSIDERATION.—The Adminis-  
4 trator may require notification under this section for  
5 the import or processing of a chemical substance as  
6 part of an article or category of articles under para-  
7 graph (1)(A)(ii) if the Administrator makes an af-  
8 firmative finding in a rule under paragraph (2) that  
9 the reasonable potential for exposure to the chemical  
10 substance through the article or category of articles  
11 subject to the rule justifies notification.”;

12 (2) in subsection (b)—

13 (A) in the subsection heading, by striking  
14 “TEST DATA” and inserting “INFORMATION”;

15 (B) in paragraph (1)—

16 (i) in subparagraph (A)—

17 (I) by striking “test data” and  
18 inserting “information”; and

19 (II) by striking “such data” and  
20 inserting “such information”; and

21 (ii) in subparagraph (B)—

22 (I) by striking “test data” and  
23 inserting “information”;



1 (II) by striking “subsection  
2 (a)(1)(A)” and inserting “subsection  
3 (a)(1)(A)(i)”; and

4 (III) by striking “subsection  
5 (a)(1)(B)” and inserting “subsection  
6 (a)(1)(A)(ii)”;

7 (C) in paragraph (2)—

8 (i) in subparagraph (A)—

9 (I) by striking “test data” in  
10 clause (ii) and inserting “informa-  
11 tion”;

12 (II) by striking “shall” and in-  
13 serting “may”; and

14 (III) by striking “data pre-  
15 scribed” and inserting “information  
16 prescribed”; and

17 (ii) in subparagraph (B)—

18 (I) by striking “Data” and in-  
19 serting “Information”;

20 (II) by striking “data” both  
21 places it appears and inserting “infor-  
22 mation”;

23 (III) by striking “show” and in-  
24 serting “shows”;

1 (IV) by striking “subsection  
2 (a)(1)(A)” in clause (i) and inserting  
3 “subsection (a)(1)(A)(i)”; and

4 (V) by striking “subsection  
5 (a)(1)(B)” in clause (ii) and inserting  
6 “subsection (a)(1)(A)(ii)”;

7 (D) in paragraph (3)—

8 (i) by striking “Data” and inserting  
9 “Information”; and

10 (ii) by striking “paragraph (1) or (2)”  
11 and inserting “paragraph (1) or (2) of this  
12 subsection or under subsection (e)”; and

13 (E) in paragraph (4)—

14 (i) in subparagraph (A)(i), by insert-  
15 ing “, without consideration of costs or  
16 other nonrisk factors” after “health or the  
17 environment”; and

18 (ii) in subparagraph (C), by striking  
19 “, except that” and all that follows  
20 through “subparagraph (A)”;

21 (3) in subsection (c)—

22 (A) in the subsection heading, by striking  
23 “NOTICE” and inserting “REVIEW”; and

24 (B) by striking “before which” and all that  
25 follows through “subsection may begin”;

1 (4) in subsection (d)—

2 (A) by striking “test data” in paragraph  
3 (1)(B) and inserting “information”;

4 (B) by striking “data” each place it ap-  
5 pears in paragraph (1)(C) and paragraph (2)  
6 and inserting “information”;

7 (C) in paragraph (2)(B), by striking “uses  
8 or intended uses of such substance” and insert-  
9 ing “uses of such substance identified in the no-  
10 tice”; and

11 (D) in paragraph (3)—

12 (i) by striking “for which the notifica-  
13 tion period prescribed by subsection (a),  
14 (b), or (c)” and inserting “for which the  
15 applicable review period”; and

16 (ii) by striking “such notification pe-  
17 riod” and inserting “such period”;

18 (5) in subsection (e)—

19 (A) in paragraph (1)(A)—

20 (i) in clause (i), by striking “; and”  
21 and inserting “; or”;

22 (ii) in clause (ii)(I), by inserting  
23 “without consideration of costs or other  
24 nonrisk factors, including an unreasonable  
25 risk to a potentially exposed subpopulation

1 identified as relevant by the Administrator  
2 under the conditions of use;” after “health  
3 or the environment;” and

4 (iii) in the matter after clause  
5 (ii)(II)—

6 (I) by striking “may issue a pro-  
7 posed order” and inserting “shall  
8 issue an order”;

9 (II) by striking “notification pe-  
10 riod applicable to the manufacturing  
11 or processing of such substance under  
12 subsection (a), (b), (c)” and inserting  
13 “applicable review period”; and

14 (III) by inserting “to the extent  
15 necessary to protect against an unrea-  
16 sonable risk of injury to health or the  
17 environment, without consideration of  
18 costs or other nonrisk factors, includ-  
19 ing an unreasonable risk to a poten-  
20 tially exposed or susceptible sub-  
21 population identified as relevant by  
22 the Administrator under the condi-  
23 tions of use, and the submitter of the  
24 notice may commence manufacture of  
25 the chemical substance, or manufac-

1                   ture or processing of the chemical  
2                   substance for a significant new use,  
3                   including while any required informa-  
4                   tion is being developed, only in com-  
5                   pliance with the order” before the pe-  
6                   riod at the end;

7                   (B) in paragraph (1)(B)—

8                   (i) by striking “A proposed order”  
9                   and inserting “An order”;

10                  (ii) by striking “notification period  
11                  applicable to the manufacture or proc-  
12                  essing of such substance under subsection  
13                  (a), (b), (c)” and inserting “applicable re-  
14                  view period”; and

15                  (iii) by striking “of the proposed  
16                  order” and inserting “of the order”;

17                  (C) by striking paragraph (1)(C); and

18                  (D) by striking paragraph (2);

19                  (6) in subsection (f)—

20                  (A) in paragraph (1)—

21                  (i) by striking “finds that there is a  
22                  reasonable basis to conclude that the man-  
23                  ufacture, processing, distribution in com-  
24                  merce, use, or disposal of a chemical sub-  
25                  stance with” and inserting “determines

1                   that a chemical substance or significant  
2                   new use with”;

3                   (ii) by striking “, or that any com-  
4                   bination of such activities,”;

5                   (iii) by striking “before a rule promul-  
6                   gated under section 6 can protect against  
7                   such risk,” and inserting “, without con-  
8                   sideration of costs or other nonrisk factors,  
9                   including an unreasonable risk to a poten-  
10                  tially exposed subpopulation identified as  
11                  relevant by the Administrator under the  
12                  conditions of use,”; and

13                  (iv) by striking “notification period  
14                  applicable under subsection (a), (b), or (c)  
15                  to the manufacturing or processing of such  
16                  substance” and inserting “applicable re-  
17                  view period”;

18                  (B) in paragraph (2), the matter following  
19                  subparagraph (C), by striking “Section  
20                  6(d)(2)(B)” and inserting “Section  
21                  6(d)(3)(B)”;

22                  (C) in paragraph (3)—

23                         (i) in subparagraph (A)—

24                                 (I) by striking “Administrator  
25                                 may” and all that follows through

1 “issue a proposed order to prohibit  
2 the” and inserting “Administrator  
3 may issue an order to prohibit or limit  
4 the”; and

5 (II) by striking “under para-  
6 graph (1)” and all that follows  
7 through “processing of such sub-  
8 stance.” and inserting “under para-  
9 graph (1). Such order shall take effect  
10 on the expiration of the applicable re-  
11 view period.”;

12 (ii) by striking subparagraph (B) and  
13 redesignating subparagraph (C) as sub-  
14 paragraph (B);

15 (iii) in subparagraph (B), as so reded-  
16 icated—

17 (I) by striking “subparagraphs  
18 (B) and (C)” and inserting “subpara-  
19 graph (B)”;

20 (II) by striking “clause (i) of”;  
21 and

22 (III) by striking “; and the provi-  
23 sions of subparagraph (C) of sub-  
24 section (e)(2) shall apply with respect

1 to an injunction issued under sub-  
2 paragraph (B)”; and

3 (iv) by striking subparagraph (D);

4 and

5 (D) by adding at the end the following:

6 “(4) TREATMENT OF NONCONFORMING USES.—

7 Not later than 90 days after taking an action under  
8 paragraph (2) or (3) or issuing an order under sub-  
9 section (e) relating to a chemical substance with re-  
10 spect to which the Administrator has made a deter-  
11 mination under subsection (a)(3)(A) or (B), the Ad-  
12 ministrator shall consider whether to promulgate a  
13 rule pursuant to subsection (a)(2) that identifies as  
14 a significant new use any manufacturing, processing,  
15 use, distribution in commerce, or disposal of the  
16 chemical substance that does not conform to the re-  
17 strictions imposed by the action or order, and, as ap-  
18 plicable, initiate such a rulemaking or publish a  
19 statement describing the reasons of the Adminis-  
20 trator for not initiating such a rulemaking.

21 “(5) WORKPLACE EXPOSURES.—To the extent  
22 practicable, the Administrator shall consult with the  
23 Assistant Secretary of Labor for Occupational Safe-  
24 ty and Health prior to adopting any prohibition or  
25 other restriction relating to a chemical substance



1 with respect to which the Administrator has made a  
2 determination under subsection (a)(3)(A) or (B) to  
3 address workplace exposures.”;

4 (7) by amending subsection (g) to read as fol-  
5 lows:

6 “(g) STATEMENT ON ADMINISTRATOR FINDING.—If  
7 the Administrator finds in accordance with subsection  
8 (a)(3)(C) that a chemical substance or significant new use  
9 is likely not to present an unreasonable risk of injury to  
10 health or the environment, or in accordance with sub-  
11 section (a)(3)(D) that the chemical substance is a low-haz-  
12 ard substance, then notwithstanding any remaining por-  
13 tion of the applicable review period, the submitter of the  
14 notice may commence manufacture of the chemical sub-  
15 stance or manufacture or processing for the significant  
16 new use, and the Administrator shall make public a state-  
17 ment of the Administrator’s finding. Such a statement  
18 shall be submitted for publication in the Federal Register  
19 as soon as is practicable before the expiration of such pe-  
20 riod. Publication of such statement in accordance with the  
21 preceding sentence is not a prerequisite to the manufac-  
22 turing or processing of the substance with respect to which  
23 the statement is to be published.”;

24 (8) in subsection (h)—

1 (A) in paragraph (1)(A), by inserting “,  
2 including an unreasonable risk to a potentially  
3 exposed or susceptible subpopulation identified  
4 by the Administrator for the specific conditions  
5 of use identified in the application” after  
6 “health or the environment”;

7 (B) in paragraph (2), by striking “data”  
8 each place it appears and inserting “informa-  
9 tion”; and

10 (C) in paragraph (4), by striking “. A rule  
11 promulgated” and all that follows through “sec-  
12 tion 6(c)” and inserting “, including an unrea-  
13 sonable risk to a potentially exposed or suscep-  
14 tible subpopulation identified by the Adminis-  
15 trator under the conditions of use”; and

16 (9) by amending subsection (i) to read as fol-  
17 lows:

18 “(i) DEFINITIONS.—(1) For purposes of this section,  
19 the terms ‘manufacture’ and ‘process’ mean manufac-  
20 turing or processing for commercial purposes.

21 “(2) For purposes of this Act, the term ‘requirement’  
22 as used in this section shall not displace any statutory or  
23 common law.

24 “(3) For purposes of this section, the term ‘applicable  
25 review period’ means the period starting on the date the

1 Administrator receives a notice under subsection (a)(1)  
2 and ending 90 days after that date, or on such date as  
3 is provided for in subsection (b)(1) or (c).”.

4 **SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-**  
5 **TION OF CHEMICAL SUBSTANCES AND MIX-**  
6 **TURES.**

7 Section 6 of the Toxic Substances Control Act (15  
8 U.S.C. 2605) is amended—

9 (1) by striking the section heading and insert-  
10 ing “**PRIORITIZATION, RISK EVALUATION, AND**  
11 **REGULATION OF CHEMICAL SUBSTANCES AND**  
12 **MIXTURES**”;

13 (2) in subsection (a)—

14 (A) by striking “finds that there is a rea-  
15 sonable basis to conclude” and inserting “deter-  
16 mines in accordance with subsection (b)(4)(A)”;

17 (B) by inserting “and subject to section  
18 18, and in accordance with subsection (c)(2),”  
19 after “shall by rule”;

20 (C) by striking “to protect adequately  
21 against such risk using the least burdensome  
22 requirements” and inserting “so that the chem-  
23 ical substance or mixture no longer presents  
24 such risk”;

1 (D) by inserting “or otherwise restricting”  
2 after “prohibiting” in paragraphs (1)(A) and  
3 (2)(A);

4 (E) by inserting “minimum” before “warn-  
5 ings” both places it appears in paragraph (3);

6 (F) by striking “and monitor or conduct  
7 tests” and inserting “or monitor or conduct  
8 tests” in paragraph (4); and

9 (G) in paragraph (7)—

10 (i) by striking “such unreasonable  
11 risk of injury” and inserting “such deter-  
12 mination”; and

13 (ii) by striking “such risk of injury”  
14 and inserting “such determination”;

15 (3) by amending subsection (b) to read as fol-  
16 lows:

17 “(b) RISK EVALUATIONS.—

18 “(1) PRIORITIZATION FOR RISK EVALUA-  
19 TIONS.—

20 “(A) ESTABLISHMENT OF PROCESS.—Not  
21 later than 1 year after the date of enactment of  
22 the Frank R. Lautenberg Chemical Safety for  
23 the 21st Century Act, the Administrator shall  
24 establish, by rule, a risk-based screening proc-  
25 ess, including criteria for designating chemical

1 substances as high-priority substances for risk  
2 evaluations or low-priority substances for which  
3 risk evaluations are not warranted at the time.  
4 The process to designate the priority of chem-  
5 ical substances shall include a consideration of  
6 the hazard and exposure potential of a chemical  
7 substance or a category of chemical substances  
8 (including consideration of persistence and bio-  
9 accumulation, potentially exposed or susceptible  
10 subpopulations and storage near significant  
11 sources of drinking water), the conditions of use  
12 or significant changes in the conditions of use  
13 of the chemical substance, and the volume or  
14 significant changes in the volume of the chem-  
15 ical substance manufactured or processed.

16 “(B) IDENTIFICATION OF PRIORITIES FOR  
17 RISK EVALUATION.—

18 “(i) HIGH-PRIORITY SUBSTANCES.—

19 The Administrator shall designate as a  
20 high-priority substance a chemical sub-  
21 stance that the Administrator concludes,  
22 without consideration of costs or other  
23 nonrisk factors, may present an unreason-  
24 able risk of injury to health or the environ-  
25 ment because of a potential hazard and a

1 potential route of exposure under the con-  
2 ditions of use, including an unreasonable  
3 risk to a potentially exposed or susceptible  
4 subpopulation identified as relevant by the  
5 Administrator.

6 “(ii) LOW-PRIORITY SUBSTANCES.—  
7 Except as provided in clause (iii), the Ad-  
8 ministrator shall designate a chemical sub-  
9 stance as a low-priority substance if the  
10 Administrator concludes, based on infor-  
11 mation sufficient to establish, without con-  
12 sideration of costs or other nonrisk factors,  
13 that such substance does not meet the  
14 standard identified in clause (i) for desig-  
15 nating a chemical substance a high-priority  
16 substance.

17 “(iii) LOW-HAZARD SUBSTANCES.—  
18 The Administrator may designate a low-  
19 priority substance as a low-hazard sub-  
20 stance if the Administrator concludes,  
21 based on information sufficient to estab-  
22 lish, without consideration of costs or other  
23 nonrisk factors or exposure, that the chem-  
24 ical substance poses no or low hazard to  
25 health or the environment, including any

1 hazard to a potentially exposed or suscep-  
2 tible subpopulation identified as relevant  
3 by the Administrator.

4 “(C) INFORMATION REQUEST AND REVIEW  
5 AND PROPOSED AND FINAL PRIORITIZATION  
6 DESIGNATION.—The rulemaking required in  
7 subparagraph (A) shall ensure that the time re-  
8 quired to make a priority designation of a  
9 chemical substance be no shorter than nine  
10 months and no longer than 1 year, and that the  
11 process for such designations includes—

12 “(i) a requirement that the Adminis-  
13 trator request interested persons to submit  
14 relevant information on a chemical sub-  
15 stance that the Administrator has initiated  
16 the prioritization process on, before pro-  
17 posing a priority designation for the chem-  
18 ical substance, and provide 90 days for  
19 such information to be provided;

20 “(ii) a requirement that the Adminis-  
21 trator publish each proposed designation of  
22 a chemical substance as a high- or low-pri-  
23 ority substance, along with an identifica-  
24 tion of the information, analysis, and basis  
25 used to make the proposed designations,

1 and provide 90 days for public comment on  
2 each such proposed designation; and

3 “(iii) a process by which the Adminis-  
4 trator may extend the deadline in clause  
5 (i) for up to three months in order to re-  
6 ceive or evaluate information required to  
7 be submitted in accordance with section  
8 4(a)(2)(B), subject to the limitation that if  
9 the information available to the Adminis-  
10 trator at the end of such an extension re-  
11 mains insufficient to enable the designa-  
12 tion of the chemical substance as a low-pri-  
13 ority substance, the Administrator shall  
14 designate the chemical substance as a  
15 high-priority substance.

16 “(2) INITIAL RISK EVALUATIONS AND SUBSE-  
17 QUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY  
18 SUBSTANCES.—

19 “(A) INITIAL RISK EVALUATIONS.—Not  
20 later than 180 days after the date of enactment  
21 of the Frank R. Lautenberg Chemical Safety  
22 for the 21st Century Act, the Administrator  
23 shall ensure that risk evaluations are being con-  
24 ducted on at least 10 chemical substances  
25 drawn from the 2014 update of the TSCA



1 Work Plan for Chemical Assessments and shall  
2 publish the list of such chemical substances  
3 during the 180 day period.

4 “(B) ADDITIONAL RISK EVALUATIONS.—  
5 Not later than three and one half years after  
6 the date of enactment of the Frank R. Lauten-  
7 berg Chemical Safety for the 21st Century Act,  
8 the Administrator shall ensure that risk evalua-  
9 tions are being conducted on at least 20 high-  
10 priority substances and that at least 20 chem-  
11 ical substances have been designated as low-pri-  
12 ority or low-hazard substances, subject to the  
13 limitation that at least 50 percent of all chem-  
14 ical substances on which risk evaluations are  
15 being conducted by the Administrator are  
16 drawn from the 2014 update of the TSCA  
17 Work Plan for Chemical Assessments.

18 “(C) CONTINUING DESIGNATIONS AND  
19 RISK EVALUATIONS.—The Administrator shall  
20 continue to designate priority substances and  
21 conduct risk evaluations in accordance with this  
22 subsection at a pace consistent with the ability  
23 of the Administrator to complete risk evalua-  
24 tions in accordance with the deadlines under  
25 paragraph (4)(G).

1           “(D) PREFERENCE.—In designating high-  
2 priority substances, the Administrator shall give  
3 preference to—

4           “(i) chemical substances that are list-  
5 ed in the 2014 update of the TSCA Work  
6 Plan for Chemical Assessments as having a  
7 Persistence and Bioaccumulation Score of  
8 3; and

9           “(ii) chemical substances that are list-  
10 ed in the 2014 update of the TSCA Work  
11 Plan for Chemical Assessments that are  
12 known human carcinogens and have high  
13 acute and chronic toxicity.

14           “(E) METALS AND METAL COMPOUNDS.—  
15 In identifying priorities for risk evaluation and  
16 conducting risk evaluations of metals and metal  
17 compounds, the Administrator shall use the  
18 Framework for Metals Risk Assessment of the  
19 Office of the Science Advisor, Risk Assessment  
20 Forum, and dated March 2007, or a successor  
21 document that addresses metals risk assessment  
22 and is peer reviewed by the Science Advisory  
23 Board.

24           “(3) INITIATION OF RISK EVALUATIONS; DES-  
25 IGNATIONS.—

1           “(A) RISK EVALUATION INITIATION.—  
2           Upon designating a chemical substance as a  
3           high-priority substance, the Administrator shall  
4           initiate a risk evaluation on the substance.

5           “(B) REVISION.—The Administrator may  
6           revise the designation of a low-priority sub-  
7           stance or a low-hazard substance based on in-  
8           formation made available to the Administrator.

9           “(C) ONGOING DESIGNATIONS.—The Ad-  
10          ministrator shall designate at least one high-  
11          priority substance upon the completion of each  
12          risk evaluation (other than risk evaluations for  
13          chemical substances designated under para-  
14          graph (4)(C)(ii)).

15          “(4) RISK EVALUATION PROCESS AND DEAD-  
16          LINES.—

17                 “(A) IN GENERAL.—The Administrator  
18                 shall conduct risk evaluations pursuant to this  
19                 paragraph to determine whether a chemical  
20                 substance presents an unreasonable risk of in-  
21                 jury to health or the environment, without con-  
22                 sideration of costs or other nonrisk factors, in-  
23                 cluding an unreasonable risk to a potentially ex-  
24                 posed or susceptible subpopulation identified as

1 relevant to the risk evaluation by the Adminis-  
2 trator, under the conditions of use.

3 “(B) ESTABLISHMENT OF PROCESS.—Not  
4 later than 1 year after the date of enactment of  
5 the Frank R. Lautenberg Chemical Safety for  
6 the 21st Century Act, the Administrator shall  
7 establish, by rule, a process to conduct risk  
8 evaluations in accordance with subparagraph  
9 (A).

10 “(C) REQUIREMENT.—The Administrator  
11 shall conduct and publish risk evaluations, in  
12 accordance with the rule promulgated under  
13 subparagraph (B), for a chemical substance—

14 “(i) that has been identified under  
15 paragraph (2)(A) or designated under  
16 paragraph (1)(B)(i); and

17 “(ii) subject to subparagraph (E),  
18 that a manufacturer of the chemical sub-  
19 stance has requested, in a form and man-  
20 ner and using the criteria prescribed by  
21 the Administrator in the rule promulgated  
22 under subparagraph (B), be subjected to a  
23 risk evaluation.

24 “(D) SCOPE.—The Administrator shall,  
25 not later than 6 months after the initiation of

1 a risk evaluation, publish the scope of the risk  
2 evaluation to be conducted, including the haz-  
3 ards, exposures, conditions of use, and the po-  
4 tentially exposed or susceptible subpopulations  
5 the Administrator expects to consider, and, for  
6 each designation of a high-priority substance,  
7 ensure not less than 12 months between the ini-  
8 tiation of the prioritization process for the  
9 chemical substance and the publication of the  
10 scope of the risk evaluation for the chemical  
11 substance, and for risk evaluations conducted  
12 on chemical substances that have been identi-  
13 fied under paragraph (2)(A) or selected under  
14 subparagraph (E)(iv)(II) of this paragraph, en-  
15 sure not less than 3 months before the Admin-  
16 istrator publishes the scope of the risk evalua-  
17 tion.

18 “(E) LIMITATION AND CRITERIA.—

19 “(i) PERCENTAGE REQUIREMENTS.—

20 The Administrator shall ensure that, of the  
21 number of chemical substances that under-  
22 go a risk evaluation under clause (i) of  
23 subparagraph (C), the number of chemical  
24 substances undergoing a risk evaluation  
25 under clause (ii) of subparagraph (C) is—

1                   “(I) not less than 25 percent, if  
2                   sufficient requests are made under  
3                   clause (ii) of subparagraph (C); and

4                   “(II) not more than 50 percent.

5                   “(ii) REQUESTED RISK EVALUA-  
6                   TIONS.—Requests for risk evaluations  
7                   under subparagraph (C)(ii) shall be subject  
8                   to the payment of fees pursuant to section  
9                   26(b), and the Administrator shall not ex-  
10                  pedite or otherwise provide special treat-  
11                  ment to such risk evaluations.

12                  “(iii) PREFERENCE.—In deciding  
13                  whether to grant requests under subpara-  
14                  graph (C)(ii), the Administrator shall give  
15                  preference to requests for risk evaluations  
16                  on chemical substances for which the Ad-  
17                  ministrator determines that restrictions  
18                  imposed by 1 or more States have the po-  
19                  tential to have a significant impact on  
20                  interstate commerce or health or the envi-  
21                  ronment.

22                  “(iv) EXCEPTIONS.—(I) Chemical  
23                  substances for which requests have been  
24                  granted under subparagraph (C)(ii) and  
25                  that are not drawn from the 2014 update

1 of the TSCA Work Plan for Chemical As-  
2 sessments shall not be subject to section  
3 18(b).

4 “(II) Requests for risk evaluations on  
5 chemical substances which are made under  
6 subparagraph (C)(ii) and that are drawn  
7 from the 2014 update of the TSCA Work  
8 Plan for Chemical Assessments shall be  
9 granted at the discretion of the Adminis-  
10 trator and not be subject to clause (i)(II).

11 “(F) REQUIREMENTS.—In conducting a  
12 risk evaluation under this subsection, the Ad-  
13 ministrator shall—

14 “(i) integrate and assess available in-  
15 formation on hazards and exposures for  
16 the conditions of use of the chemical sub-  
17 stance, including information that is rel-  
18 evant to specific risks of injury to health or  
19 the environment and information on poten-  
20 tially exposed or susceptible subpopulations  
21 identified as relevant by the Administrator;

22 “(ii) describe whether aggregate or  
23 sentinel exposures to a chemical substance  
24 under the conditions of use were consid-  
25 ered, and the basis for that consideration;

1           “(iii) not consider costs or other  
2 nonrisk factors;

3           “(iv) take into account, where rel-  
4 evant, the likely duration, intensity, fre-  
5 quency, and number of exposures under  
6 the conditions of use of the chemical sub-  
7 stance; and

8           “(v) describe the weight of the sci-  
9 entific evidence for the identified hazard  
10 and exposure.

11           “(G) DEADLINES.—The Administrator—

12           “(i) shall complete a risk evaluation  
13 for a chemical substance as soon as prac-  
14 ticable, but not later than 3 years after the  
15 date on which the Administrator initiates  
16 the risk evaluation under subparagraph  
17 (C); and

18           “(ii) may extend the deadline for a  
19 risk evaluation for not more than 6  
20 months.

21           “(H) NOTICE AND COMMENT.—The Ad-  
22 ministrator shall provide no less than 30 days  
23 public notice and an opportunity for comment  
24 on a draft risk evaluation prior to publishing a  
25 final risk evaluation.”;



1           (4) by amending subsection (c) to read as fol-  
2           lows:

3           “(c) PROMULGATION OF SUBSECTION (a) RULES.—

4           “(1) DEADLINES.—If the Administrator deter-  
5           mines that a chemical substance presents an unrea-  
6           sonable risk of injury to health or the environment  
7           in accordance with subsection (b)(4)(A), the Admin-  
8           istrator—

9                   “(A) shall propose in the Federal Register  
10                   a rule under subsection (a) for the chemical  
11                   substance not later than 1 year after the date  
12                   on which the final risk evaluation regarding the  
13                   chemical substance is published;

14                   “(B) shall publish in the Federal Register  
15                   a final rule not later than 2 years after the date  
16                   on which the final risk evaluation regarding the  
17                   chemical substance is published; and

18                   “(C) may extend the deadlines under this  
19                   paragraph for not more than two years, subject  
20                   to the condition that the aggregate length of ex-  
21                   tensions under this subparagraph and sub-  
22                   section (b)(4)(G)(ii) does not exceed two years,  
23                   and subject to the limitation that the Adminis-  
24                   trator may not extend a deadline for the publi-  
25                   cation of a proposed or final rule regarding a

1 chemical substance drawn from the 2014 up-  
2 date of the TSCA Work Plan for Chemical As-  
3 sessments or a chemical substance that, with  
4 respect to persistence and bioaccumulation,  
5 scores high for 1 and either high or moderate  
6 for the other, pursuant to the TSCA Work Plan  
7 Chemicals Methods Document published by the  
8 Administrator in February 2012 (or a successor  
9 scoring system), without adequate public jus-  
10 tification that demonstrates, following a review  
11 of the information reasonably available to the  
12 Administrator, that the Administrator cannot  
13 complete the proposed or final rule without ad-  
14 ditional information regarding the chemical  
15 substance.

16 “(2) REQUIREMENTS FOR RULE.—

17 “(A) STATEMENT OF EFFECTS.—In pro-  
18 posing and promulgating a rule under sub-  
19 section (a) with respect to a chemical substance  
20 or mixture, the Administrator shall consider  
21 and publish a statement based on reasonably  
22 available information with respect to—

23 “(i) the effects of the chemical sub-  
24 stance or mixture on health and the mag-

1                   nitude of the exposure of human beings to  
2                   the chemical substance or mixture;

3                   “(ii) the effects of the chemical sub-  
4                   stance or mixture on the environment and  
5                   the magnitude of the exposure of the envi-  
6                   ronment to such substance or mixture;

7                   “(iii) the benefits of the chemical sub-  
8                   stance or mixture for various uses; and

9                   “(iv) the reasonably ascertainable eco-  
10                  nomic consequences of the rule, including  
11                  consideration of—

12                   “(I) the likely effect of the rule  
13                   on the national economy, small busi-  
14                   ness, technological innovation, the en-  
15                   vironment, and public health;

16                   “(II) the costs and benefits of  
17                   the proposed and final regulatory ac-  
18                   tion and of the 1 or more primary al-  
19                   ternative regulatory actions considered  
20                   by the Administrator; and

21                   “(III) the cost effectiveness of  
22                   the proposed regulatory action and of  
23                   the 1 or more primary alternative reg-  
24                   ulatory actions considered by the Ad-  
25                   ministrator.

1           “(B) SELECTING REQUIREMENTS.—In se-  
2           lecting among prohibitions and other restric-  
3           tions, the Administrator shall factor in, to the  
4           extent practicable, the considerations under  
5           subparagraph (A) in accordance with subsection  
6           (a).

7           “(C) CONSIDERATION OF ALTER-  
8           NATIVES.—Based on the information published  
9           under subparagraph (A), in deciding whether to  
10          prohibit or restrict in a manner that substan-  
11          tially prevents a specific condition of use of a  
12          chemical substance or mixture, and in setting  
13          an appropriate transition period for such ac-  
14          tion, the Administrator shall consider, to the  
15          extent practicable, whether technically and eco-  
16          nomically feasible alternatives that benefit  
17          health or the environment, compared to the use  
18          so proposed to be prohibited or restricted, will  
19          be reasonably available as a substitute when the  
20          proposed prohibition or other restriction takes  
21          effect.

22          “(D) REPLACEMENT PARTS.—

23                 “(i) IN GENERAL.—The Administrator  
24                 shall exempt replacement parts for complex  
25                 durable goods and complex consumer goods

1 that are designed prior to the date of pub-  
2 lication in the Federal Register of the rule  
3 under subsection (a), unless the Adminis-  
4 trator finds that such replacement parts  
5 contribute significantly to the risk, identi-  
6 fied in a risk evaluation conducted under  
7 subsection (b)(4)(A), to the general popu-  
8 lation or to an identified potentially ex-  
9 posed or susceptible subpopulation.

10 “(ii) DEFINITIONS.—In this subpara-  
11 graph—

12 “(I) the term ‘complex consumer  
13 goods’ means electronic or mechanical  
14 devices composed of multiple manu-  
15 factured components, with an in-  
16 tended useful life of 3 or more years,  
17 where the product is typically not con-  
18 sumed, destroyed, or discarded after a  
19 single use, and the components of  
20 which would be impracticable to rede-  
21 sign or replace; and

22 “(II) the term ‘complex durable  
23 goods’ means manufactured goods  
24 composed of 100 or more manufac-  
25 tured components, with an intended

1                   useful life of 5 or more years, where  
2                   the product is typically not consumed,  
3                   destroyed, or discarded after a single  
4                   use.

5                   “(E) ARTICLES.—In selecting among pro-  
6                   hibitions and other restrictions, the Adminis-  
7                   trator shall apply such prohibitions or other re-  
8                   strictions to an article or category of articles  
9                   containing the chemical substance or mixture  
10                  only to the extent necessary to address the  
11                  identified risks from exposure to the chemical  
12                  substance or mixture from the article or cat-  
13                  egory of articles so that the substance or mix-  
14                  ture does not present an unreasonable risk of  
15                  injury to health or the environment identified in  
16                  the risk evaluation conducted in accordance  
17                  with subsection (b)(4)(A).

18                  “(3) PROCEDURES.—When prescribing a rule  
19                  under subsection (a) the Administrator shall proceed  
20                  in accordance with section 553 of title 5, United  
21                  States Code (without regard to any reference in such  
22                  section to sections 556 and 557 of such title), and  
23                  shall also—

1           “(A) publish a notice of proposed rule-  
2 making stating with particularity the reason for  
3 the proposed rule;

4           “(B) allow interested persons to submit  
5 written data, views, and arguments, and make  
6 all such submissions publicly available;

7           “(C) promulgate a final rule based on the  
8 matter in the rulemaking record; and

9           “(D) make and publish with the rule the  
10 determination described in subsection (a).”;

11           (5) in subsection (d)—

12           (A) by redesignating paragraph (2) as  
13 paragraph (3);

14           (B) by striking paragraph (1) and insert-  
15 ing the following:

16           “(1) IN GENERAL.—In any rule under sub-  
17 section (a), the Administrator shall—

18           (A) specify the date on which it shall take  
19 effect, which date shall be as soon as prac-  
20 ticable;

21           (B) except as provided in subparagraphs  
22 (C) and (D), specify mandatory compliance  
23 dates for all of the requirements under a rule  
24 under subsection (a), which shall be as soon as  
25 practicable, but not later than 5 years after the

1 date of promulgation of the rule, except in a  
2 case of a use exempted under subsection (g);

3 “(C) specify mandatory compliance dates  
4 for the start of ban or phase-out requirements  
5 under a rule under subsection (a), which shall  
6 be as soon as practicable, but not later than 5  
7 years after the date of promulgation of the rule,  
8 except in the case of a use exempted under sub-  
9 section (g);

10 “(D) specify mandatory compliance dates  
11 for full implementation of ban or phase-out re-  
12 quirements under a rule under subsection (a),  
13 which shall be as soon as practicable; and

14 “(E) provide for a reasonable transition  
15 period.

16 “(2) VARIABILITY.—As determined by the Ad-  
17 ministrator, the compliance dates established under  
18 paragraph (1) may vary for different affected per-  
19 sons.”; and

20 (C) in paragraph (3), as so redesignated  
21 by subparagraph (A) of this paragraph—

22 (i) in subparagraph (A)—

23 (I) by striking “upon its publica-  
24 tion” and all that follows through “re-  
25 specting such rule if” and inserting “,



1 and compliance with the proposed re-  
2 quirements to be mandatory, upon  
3 publication in the Federal Register of  
4 the proposed rule and until the com-  
5 pliance dates applicable to such re-  
6 quirements in a final rule promul-  
7 gated under section 6(a) or until the  
8 Administrator revokes such proposed  
9 rule, in accordance with subparagraph  
10 (B), if”; and

11 (II) in clause (i)(I), by inserting  
12 “without consideration of costs or  
13 other non-risk factors” after “effective  
14 date”; and

15 (ii) in subparagraph (B), by striking  
16 “, provide reasonable opportunity” and all  
17 that follows through the period at the end  
18 and inserting “in accordance with sub-  
19 section (c), and either promulgate such  
20 rule (as proposed or with modifications) or  
21 revoke it.”;

22 (6) in subsection (e)(4), by striking “para-  
23 graphs (2), (3), and (4)” and inserting “paragraph  
24 (3)”; and

1 (7) by adding at the end the following new sub-  
2 sections:

3 “(g) EXEMPTIONS.—

4 “(1) CRITERIA FOR EXEMPTION.—The Admin-  
5 istrator may, as part of a rule promulgated under  
6 subsection (a), or in a separate rule, grant an ex-  
7 emption from a requirement of a subsection (a) rule  
8 for a specific condition of use of a chemical sub-  
9 stance or mixture, if the Administrator finds that—

10 “(A) the specific condition of use is a crit-  
11 ical or essential use for which no technically  
12 and economically feasible safer alternative is  
13 available, taking into consideration hazard and  
14 exposure;

15 “(B) compliance with the requirement, as  
16 applied with respect to the specific condition of  
17 use, would significantly disrupt the national  
18 economy, national security, or critical infra-  
19 structure; or

20 “(C) the specific condition of use of the  
21 chemical substance or mixture, as compared to  
22 reasonably available alternatives, provides a  
23 substantial benefit to health, the environment,  
24 or public safety.

1           “(2) EXEMPTION ANALYSIS AND STATEMENT.—  
2           In proposing an exemption under this subsection,  
3           the Administrator shall analyze the need for the ex-  
4           emption, and shall make public the analysis and a  
5           statement describing how the analysis was taken  
6           into account.

7           “(3) PERIOD OF EXEMPTION.—The Adminis-  
8           trator shall establish, as part of a rule under this  
9           subsection, a time limit on any exemption for a time  
10          to be determined by the Administrator as reasonable  
11          on a case-by-case basis, and, by rule, may extend,  
12          modify, or eliminate an exemption if the Adminis-  
13          trator determines, on the basis of reasonably avail-  
14          able information and after adequate public justifica-  
15          tion, the exemption warrants extension or modifica-  
16          tion or is no longer necessary.

17          “(4) CONDITIONS.—As part of a rule promul-  
18          gated under this subsection, the Administrator shall  
19          include conditions, including reasonable record-  
20          keeping, monitoring, and reporting requirements, to  
21          the extent that the Administrator determines the  
22          conditions are necessary to protect health and the  
23          environment while achieving the purposes of the ex-  
24          emption.

1       “(h) CHEMICALS THAT ARE PERSISTENT, BIO-  
2 ACCUMULATIVE, AND TOXIC.—

3               “(1) EXPEDITED ACTION.—Not later than 3  
4 years after the date of enactment of the Frank R.  
5 Lautenberg Chemical Safety for the 21st Century  
6 Act, the Administrator shall propose rules under  
7 subsection (a) with respect to chemical substances  
8 identified in the 2014 update of the TSCA Work  
9 Plan for Chemical Assessments—

10               “(A) that the Administrator has a reason-  
11 able basis to conclude are toxic and that with  
12 respect to persistence and bioaccumulation  
13 score high for one and either high or moderate  
14 for the other, pursuant to the TSCA Work Plan  
15 Chemicals Methods Document published by the  
16 Administrator in February 2012 (or a successor  
17 scoring system), and are not a metal or a metal  
18 compound, and for which the Administrator has  
19 not completed a Work Plan Problem Formula-  
20 tion, initiated a review under section 5, or en-  
21 tered into a consent agreement under section 4,  
22 prior to the date of enactment of the Frank R.  
23 Lautenberg Chemical Safety for the 21st Cen-  
24 tury Act; and

1           “(B) exposure to which under the condi-  
2           tions of use is likely to the general population  
3           or to a potentially exposed or susceptible sub-  
4           population identified by the Administrator, or  
5           the environment, on the basis of an exposure  
6           and use assessment conducted by the Adminis-  
7           trator.

8           “(2) NO RISK EVALUATION REQUIRED.—The  
9           Administrator shall not be required to conduct risk  
10          evaluations on chemical substances that are subject  
11          to paragraph (1).

12          “(3) FINAL RULE.—Not later than 18 months  
13          after proposing a rule pursuant to paragraph (1),  
14          the Administrator shall promulgate a final rule  
15          under subsection (a).

16          “(4) SELECTING RESTRICTIONS.—In selecting  
17          among prohibitions and other restrictions promul-  
18          gated in a rule under subsection (a) pursuant to  
19          paragraph (1), the Administrator shall address the  
20          risks of injury to health or the environment that the  
21          Administrator determines are presented by the  
22          chemical substance and shall reduce exposure to the  
23          substance to the extent practicable.

24          “(5) RELATIONSHIP TO SUBSECTION (b).—If,  
25          at any time prior to the date that is 90 days after

1 the date of enactment of the Frank R. Lautenberg  
2 Chemical Safety for the 21st Century Act, the Ad-  
3 ministrator makes a designation under subsection  
4 (b)(1)(B)(i), or receives a request under subsection  
5 (b)(4)(C)(ii) that meets the criteria prescribed by  
6 the Administrator in the rule promulgated under  
7 subsection (b)(4)(B), such chemical substance shall  
8 not be subject to this subsection, except that in se-  
9 lecting among prohibitions and other restrictions  
10 promulgated in a rule pursuant to subsection (a),  
11 the Administrator shall both ensure that the chem-  
12 ical substance meets the rulemaking standard under  
13 subsection (a) and reduce exposure to the substance  
14 to the extent practicable.

15 “(i) FINAL AGENCY ACTION.—Under this section  
16 and subject to section 18—

17 “(1) a determination by the Administrator  
18 under subsection (b)(4)(A) that a chemical sub-  
19 stance does not present an unreasonable risk of in-  
20 jury to health or the environment shall be issued by  
21 order and considered to be a final agency action, ef-  
22 fective beginning on the date of issuance of the  
23 order; and

24 “(2) a final rule promulgated under subsection  
25 (a), including the associated determination by the

1 Administrator under subsection (b)(4)(A) that a  
2 chemical substance presents an unreasonable risk of  
3 injury to health or the environment, shall be consid-  
4 ered to be a final agency action, effective beginning  
5 on the date of promulgation of the final rule.

6 “(j) DEFINITION.—For the purposes of this Act, the  
7 term ‘requirement’ as used in this section shall not dis-  
8 place statutory or common law.”.

9 **SEC. 7. IMMINENT HAZARDS.**

10 Section 7 of the Toxic Substances Control Act (15  
11 U.S.C. 2606) is amended—

12 (1) in subsection (b)(1), by inserting “(as iden-  
13 tified by the Administrator without consideration of  
14 costs or other nonrisk factors)” after “from the un-  
15 reasonable risk”; and

16 (2) in subsection (f), by inserting “, without  
17 consideration of costs or other nonrisk factors” after  
18 “widespread injury to health or the environment”.

19 **SEC. 8. REPORTING AND RETENTION OF INFORMATION.**

20 (a) IN GENERAL.—Section 8 of the Toxic Substances  
21 Control Act (15 U.S.C. 2607) is amended—

22 (1) in subsection (a)—

23 (A) in paragraph (2), by striking the mat-  
24 ter that follows subparagraph (G);

1 (B) in paragraph (3), by adding at the end  
2 the following:

3 “(C) Not later than 180 days after the date of enact-  
4 ment of the Frank R. Lautenberg Chemical Safety for the  
5 21st Century Act, and not less frequently than once every  
6 10 years thereafter, the Administrator, after consultation  
7 with the Administrator of the Small Business Administra-  
8 tion, shall—

9 (i) review the adequacy of the standards pre-  
10 scribed under subparagraph (B); and

11 (ii) after providing public notice and an oppor-  
12 tunity for comment, make a determination as to  
13 whether revision of the standards is warranted.”;  
14 and

15 (C) by adding at the end the following:

16 “(4) CONTENTS.—The rules promulgated pur-  
17 suant to paragraph (1)—

18 (A) may impose differing reporting and  
19 recordkeeping requirements on manufacturers  
20 and processors; and

21 (B) shall include the level of detail nec-  
22 essary to be reported, including the manner by  
23 which use and exposure information may be re-  
24 ported.



1           “(5) ADMINISTRATION.—In carrying out this  
2 section, the Administrator shall, to the extent fea-  
3 sible—

4                   “(A) not require reporting which is unnec-  
5 essary or duplicative;

6                   “(B) minimize the cost of compliance with  
7 this section and the rules issued thereunder on  
8 small manufacturers and processors; and

9                   “(C) apply any reporting obligations to  
10 those persons likely to have information rel-  
11 evant to the effective implementation of this  
12 title.

13           “(6) NEGOTIATED RULEMAKING.—(A) The Ad-  
14 ministrator shall enter into a negotiated rulemaking  
15 pursuant to subchapter III of chapter 5 of title 5,  
16 United States Code, to develop and publish, not  
17 later than 3 years after the date of enactment of the  
18 Frank R. Lautenberg Chemical Safety for the 21st  
19 Century Act, a proposed rule providing for limiting  
20 the reporting requirements, under this subsection,  
21 for manufacturers of any inorganic byproducts,  
22 when such byproducts, whether by the byproduct  
23 manufacturer or by any other person, are subse-  
24 quently recycled, reused, or reprocessed.

1           “(B) Not later than 3 and one-half years after  
2 such date of enactment, the Administrator shall pub-  
3 lish a final rule resulting from such negotiated rule-  
4 making.”; and

5           (2) in subsection (b), by adding at the end the  
6 following:

7           “(3) NOMENCLATURE.—

8           “(A) IN GENERAL.—In carrying out para-  
9 graph (1), the Administrator shall—

10           “(i) maintain the use of Class 2 no-  
11 menclature in use on the date of enact-  
12 ment of the Frank R. Lautenberg Chem-  
13 ical Safety for the 21st Century Act;

14           “(ii) maintain the use of the Soap and  
15 Detergent Association Nomenclature Sys-  
16 tem, published in March 1978 by the Ad-  
17 ministrator in section 1 of addendum III  
18 of the document entitled ‘Candidate List of  
19 Chemical Substances’, and further de-  
20 scribed in the appendix A of volume I of  
21 the 1985 edition of the Toxic Substances  
22 Control Act Substances Inventory (EPA  
23 Document No. EPA-560/7-85-002a); and

24           “(iii) treat the individual members of  
25 the categories of chemical substances iden-

1           tified by the Administrator as statutory  
2           mixtures, as defined in Inventory descrip-  
3           tions established by the Administrator, as  
4           being included on the list established under  
5           paragraph (1).

6           “(B) MULTIPLE NOMENCLATURE LIST-  
7           INGS.—If a manufacturer or processor dem-  
8           onstrates to the Administrator that a chemical  
9           substance appears multiple times on the list  
10          published under paragraph (1) under different  
11          CAS numbers, the Administrator may recognize  
12          the multiple listings as a single chemical sub-  
13          stance.

14          “(C) RELATIONSHIP TO SECTION 5.—  
15          Nothing in subparagraph (B), nor any action of  
16          the Administrator pursuant to subparagraph  
17          (B), shall be construed as a basis to conclude  
18          that any chemical substance is not a new chem-  
19          ical substance.

20          “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

21                  “(A) RULES.—

22                          “(i) IN GENERAL.—Not later than 1  
23                          year after the date of enactment of the  
24                          Frank R. Lautenberg Chemical Safety for  
25                          the 21st Century Act, the Administrator,

1 by rule, shall require manufacturers, and  
2 may require processors, subject to the limi-  
3 tations under subsection (a)(5)(A), to no-  
4 tify the Administrator, by not later than  
5 180 days after the date on which the final  
6 rule is published in the Federal Register,  
7 of each chemical substance on the list pub-  
8 lished under paragraph (1) that the manu-  
9 facturer or processor, as applicable, has  
10 manufactured or processed for a non-  
11 exempt commercial purpose during the 10-  
12 year period ending on the day before the  
13 date of enactment of the Frank R. Lauten-  
14 berg Chemical Safety for the 21st Century  
15 Act.

16 “(ii) ACTIVE SUBSTANCES.—The Ad-  
17 ministrator shall designate chemical sub-  
18 stances for which notices are received  
19 under clause (i) to be active substances on  
20 the list published under paragraph (1).

21 “(iii) INACTIVE SUBSTANCES.—The  
22 Administrator shall designate chemical  
23 substances for which no notices are re-  
24 ceived under clause (i) to be inactive sub-

1 stances on the list published under para-  
2 graph (1).

3 “(iv) LIMITATION.—No chemical sub-  
4 stance on the list published under para-  
5 graph (1) shall be removed from such list  
6 by reason of the implementation of this  
7 subparagraph, or be subject to section  
8 5(a)(1)(A)(i) by reason of a change to ac-  
9 tive status under paragraph (5)(B).

10 “(B) CONFIDENTIAL CHEMICAL SUB-  
11 STANCES.—In promulgating a rule under sub-  
12 paragraph (A), the Administrator shall—

13 “(i) maintain the list under paragraph  
14 (1), which shall include a confidential por-  
15 tion and a nonconfidential portion con-  
16 sistent with this section and section 14;

17 “(ii) require any manufacturer or  
18 processor of a chemical substance on the  
19 confidential portion of the list published  
20 under paragraph (1) that seeks to main-  
21 tain an existing claim for protection  
22 against disclosure of the specific chemical  
23 identity of the chemical substance as con-  
24 fidential pursuant to section 14 to submit

1 a notice under subparagraph (A) that in-  
2 cludes such request;

3 “(iii) require the substantiation of  
4 those claims pursuant to section 14 and in  
5 accordance with the review plan described  
6 in subparagraph (C); and

7 “(iv) move any active chemical sub-  
8 stance for which no request was received to  
9 maintain an existing claim for protection  
10 against disclosure of the specific chemical  
11 identity of the chemical substance as con-  
12 fidential from the confidential portion of  
13 the list published under paragraph (1) to  
14 the nonconfidential portion of that list.

15 “(C) REVIEW PLAN.—Not later than 1  
16 year after the date on which the Administrator  
17 compiles the initial list of active substances pur-  
18 suant to subparagraph (A), the Administrator  
19 shall promulgate a rule that establishes a plan  
20 to review all claims to protect the specific chem-  
21 ical identities of chemical substances on the  
22 confidential portion of the list published under  
23 paragraph (1) that are asserted pursuant to  
24 subparagraph (B).

1                   “(D) REQUIREMENTS OF REVIEW PLAN.—

2                   In establishing the review plan under subpara-  
3                   graph (C), the Administrator shall—

4                   “(i) require, at a time specified by the  
5                   Administrator, all manufacturers or proc-  
6                   essors asserting claims under subpara-  
7                   graph (B) to substantiate the claim, in ac-  
8                   cordance with section 14, unless the manu-  
9                   facturer or processor has substantiated the  
10                  claim in a submission made to the Admin-  
11                  istrator during the 5-year period ending on  
12                  the last day of the of the time period speci-  
13                  fied by the Administrator; and

14                  “(ii) in accordance with section 14—

15                   “(I) review each substantiation—

16                   “(aa) submitted pursuant to  
17                   clause (i) to determine if the  
18                   claim qualifies for protection  
19                   from disclosure; and

20                   “(bb) submitted previously  
21                   by a manufacturer or processor  
22                   and relied on in lieu of the sub-  
23                   stantiation required pursuant to  
24                   clause (i), if the substantiation  
25                   has not been previously reviewed

1 by the Administrator, to deter-  
2 mine if the claim warrants pro-  
3 tection from disclosure;

4 “(II) approve, approve in part  
5 and deny in part, or deny each claim;  
6 and

7 “(III) except as provided in this  
8 section and section 14, protect from  
9 disclosure information for which the  
10 Administrator approves such a claim  
11 for a period of 10 years, unless, prior  
12 to the expiration of the period—

13 “(aa) the person notifies the  
14 Administrator that the person is  
15 withdrawing the claim, in which  
16 case the Administrator shall not  
17 protect the information from dis-  
18 closure; or

19 “(bb) the Administrator oth-  
20 erwise becomes aware that the  
21 information does not qualify for  
22 protection from disclosure, in  
23 which case the Administrator  
24 shall take the actions described  
25 in section 14(g)(2).



1                   “(E) TIMELINE FOR COMPLETION OF RE-  
2                   VIEWS.—

3                   “(i) IN GENERAL.—The Administrator  
4                   shall implement the review plan so as to  
5                   complete reviews of all claims specified in  
6                   subparagraph (C) not later than 5 years  
7                   after the date on which the Administrator  
8                   compiles the initial list of active substances  
9                   pursuant to subparagraph (A).

10                   “(ii) CONSIDERATIONS.—

11                   “(I) IN GENERAL.—The Admin-  
12                   istrator may extend the deadline for  
13                   completion of the reviews for not more  
14                   than 2 additional years, after an ade-  
15                   quate public justification, if the Ad-  
16                   ministrator determines that the exten-  
17                   sion is necessary based on the number  
18                   of claims needing review and the  
19                   available resources.

20                   “(II) ANNUAL REVIEW GOAL AND  
21                   RESULTS.—At the beginning of each  
22                   year, the Administrator shall publish  
23                   an annual goal for reviews and the  
24                   number of reviews completed in the  
25                   prior year.

1           “(5) ACTIVE AND INACTIVE SUBSTANCES.—

2           “(A) IN GENERAL.—The Administrator  
3 shall keep designations of active substances and  
4 inactive substances on the list published under  
5 paragraph (1) current.

6           “(B) CHANGE TO ACTIVE STATUS.—

7           “(i) IN GENERAL.—Any person that  
8 intends to manufacture or process for a  
9 nonexempt commercial purpose a chemical  
10 substance that is designated as an inactive  
11 substance shall notify the Administrator  
12 before the date on which the inactive sub-  
13 stance is manufactured or processed.

14           “(ii) CONFIDENTIAL CHEMICAL IDEN-  
15 TITY.—If a person submitting a notice  
16 under clause (i) for an inactive substance  
17 on the confidential portion of the list pub-  
18 lished under paragraph (1) seeks to main-  
19 tain an existing claim for protection  
20 against disclosure of the specific chemical  
21 identity of the inactive substance as con-  
22 fidential, the person shall, consistent with  
23 the requirements of section 14—

24           “(I) in the notice submitted  
25 under clause (i), assert the claim; and

1                   “(II) by not later than 30 days  
2                   after providing the notice under clause  
3                   (i), substantiate the claim.

4                   “(iii) ACTIVE STATUS.—On receiving  
5                   a notification under clause (i), the Admin-  
6                   istrator shall—

7                   “(I) designate the applicable  
8                   chemical substance as an active sub-  
9                   stance;

10                  “(II) pursuant to section 14,  
11                  promptly review any claim and associ-  
12                  ated substantiation submitted pursu-  
13                  ant to clause (ii) for protection  
14                  against disclosure of the specific  
15                  chemical identity of the chemical sub-  
16                  stance and approve, approve in part  
17                  and deny in part, or deny the claim;

18                  “(III) except as provided in this  
19                  section and section 14, protect from  
20                  disclosure the specific chemical iden-  
21                  tity of the chemical substance for  
22                  which the Administrator approves a  
23                  claim under subclause (II) for a pe-  
24                  riod of 10 years, unless, prior to the  
25                  expiration of the period—

1                   “(aa) the person notifies the  
2 Administrator that the person is  
3 withdrawing the claim, in which  
4 case the Administrator shall not  
5 protect the information from dis-  
6 closure; or

7                   “(bb) the Administrator oth-  
8 erwise becomes aware that the  
9 information does not qualify for  
10 protection from disclosure, in  
11 which case the Administrator  
12 shall take the actions described  
13 in section 14(g)(2); and

14                   “(IV) pursuant to section 6(b),  
15 review the priority of the chemical  
16 substance as the Administrator deter-  
17 mines to be necessary.

18                   “(C) CATEGORY STATUS.—The list of inac-  
19 tive substances shall not be considered to be a  
20 category for purposes of section 26(c).

21                   “(6) INTERIM LIST OF ACTIVE SUBSTANCES.—  
22 Prior to the promulgation of the rule required under  
23 paragraph (4)(A), the Administrator shall designate  
24 the chemical substances reported under part 711 of  
25 title 40, Code of Federal Regulations (as in effect on

1 the date of enactment of the Frank R. Lautenberg  
2 Chemical Safety for the 21st Century Act), during  
3 the reporting period that most closely preceded the  
4 date of enactment of the Frank R. Lautenberg  
5 Chemical Safety for the 21st Century Act, as the in-  
6 terim list of active substances for the purposes of  
7 section 6(b).

8 “(7) PUBLIC INFORMATION.—Subject to this  
9 subsection and section 14, the Administrator shall  
10 make available to the public—

11 “(A) each specific chemical identity on the  
12 nonconfidential portion of the list published  
13 under paragraph (1) along with the Administra-  
14 tor’s designation of the chemical substance as  
15 an active or inactive substance;

16 “(B) the unique identifier assigned under  
17 section 14, accession number, generic name,  
18 and, if applicable, premanufacture notice case  
19 number for each chemical substance on the con-  
20 fidential portion of the list published under  
21 paragraph (1) for which a claim of confiden-  
22 tiality was received; and

23 “(C) the specific chemical identity of any  
24 active substance for which—

1                   “(i) a claim for protection against dis-  
2                   closure of the specific chemical identity of  
3                   the active substance was not asserted, as  
4                   required under this subsection or section  
5                   14;

6                   “(ii) all claims for protection against  
7                   disclosure of the specific chemical identity  
8                   of the active substance have been denied  
9                   by the Administrator; or

10                   “(iii) the time period for protection  
11                   against disclosure of the specific chemical  
12                   identity of the active substance has ex-  
13                   pired.

14                   “(8) LIMITATION.—No person may assert a  
15                   new claim under this subsection or section 14 for  
16                   protection from disclosure of a specific chemical  
17                   identity of any active or inactive substance for which  
18                   a notice is received under paragraph (4)(A)(i) or  
19                   (5)(B)(i) that is not on the confidential portion of  
20                   the list published under paragraph (1).

21                   “(9) CERTIFICATION.—Under the rules promul-  
22                   gated under this subsection, manufacturers and  
23                   processors, as applicable, shall be required—

24                   “(A) to certify that each notice or substan-  
25                   tiation the manufacturer or processor submits

1           complies with the requirements of the rule, and  
2           that any confidentiality claims are true and cor-  
3           rect; and

4                   “(B) to retain a record documenting com-  
5           pliance with the rule and supporting confiden-  
6           tiality claims for a period of 5 years beginning  
7           on the last day of the submission period.”.

8           (b) MERCURY INVENTORY.—Section 8(b) of the  
9   Toxic Substances Control Act (15 U.S.C. 2607(b)) (as  
10   amended by subsection (a)) is further amended by adding  
11   at the end the following:

12                   “(10) MERCURY.—

13                           “(A) DEFINITION OF MERCURY.—In this  
14           paragraph, notwithstanding section 3(2)(B), the  
15           term ‘mercury’ means—

16                                   “(i) elemental mercury; and

17                                   “(ii) a mercury compound.

18                           “(B) PUBLICATION.—Not later than April  
19           1, 2017, and every 3 years thereafter, the Ad-  
20           ministrators shall carry out and publish in the  
21           Federal Register an inventory of mercury sup-  
22           ply, use, and trade in the United States.

23                           “(C) PROCESS.—In carrying out the inven-  
24           tory under subparagraph (B), the Adminis-  
25           trator shall—

1           “(i) identify any manufacturing proc-  
2           esses or products that intentionally add  
3           mercury; and

4           “(ii) recommend actions, including  
5           proposed revisions of Federal law or regu-  
6           lations, to achieve further reductions in  
7           mercury use.

8           “(D) REPORTING.—

9           “(i) IN GENERAL.—To assist in the  
10          preparation of the inventory under sub-  
11          paragraph (B), any person who manufac-  
12          tures mercury or mercury-added products  
13          or otherwise intentionally uses mercury in  
14          a manufacturing process shall make peri-  
15          odic reports to the Administrator, at such  
16          time and including such information as the  
17          Administrator shall determine by rule pro-  
18          mulgated not later than 2 years after the  
19          date of enactment of this paragraph.

20          “(ii) COORDINATION.—To avoid dupli-  
21          cation, the Administrator shall coordinate  
22          the reporting under this subparagraph  
23          with the Interstate Mercury Education and  
24          Reduction Clearinghouse.



1                   “(iii) EXEMPTION.—Clause (i) shall  
2                   not apply to a person engaged in the gen-  
3                   eration, handling, or management of mer-  
4                   cury-containing waste, unless that person  
5                   manufactures or recovers mercury in the  
6                   management of that waste.”.

7 **SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.**

8           Section 9 of the Toxic Substances Control Act (15  
9 U.S.C. 2608) is amended—

10                   (1) in subsection (a)—

11                           (A) in paragraph (1)—

12                                   (i) by striking “has reasonable basis  
13                                   to conclude” and inserting “determines”;  
14                                   and

15                                   (ii) by inserting “, without consider-  
16                                   ation of costs or other nonrisk factors, in-  
17                                   cluding an unreasonable risk to a poten-  
18                                   tially exposed or susceptible subpopulation  
19                                   identified as relevant by the Administrator,  
20                                   under the conditions of use,” after “or the  
21                                   environment”;

22                           (B) in paragraph (2)—

23                                   (i) in subparagraph (A), by inserting  
24                                   “, within the time period specified by the

1 Administrator in the report,” after “issues  
2 an order”; and

3 (ii) in subparagraph (B), by inserting  
4 “responds within the time period specified  
5 by the Administrator in the report and”  
6 before “initiates, within 90”;

7 (C) by redesignating paragraph (3) as  
8 paragraph (6); and

9 (D) by inserting after paragraph (2) the  
10 following:

11 “(3) The Administrator shall take the actions de-  
12 scribed in paragraph (4) if the Administrator makes a re-  
13 port under paragraph (1) with respect to a chemical sub-  
14 stance or mixture and the agency to which the report was  
15 made does not—

16 “(A) issue the order described in paragraph  
17 (2)(A) within the time period specified by the Ad-  
18 ministrator in the report; or

19 “(B)(i) respond under paragraph (1) within the  
20 timeframe specified by the Administrator in the re-  
21 port; and

22 “(ii) initiate action within 90 days of publica-  
23 tion in the Federal Register of the response de-  
24 scribed in clause (i).

1 “(4) If an agency to which a report is submitted  
2 under paragraph (1) does not take the actions described  
3 in subparagraph (A) or (B) of paragraph (3), the Admin-  
4 istrator shall—

5 “(A) initiate or complete appropriate action  
6 under section 6; or

7 “(B) take any action authorized or required  
8 under section 7, as applicable.

9 “(5) This subsection shall not relieve the Adminis-  
10 trator of any obligation to take any appropriate action  
11 under section 6(a) or 7 to address risks from the manufac-  
12 ture, processing, distribution in commerce, use, or disposal  
13 of a chemical substance or mixture, or any combination  
14 of those activities, that are not identified in a report issued  
15 by the Administrator under paragraph (1).”;

16 (2) in subsection (b)—

17 (A) by striking “The Administrator shall  
18 coordinate” and inserting “(1) The Adminis-  
19 trator shall coordinate”; and

20 (B) by adding at the end the following:

21 “(2) In making a determination under paragraph (1)  
22 that it is in the public interest for the Administrator to  
23 take an action under this title with respect to a chemical  
24 substance or mixture rather than under another law ad-  
25 ministered in whole or in part by the Administrator, the

1 Administrator shall consider, based on information rea-  
2 sonably available to the Administrator, all relevant aspects  
3 of the risk described in paragraph (1) and a comparison  
4 of the estimated costs and efficiencies of the action to be  
5 taken under this title and an action to be taken under  
6 such other law to protect against such risk.”; and

7 (3) by adding at the end the following:

8 “(e) EXPOSURE INFORMATION.—In addition to the  
9 requirements of subsection (a), if the Administrator ob-  
10 tains information related to exposures or releases of a  
11 chemical substance or mixture that may be prevented or  
12 reduced under another Federal law, including a law not  
13 administered by the Administrator, the Administrator  
14 shall make such information available to the relevant Fed-  
15 eral agency or office of the Environmental Protection  
16 Agency.”.

17 **SEC. 10. EXPORTS OF ELEMENTAL MERCURY.**

18 (a) PROHIBITION ON EXPORT OF CERTAIN MERCURY  
19 COMPOUNDS.—Section 12(c) of the Toxic Substances  
20 Control Act (15 U.S.C. 2611(c)) is amended—

21 (1) in the subsection heading, by inserting  
22 “AND MERCURY COMPOUNDS” after “MERCURY”;  
23 and

24 (2) by adding at the end the following:

1           “(7) PROHIBITION ON EXPORT OF CERTAIN  
2           MERCURY COMPOUNDS.—

3           “(A) IN GENERAL.—Effective January 1,  
4           2020, the export of the following mercury com-  
5           pounds is prohibited:

6                   “(i) Mercury (I) chloride or calomel.

7                   “(ii) Mercury (II) oxide.

8                   “(iii) Mercury (II) sulfate.

9                   “(iv) Mercury (II) nitrate.

10                   “(v) Cinnabar or mercury sulphide.

11                   “(vi) Any mercury compound that the  
12           Administrator adds to the list published  
13           under subparagraph (B) by rule, on deter-  
14           mining that exporting that mercury com-  
15           pound for the purpose of regenerating ele-  
16           mental mercury is technically feasible.

17           “(B) PUBLICATION.—Not later than 90  
18           days after the date of enactment of the Frank  
19           R. Lautenberg Chemical Safety for the 21st  
20           Century Act, and as appropriate thereafter, the  
21           Administrator shall publish in the Federal Reg-  
22           ister a list of the mercury compounds that are  
23           prohibited from export under this paragraph.

1           “(C) PETITION.—Any person may petition  
2 the Administrator to add a mercury compound  
3 to the list published under subparagraph (B).

4           “(D) ENVIRONMENTALLY SOUND DIS-  
5 POSAL.—This paragraph does not prohibit the  
6 export of mercury compounds on the list pub-  
7 lished under subparagraph (B) to member  
8 countries of the Organization for Economic Co-  
9 operation and Development for environmentally  
10 sound disposal, on the condition that no mer-  
11 cury or mercury compounds so exported are to  
12 be recovered, recycled, or reclaimed for use, or  
13 directly reused, after such export.

14           “(E) REPORT.—Not later than 5 years  
15 after the date of enactment of the Frank R.  
16 Lautenberg Chemical Safety for the 21st Cen-  
17 tury Act, the Administrator shall evaluate any  
18 exports of mercury compounds on the list pub-  
19 lished under subparagraph (B) for disposal that  
20 occurred after such date of enactment and shall  
21 submit to Congress a report that—

22                   “(i) describes volumes and sources of  
23 mercury compounds on the list published  
24 under subparagraph (B) exported for dis-  
25 posal;

1                   “(ii) identifies receiving countries of  
2                   such exports;

3                   “(iii) describes methods of disposal  
4                   used after such export;

5                   “(iv) identifies issues, if any, pre-  
6                   sented by the export of mercury com-  
7                   pounds on the list published under sub-  
8                   paragraph (B);

9                   “(v) includes an evaluation of man-  
10                  agement options in the United States for  
11                  mercury compounds on the list published  
12                  under subparagraph (B), if any, that are  
13                  commercially available and comparable in  
14                  cost and efficacy to methods being utilized  
15                  in such receiving countries; and

16                  “(vi) makes a recommendation re-  
17                  garding whether Congress should further  
18                  limit or prohibit the export of mercury  
19                  compounds on the list published under  
20                  subparagraph (B) for disposal.

21                  “(F) EFFECT ON OTHER LAW.—Nothing  
22                  in this paragraph shall be construed to affect  
23                  the authority of the Administrator under the  
24                  Solid Waste Disposal Act (42 U.S.C. 6901 et  
25                  seq.).”.

1 (b) TEMPORARY GENERATOR ACCUMULATION.—Sec-  
2 tion 5 of the Mercury Export Ban Act of 2008 (42 U.S.C.  
3 6939f) is amended—

4 (1) in subsection (a)(2), by striking “2013” and  
5 inserting “2019”;

6 (2) in subsection (b)—

7 (A) in paragraph (1)—

8 (i) by redesignating subparagraphs  
9 (A), (B), and (C), as clauses (i), (ii), and  
10 (iii), respectively and indenting appro-  
11 priately;

12 (ii) in the first sentence, by striking  
13 “After consultation” and inserting the fol-  
14 lowing:

15 “(A) ASSESSMENT AND COLLECTION.—  
16 After consultation”;

17 (iii) in the second sentence, by strik-  
18 ing “The amount of such fees” and insert-  
19 ing the following:

20 “(B) AMOUNT.—The amount of the fees  
21 described in subparagraph (A)”;

22 (iv) in subparagraph (B) (as so des-  
23 ignated)—

24 (I) in clause (i) (as so redesign-  
25 ated), by striking “publically avail-



1           able not later than October 1, 2012”  
2           and inserting “publicly available not  
3           later than October 1, 2018”;

4                   (II) in clause (ii) (as so redesign-  
5                   nated), by striking “and”;

6                   (III) in clause (iii) (as so redesign-  
7                   nated), by striking the period at the  
8                   end and inserting “, subject to clause  
9                   (iv); and”; and

10                   (IV) by adding at the end the fol-  
11                   lowing:

12                   “(iv) for generators temporarily accu-  
13                   mulating elemental mercury in a facility  
14                   subject to subparagraphs (B) and (D)(iv)  
15                   of subsection (g)(2) if the facility des-  
16                   ignated in subsection (a) is not operational  
17                   by January 1, 2019, shall be adjusted to  
18                   subtract the cost of the temporary accumu-  
19                   lation during the period in which the facil-  
20                   ity designated under subsection (a) is not  
21                   operational.”; and

22                   (v) by adding at the end the following:

23                   “(C) CONVEYANCE OF TITLE AND PERMIT-  
24                   TING.—If the facility designated in subsection

1 (a) is not operational by January 1, 2020, the  
2 Secretary—

3 “(i) shall immediately accept the con-  
4 veyance of title to all elemental mercury  
5 that has accumulated in facilities in ac-  
6 cordance with subsection (g)(2)(D), before  
7 January 1, 2020, and deliver the accumu-  
8 lated mercury to the facility designated  
9 under subsection (a) on the date on which  
10 the facility becomes operational;

11 “(ii) shall pay any applicable Federal  
12 permitting costs, including the costs for  
13 permits issued under section 3005(c) of  
14 the Solid Waste Disposal Act (42 U.S.C.  
15 6925(c)); and

16 “(iii) shall store, or pay the cost of  
17 storage of, until the time at which a facil-  
18 ity designated in subsection (a) is oper-  
19 ational, accumulated mercury to which the  
20 Secretary has title under this subpara-  
21 graph in a facility that has been issued a  
22 permit under section 3005(c) of the Solid  
23 Waste Disposal Act (42 U.S.C. 6925(c)).”;  
24 and

1 (B) in paragraph (2), in the first sentence,  
2 by striking “paragraph (1)(C)” and inserting  
3 “paragraph (1)(B)(iii)”; and  
4 (3) in subsection (g)(2)—

5 (A) in the undesignated material at the  
6 end, by striking “This subparagraph” and in-  
7 serting the following:

8 “(C) Subparagraph (B)”;

9 (B) in subparagraph (C) (as designated by  
10 subparagraph (A)), by inserting “of that sub-  
11 paragraph” before the period at the end; and

12 (C) by adding at the end the following:

13 “(D) A generator producing elemental  
14 mercury incidentally from the beneficiation or  
15 processing of ore or related pollution control ac-  
16 tivities may accumulate the mercury produced  
17 onsite that is destined for a facility designated  
18 by the Secretary under subsection (a) for more  
19 than 90 days without a permit issued under  
20 section 3005(e) of the Solid Waste Disposal Act  
21 (42 U.S.C. 6925(e)), and shall not be subject to  
22 the storage prohibition of section 3004(j) of  
23 that Act (42 U.S.C. 6924(j)), if—

24 “(i) the Secretary is unable to accept  
25 the mercury at a facility designated by the

1 Secretary under subsection (a) for reasons  
2 beyond the control of the generator;

3 “(ii) the generator certifies in writing  
4 to the Secretary that the generator will  
5 ship the mercury to a designated facility  
6 when the Secretary is able to accept the  
7 mercury;

8 “(iii) the generator certifies in writing  
9 to the Secretary that the generator is stor-  
10 ing only mercury the generator has pro-  
11 duced or recovered onsite and will not sell,  
12 or otherwise place into commerce, the mer-  
13 cury; and

14 “(iv) the generator has obtained an  
15 identification number under section 262.12  
16 of title 40, Code of Federal Regulations,  
17 and complies with the requirements de-  
18 scribed in paragraphs (1) through (4) of  
19 section 262.34(a) of title 40, Code of Fed-  
20 eral Regulations (as in effect on the date  
21 of enactment of this subparagraph).

22 “(E) MANAGEMENT STANDARDS FOR TEM-  
23 PORARY STORAGE.—Not later than January 1,  
24 2017, the Secretary, after consultation with the  
25 Administrator of the Environmental Protection

1 Agency and State agencies in affected States,  
2 shall develop and make available guidance that  
3 establishes procedures and standards for the  
4 management and short-term storage of ele-  
5 mental mercury at a generator covered under  
6 subparagraph (D), including requirements to  
7 ensure appropriate use of flasks or other suit-  
8 able containers. Such procedures and standards  
9 shall be protective of health and the environ-  
10 ment and shall ensure that the elemental mer-  
11 cury is stored in a safe, secure, and effective  
12 manner. A generator may accumulate mercury  
13 in accordance with subparagraph (D) imme-  
14 diately upon enactment of this subparagraph,  
15 and notwithstanding that guidance called for by  
16 this paragraph has not been developed or made  
17 available.”.

18 (c) INTERIM STATUS.—Section 5(d)(1) of the Mer-  
19 cury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is  
20 amended—

21 (1) in the fourth sentence, by striking “in exist-  
22 ence on or before January 1, 2013,”; and

23 (2) in the last sentence, by striking “January  
24 1, 2015” and inserting “January 1, 2020”.

1 **SEC. 11. CONFIDENTIAL INFORMATION.**

2 Section 14 of the Toxic Substances Control Act (15  
3 U.S.C. 2613) is amended to read as follows:

4 **“SEC. 14. CONFIDENTIAL INFORMATION.**

5 “(a) IN GENERAL.—Except as provided in this sec-  
6 tion, the Administrator shall not disclose information that  
7 is exempt from disclosure pursuant to subsection (a) of  
8 section 552 of title 5, United States Code, by reason of  
9 subsection (b)(4) of that section—

10 “(1) that is reported to, or otherwise obtained  
11 by, the Administrator under this Act; and

12 “(2) for which the requirements of subsection  
13 (c) are met.

14 In any proceeding under section 552(a) of title 5, United  
15 States Code, to obtain information the disclosure of which  
16 has been denied because of the provisions of this sub-  
17 section, the Administrator may not rely on section  
18 552(b)(3) of such title to sustain the Administrator’s ac-  
19 tion.

20 “(b) INFORMATION NOT PROTECTED FROM DISCLO-  
21 SURE.—

22 “(1) MIXED CONFIDENTIAL AND NONCON-  
23 FIDENTIAL INFORMATION.—Information that is pro-  
24 tected from disclosure under this section, and which  
25 is mixed with information that is not protected from  
26 disclosure under this section, does not lose its pro-

1       tection from disclosure notwithstanding that it is  
2       mixed with information that is not protected from  
3       disclosure.

4               “(2) INFORMATION FROM HEALTH AND SAFETY  
5       STUDIES.—Subsection (a) does not prohibit the dis-  
6       closure of—

7               “(A) any health and safety study which is  
8       submitted under this Act with respect to—

9               “(i) any chemical substance or mix-  
10       ture which, on the date on which such  
11       study is to be disclosed has been offered  
12       for commercial distribution; or

13               “(ii) any chemical substance or mix-  
14       ture for which testing is required under  
15       section 4 or for which notification is re-  
16       quired under section 5; and

17               “(B) any information reported to, or other-  
18       wise obtained by, the Administrator from a  
19       health and safety study which relates to a  
20       chemical substance or mixture described in  
21       clause (i) or (ii) of subparagraph (A).

22       This paragraph does not authorize the disclosure of  
23       any information, including formulas (including mo-  
24       lecular structures) of a chemical substance or mix-  
25       ture, that discloses processes used in the manufac-

1 turing or processing of a chemical substance or mix-  
2 ture or, in the case of a mixture, the portion of the  
3 mixture comprised by any of the chemical substances  
4 in the mixture.

5 “(3) OTHER INFORMATION NOT PROTECTED  
6 FROM DISCLOSURE.—Subsection (a) does not pro-  
7 hibit the disclosure of—

8 “(A) any general information describing  
9 the manufacturing volumes, expressed as spe-  
10 cific aggregated volumes or, if the Adminis-  
11 trator determines that disclosure of specific ag-  
12 gregated volumes would reveal confidential in-  
13 formation, expressed in ranges; or

14 “(B) a general description of a process  
15 used in the manufacture or processing and in-  
16 dustrial, commercial, or consumer functions and  
17 uses of a chemical substance, mixture, or article  
18 containing a chemical substance or mixture, in-  
19 cluding information specific to an industry or  
20 industry sector that customarily would be  
21 shared with the general public or within an in-  
22 dustry or industry sector.

23 “(4) BANS AND PHASE-OUTS.—

24 “(A) IN GENERAL.—If the Administrator  
25 promulgates a rule pursuant to section 6(a)



1           that establishes a ban or phase-out of a chem-  
2           ical substance or mixture, the protection from  
3           disclosure of any information under this section  
4           with respect to the chemical substance or mix-  
5           ture shall be presumed to no longer apply, sub-  
6           ject to subsection (g)(1)(E) and subparagraphs  
7           (B) and (C) of this paragraph.

8           “(B) LIMITATIONS.—

9           “(i) CRITICAL USE.—In the case of a  
10          chemical substance or mixture for which a  
11          specific condition of use is subject to an  
12          exemption pursuant to section 6(g), if the  
13          Administrator establishes a ban or phase-  
14          out described in subparagraph (A) with re-  
15          spect to the chemical substance or mixture,  
16          the presumption against protection under  
17          such subparagraph shall only apply to in-  
18          formation that relates solely to any condi-  
19          tions of use of the chemical substance or  
20          mixture to which the exemption does not  
21          apply.

22          “(ii) EXPORT.—In the case of a chem-  
23          ical substance or mixture for which there is  
24          manufacture, processing, or distribution in  
25          commerce that meets the conditions of sec-

1                   tion 12(a)(1), if the Administrator estab-  
2                   lishes a ban or phase-out described in sub-  
3                   paragraph (A) with respect to the chemical  
4                   substance or mixture, the presumption  
5                   against protection under such subpara-  
6                   graph shall only apply to information that  
7                   relates solely to any other manufacture,  
8                   processing, or distribution in commerce of  
9                   the chemical substance or mixture for the  
10                  conditions of use subject to the ban or  
11                  phase-out, unless the Administrator makes  
12                  the determination in section 12(a)(2).

13                  “(iii) SPECIFIC CONDITIONS OF  
14                  USE.—In the case of a chemical substance  
15                  or mixture for which the Administrator es-  
16                  tablishes a ban or phase-out described in  
17                  subparagraph (A) with respect to a specific  
18                  condition of use of the chemical substance  
19                  or mixture, the presumption against pro-  
20                  tection under such subparagraph shall only  
21                  apply to information that relates solely to  
22                  the condition of use of the chemical sub-  
23                  stance or mixture for which the ban or  
24                  phase-out is established.

25                  “(C) REQUEST FOR NONDISCLOSURE.—

1           “(i) IN GENERAL.—A manufacturer  
2           or processor of a chemical substance or  
3           mixture subject to a ban or phase-out de-  
4           scribed in this paragraph may submit to  
5           the Administrator, within 30 days of re-  
6           ceiving a notification under subsection  
7           (g)(2)(A), a request, including documenta-  
8           tion supporting such request, that some or  
9           all of the information to which the notice  
10          applies should not be disclosed or that its  
11          disclosure should be delayed, and the Ad-  
12          ministrator shall review the request under  
13          subsection (g)(1)(E).

14          “(ii) EFFECT OF NO REQUEST OR DE-  
15          NIAL.—If no request for nondisclosure or  
16          delay is submitted to the Administrator  
17          under this subparagraph, or the Adminis-  
18          trator denies such a request under sub-  
19          section (g)(1)(A), the information shall not  
20          be protected from disclosure under this  
21          section.

22          “(5) CERTAIN REQUESTS.—If a request is made  
23          to the Administrator under section 552(a) of title 5,  
24          United States Code, for information reported to or  
25          otherwise obtained by the Administrator under this

1 Act that is not protected from disclosure under this  
2 subsection, the Administrator may not deny the re-  
3 quest on the basis of section 552(b)(4) of title 5,  
4 United States Code.

5 “(c) REQUIREMENTS FOR CONFIDENTIALITY  
6 CLAIMS.—

7 “(1) ASSERTION OF CLAIMS.—

8 “(A) IN GENERAL.—A person seeking to  
9 protect from disclosure any information that  
10 person submits under this Act (including infor-  
11 mation described in paragraph (2)) shall assert  
12 to the Administrator a claim for protection  
13 from disclosure concurrent with submission of  
14 the information, in accordance with such rules  
15 regarding a claim for protection from disclosure  
16 as the Administrator has promulgated or may  
17 promulgate pursuant to this title.

18 “(B) INCLUSION.—An assertion of a claim  
19 under subparagraph (A) shall include a state-  
20 ment that the person has—

21 “(i) taken reasonable measures to pro-  
22 tect the confidentiality of the information;

23 “(ii) determined that the information  
24 is not required to be disclosed or otherwise

1           made available to the public under any  
2           other Federal law;

3           “(iii) a reasonable basis to conclude  
4           that disclosure of the information is likely  
5           to cause substantial harm to the competi-  
6           tive position of the person; and

7           “(iv) a reasonable basis to believe that  
8           the information is not readily discoverable  
9           through reverse engineering.

10          “(C)   ADDITIONAL   REQUIREMENTS   FOR  
11          CLAIMS   REGARDING   CHEMICAL   IDENTITY   IN-  
12          FORMATION.—In the case of a claim under sub-  
13          paragraph (A) for protection from disclosure of  
14          a specific chemical identity, the claim shall in-  
15          clude a structurally descriptive generic name for  
16          the chemical substance that the Administrator  
17          may disclose to the public, subject to the condi-  
18          tion that such generic name shall—

19                 “(i) be consistent with guidance devel-  
20                 oped by the Administrator under para-  
21                 graph (4)(A); and

22                 “(ii) describe the chemical structure  
23                 of the chemical substance as specifically as  
24                 practicable while protecting those features  
25                 of the chemical structure—

1                   “(I) that are claimed as confiden-  
2                   tial; and

3                   “(II) the disclosure of which  
4                   would be likely to cause substantial  
5                   harm to the competitive position of  
6                   the person.

7                   “(2) INFORMATION GENERALLY NOT SUBJECT  
8                   TO SUBSTANTIATION REQUIREMENTS.—Subject to  
9                   subsection (f), the following information shall not be  
10                  subject to substantiation requirements under para-  
11                  graph (3):

12                  “(A) Specific information describing the  
13                  processes used in manufacture or processing of  
14                  a chemical substance, mixture, or article.

15                  “(B) Marketing and sales information.

16                  “(C) Information identifying a supplier or  
17                  customer.

18                  “(D) In the case of a mixture, details of  
19                  the full composition of the mixture and the re-  
20                  spective percentages of constituents.

21                  “(E) Specific information regarding the  
22                  use, function, or application of a chemical sub-  
23                  stance or mixture in a process, mixture, or arti-  
24                  cle.

1           “(F) Specific production or import volumes  
2 of the manufacturer or processor.

3           “(G) Prior to the date on which a chemical  
4 substance is first offered for commercial dis-  
5 tribution, the specific chemical identity of the  
6 chemical substance, including the chemical  
7 name, molecular formula, Chemical Abstracts  
8 Service number, and other information that  
9 would identify the specific chemical substance,  
10 if the specific chemical identity was claimed as  
11 confidential at the time it was submitted in a  
12 notice under section 5.

13           “(3) SUBSTANTIATION REQUIREMENTS.—Ex-  
14 cept as provided in paragraph (2), a person assert-  
15 ing a claim to protect information from disclosure  
16 under this section shall substantiate the claim, in ac-  
17 cordance with such rules as the Administrator has  
18 promulgated or may promulgate pursuant to this  
19 section.

20           “(4) GUIDANCE.—The Administrator shall de-  
21 velop guidance regarding—

22           “(A) the determination of structurally de-  
23 scriptive generic names, in the case of claims  
24 for the protection from disclosure of specific  
25 chemical identity; and

1           “(B) the content and form of the state-  
2           ments of need and agreements required under  
3           paragraphs (4), (5), and (6) of subsection (d).

4           “(5) CERTIFICATION.—An authorized official of  
5           a person described in paragraph (1)(A) shall certify  
6           that the statement required to assert a claim sub-  
7           mitted pursuant to paragraph (1)(B), and any infor-  
8           mation required to substantiate a claim submitted  
9           pursuant to paragraph (3), are true and correct.

10          “(d) EXCEPTIONS TO PROTECTION FROM DISCLO-  
11          SURE.—Information described in subsection (a)—

12                 “(1) shall be disclosed to an officer or employee  
13                 of the United States—

14                         “(A) in connection with the official duties  
15                         of that person under any Federal law for the  
16                         protection of health or the environment; or

17                         “(B) for a specific Federal law enforce-  
18                         ment purpose;

19                 “(2) shall be disclosed to a contractor of the  
20                 United States and employees of that contractor—

21                         “(A) if, in the opinion of the Adminis-  
22                         trator, the disclosure is necessary for the satis-  
23                         factory performance by the contractor of a con-  
24                         tract with the United States for the perform-  
25                         ance of work in connection with this Act; and



1           “(B) subject to such conditions as the Ad-  
2           ministrator may specify;

3           “(3) shall be disclosed if the Administrator de-  
4           termines that disclosure is necessary to protect  
5           health or the environment against an unreasonable  
6           risk of injury to health or the environment, without  
7           consideration of costs or other nonrisk factors, in-  
8           cluding an unreasonable risk to a potentially exposed  
9           or susceptible subpopulation identified as relevant by  
10          the Administrator under the conditions of use;

11          “(4) shall be disclosed to a State, political sub-  
12          division of a State, or tribal government, on written  
13          request, for the purpose of administration or en-  
14          forcement of a law, if such entity has 1 or more ap-  
15          plicable agreements with the Administrator that are  
16          consistent with the guidance developed under sub-  
17          section (c)(4)(B) and ensure that the entity will take  
18          appropriate measures, and has adequate authority,  
19          to maintain the confidentiality of the information in  
20          accordance with procedures comparable to the proce-  
21          dures used by the Administrator to safeguard the in-  
22          formation;

23          “(5) shall be disclosed to a health or environ-  
24          mental professional employed by a Federal or State  
25          agency or tribal government or a treating physician

1 or nurse in a nonemergency situation if such person  
2 provides a written statement of need and agrees to  
3 sign a written confidentiality agreement with the Ad-  
4 ministrator, subject to the conditions that—

5 “(A) the statement of need and confiden-  
6 tiality agreement are consistent with the guid-  
7 ance developed under subsection (c)(4)(B);

8 “(B) the statement of need shall be a  
9 statement that the person has a reasonable  
10 basis to suspect that—

11 “(i) the information is necessary for,  
12 or will assist in—

13 “(I) the diagnosis or treatment of  
14 1 or more individuals; or

15 “(II) responding to an environ-  
16 mental release or exposure; and

17 “(ii) 1 or more individuals being diag-  
18 nosed or treated have been exposed to the  
19 chemical substance or mixture concerned,  
20 or an environmental release of or exposure  
21 to the chemical substance or mixture con-  
22 cerned has occurred; and

23 “(C) the person will not use the informa-  
24 tion for any purpose other than the health or  
25 environmental needs asserted in the statement

1           of need, except as otherwise may be authorized  
2           by the terms of the agreement or by the person  
3           who has a claim under this section with respect  
4           to the information, except that nothing in this  
5           title prohibits the disclosure of any such infor-  
6           mation through discovery, subpoena, other  
7           court order, or any other judicial process other-  
8           wise allowed under applicable Federal or State  
9           law;

10           “(6) shall be disclosed in the event of an emer-  
11           gency to a treating or responding physician, nurse,  
12           agent of a poison control center, public health or en-  
13           vironmental official of a State, political subdivision  
14           of a State, or tribal government, or first responder  
15           (including any individual duly authorized by a Fed-  
16           eral agency, State, political subdivision of a State, or  
17           tribal government who is trained in urgent medical  
18           care or other emergency procedures, including a po-  
19           lice officer, firefighter, or emergency medical techni-  
20           cian) if such person requests the information, sub-  
21           ject to the conditions that such person shall—

22                   “(A) have a reasonable basis to suspect  
23           that—

24                           “(i) a medical, public health, or envi-  
25                           ronmental emergency exists;

1           “(ii) the information is necessary for,  
2           or will assist in, emergency or first-aid di-  
3           agnosis or treatment; or

4           “(iii) 1 or more individuals being di-  
5           agnosed or treated have likely been ex-  
6           posed to the chemical substance or mixture  
7           concerned, or a serious environmental re-  
8           lease of or exposure to the chemical sub-  
9           stance or mixture concerned has occurred;  
10          and

11          “(B) if requested by a person who has a  
12          claim with respect to the information under this  
13          section—

14                 “(i) provide a written statement of  
15                 need and agree to sign a confidentiality  
16                 agreement, as described in paragraph (5);  
17                 and

18                 “(ii) submit to the Administrator such  
19                 statement of need and confidentiality  
20                 agreement as soon as practicable, but not  
21                 necessarily before the information is dis-  
22                 closed;

23          “(7) may be disclosed if the Administrator de-  
24          termines that disclosure is relevant in a proceeding  
25          under this Act, subject to the condition that the dis-

1 closure is made in such a manner as to preserve con-  
2 fidentiality to the extent practicable without impair-  
3 ing the proceeding; and

4 “(8) shall be disclosed if the information is re-  
5 quired to be made public under any other provision  
6 of Federal law.

7 “(e) DURATION OF PROTECTION FROM DISCLO-  
8 SURE.—

9 “(1) IN GENERAL.—Subject to paragraph (2),  
10 subsection (f)(3), and section 8(b), the Adminis-  
11 trator shall protect from disclosure information de-  
12 scribed in subsection (a)—

13 “(A) in the case of information described  
14 in subsection (c)(2), until such time as—

15 “(i) the person that asserted the claim  
16 notifies the Administrator that the person  
17 is withdrawing the claim, in which case the  
18 information shall not be protected from  
19 disclosure under this section; or

20 “(ii) the Administrator becomes aware  
21 that the information does not qualify for  
22 protection from disclosure under this sec-  
23 tion, in which case the Administrator shall  
24 take any actions required under sub-  
25 sections (f) and (g); and

1           “(B) in the case of information other than  
2 information described in subsection (c)(2)—

3           “(i) for a period of 10 years from the  
4 date on which the person asserts the claim  
5 with respect to the information submitted  
6 to the Administrator; or

7           “(ii) if applicable before the expiration  
8 of such 10-year period, until such time  
9 as—

10           “(I) the person that asserted the  
11 claim notifies the Administrator that  
12 the person is withdrawing the claim,  
13 in which case the information shall  
14 not be protected from disclosure  
15 under this section; or

16           “(II) the Administrator becomes  
17 aware that the information does not  
18 qualify for protection from disclosure  
19 under this section, in which case the  
20 Administrator shall take any actions  
21 required under subsections (f) and  
22 (g).

23           “(2) EXTENSIONS.—

24           “(A) IN GENERAL.—In the case of infor-  
25 mation other than information described in sub-

1 section (c)(2), not later than the date that is 60  
2 days before the expiration of the period de-  
3 scribed in paragraph (1)(B)(i), the Adminis-  
4 trator shall provide to the person that asserted  
5 the claim a notice of the impending expiration  
6 of the period.

7 “(B) REQUEST.—

8 “(i) IN GENERAL.—Not later than the  
9 date that is 30 days before the expiration  
10 of the period described in paragraph  
11 (1)(B)(i), a person reasserting the relevant  
12 claim shall submit to the Administrator a  
13 request for extension substantiating, in ac-  
14 cordance with subsection (c)(3), the need  
15 to extend the period.

16 “(ii) ACTION BY ADMINISTRATOR.—  
17 Not later than the date of expiration of the  
18 period described in paragraph (1)(B)(i),  
19 the Administrator shall, in accordance with  
20 subsection (g)(1)—

21 “(I) review the request submitted  
22 under clause (i);

23 “(II) make a determination re-  
24 garding whether the claim for which  
25 the request was submitted continues

1 to meet the relevant requirements of  
2 this section; and

3 “(III)(aa) grant an extension of  
4 10 years; or

5 “(bb) deny the request.

6 “(C) NO LIMIT ON NUMBER OF EXTEN-  
7 SIONS.—There shall be no limit on the number  
8 of extensions granted under this paragraph, if  
9 the Administrator determines that the relevant  
10 request under subparagraph (B)(i)—

11 “(i) establishes the need to extend the  
12 period; and

13 “(ii) meets the requirements estab-  
14 lished by the Administrator.

15 “(f) REVIEW AND RESUBSTANTIATION.—

16 “(1) DISCRETION OF ADMINISTRATOR.—The  
17 Administrator may require any person that has  
18 claimed protection for information from disclosure  
19 under this section, whether before, on, or after the  
20 date of enactment of the Frank R. Lautenberg  
21 Chemical Safety for the 21st Century Act, to re-  
22 assert and substantiate or resubstantiate the claim  
23 in accordance with this section—



1           “(A) after the chemical substance is des-  
2           signed as a high-priority substance under sec-  
3           tion 6(b);

4           “(B) for any chemical substance des-  
5           signed as an active substance under section  
6           8(b)(5)(B)(iii); or

7           “(C) if the Administrator determines that  
8           disclosure of certain information currently pro-  
9           tected from disclosure would be important to  
10          assist the Administrator in conducting risk  
11          evaluations or promulgating rules under section  
12          6.

13          “(2) REVIEW REQUIRED.—The Administrator  
14          shall review a claim for protection of information  
15          from disclosure under this section and require any  
16          person that has claimed protection for that informa-  
17          tion, whether before, on, or after the date of enact-  
18          ment of the Frank R. Lautenberg Chemical Safety  
19          for the 21st Century Act, to reassert and substan-  
20          tiate or resubstantiate the claim in accordance with  
21          this section—

22                 “(A) as necessary to determine whether  
23                 the information qualifies for an exemption from  
24                 disclosure in connection with a request for in-

1           formation received by the Administrator under  
2           section 552 of title 5, United States Code;

3           “(B) if the Administrator has a reasonable  
4           basis to believe that the information does not  
5           qualify for protection from disclosure under this  
6           section; or

7           “(C) for any chemical substance the Ad-  
8           ministrator determines under section 6(b)(4)(A)  
9           presents an unreasonable risk of injury to  
10          health or the environment.

11          “(3) PERIOD OF PROTECTION.—If the Adminis-  
12          trator requires a person to reassert and substantiate  
13          or resubstantiate a claim under this subsection, and  
14          determines that the claim continues to meet the rel-  
15          evant requirements of this section, the Administrator  
16          shall protect the information subject to the claim  
17          from disclosure for a period of 10 years from the  
18          date of such determination, subject to any subse-  
19          quent requirement by the Administrator under this  
20          subsection.

21          “(g) DUTIES OF ADMINISTRATOR.—

22                  “(1) DETERMINATION.—

23                          “(A) IN GENERAL.—Except for claims re-  
24                          garding information described in subsection  
25                          (c)(2), the Administrator shall, subject to sub-

1 paragraph (C), not later than 90 days after the  
2 receipt of a claim under subsection (e), and not  
3 later than 30 days after the receipt of a request  
4 for extension of a claim under subsection (e) or  
5 a request under subsection (b)(4)(C), review  
6 and approve, approve in part and deny in part,  
7 or deny the claim or request.

8 “(B) REASONS FOR DENIAL.—If the Ad-  
9 ministrator denies or denies in part a claim or  
10 request under subparagraph (A) the Adminis-  
11 trator shall provide to the person that asserted  
12 the claim or submitted the request a written  
13 statement of the reasons for the denial or de-  
14 nial in part of the claim or request.

15 “(C) SUBSETS.—The Administrator  
16 shall—

17 “(i) except with respect to information  
18 described in subsection (c)(2)(G), review  
19 all claims or requests under this section for  
20 the protection from disclosure of the spe-  
21 cific chemical identity of a chemical sub-  
22 stance; and

23 “(ii) review a representative subset,  
24 comprising at least 25 percent, of all other

1           claims or requests for protection from dis-  
2           closure under this section.

3           “(D) EFFECT OF FAILURE TO ACT.—The  
4           failure of the Administrator to make a decision  
5           regarding a claim or request for protection from  
6           disclosure or extension under this section shall  
7           not have the effect of denying or eliminating a  
8           claim or request for protection from disclosure.

9           “(E) DETERMINATION OF REQUESTS  
10          UNDER SUBSECTION (b)(4)(C).—With respect to  
11          a request submitted under subsection (b)(4)(C),  
12          the Administrator shall, with the objective of  
13          ensuring that information relevant to the pro-  
14          tection of health and the environment is dis-  
15          closed to the extent practicable, determine  
16          whether the documentation provided by the per-  
17          son rebuts what shall be the presumption of the  
18          Administrator that the public interest in the  
19          disclosure of the information outweighs the  
20          public or proprietary interest in maintaining the  
21          protection for all or a portion of the informa-  
22          tion that the person has requested not be dis-  
23          closed or for which disclosure be delayed.

24          “(2) NOTIFICATION.—

1           “(A) IN GENERAL.—Except as provided in  
2           subparagraph (B) and subsections (b), (d), and  
3           (e), if the Administrator denies or denies in  
4           part a claim or request under paragraph (1),  
5           concludes, in accordance with this section, that  
6           the information does not qualify for protection  
7           from disclosure, intends to disclose information  
8           pursuant to subsection (d), or promulgates a  
9           rule under section 6(a) establishing a ban or  
10          phase-out with respect to a chemical substance  
11          or mixture, the Administrator shall notify, in  
12          writing, the person that asserted the claim or  
13          submitted the request of the intent of the Ad-  
14          ministrator to disclose the information or not  
15          protect the information from disclosure under  
16          this section. The notice shall be furnished by  
17          certified mail (return receipt requested), by per-  
18          sonal delivery, or by other means that allows  
19          verification of the fact and date of receipt.

20          “(B) DISCLOSURE OF INFORMATION.—Ex-  
21          cept as provided in subparagraph (C), the Ad-  
22          ministrator shall not disclose information under  
23          this subsection until the date that is 30 days  
24          after the date on which the person that asserted

1 the claim or submitted the request receives noti-  
2 fication under subparagraph (A).

3 “(C) EXCEPTIONS.—

4 “(i) FIFTEEN DAY NOTIFICATION.—

5 For information the Administrator intends  
6 to disclose under subsections (d)(3), (d)(4),  
7 (d)(5), and (j), the Administrator shall not  
8 disclose the information until the date that  
9 is 15 days after the date on which the per-  
10 son that asserted the claim or submitted  
11 the request receives notification under sub-  
12 paragraph (A), except that, with respect to  
13 information to be disclosed under sub-  
14 section (d)(3), if the Administrator deter-  
15 mines that disclosure of the information is  
16 necessary to protect against an imminent  
17 and substantial harm to health or the envi-  
18 ronment, no prior notification shall be nec-  
19 essary.

20 “(ii) NOTIFICATION AS SOON AS PRAC-

21 TICABLE.—For information the Adminis-  
22 trator intends to disclose under paragraph  
23 (6) of subsection (d), the Administrator  
24 shall notify the person that submitted the  
25 information that the information has been

1 disclosed as soon as practicable after dis-  
2 closure of the information.

3 “(iii) NO NOTIFICATION REQUIRED.—  
4 Notification shall not be required—

5 “(I) for the disclosure of infor-  
6 mation under paragraphs (1), (2), (7),  
7 or (8) of subsection (d); or

8 “(II) for the disclosure of infor-  
9 mation for which—

10 “(aa) the Administrator has  
11 provided to the person that as-  
12 serted the claim a notice under  
13 subsection (e)(2)(A); and

14 “(bb) such person does not  
15 submit to the Administrator a re-  
16 quest under subsection (e)(2)(B)  
17 on or before the deadline estab-  
18 lished in subsection (e)(2)(B)(i).

19 “(D) APPEALS.—

20 “(i) ACTION TO RESTRAIN DISCLO-  
21 SURE.—If a person receives a notification  
22 under this paragraph and believes the in-  
23 formation is protected from disclosure  
24 under this section, before the date on  
25 which the information is to be disclosed

1                   pursuant to subparagraph (B) or (C) the  
2                   person may bring an action to restrain dis-  
3                   closure of the information in—

4                   “(I) the United States district  
5                   court of the district in which the com-  
6                   plainant resides or has the principal  
7                   place of business; or

8                   “(II) the United States District  
9                   Court for the District of Columbia.

10                  “(ii) NO DISCLOSURE.—

11                  “(I) IN GENERAL.—Subject to  
12                  subsection (d), the Administrator shall  
13                  not disclose information that is the  
14                  subject of an appeal under this para-  
15                  graph before the date on which the  
16                  applicable court rules on an action  
17                  under clause (i).

18                  “(II) EXCEPTION.—Subclause (I)  
19                  shall not apply to disclosure of infor-  
20                  mation described under subsections  
21                  (d)(4) and (j).

22                  “(3) REQUEST AND NOTIFICATION SYSTEM.—  
23                  The Administrator, in consultation with the Director  
24                  of the Centers for Disease Control and Prevention,  
25                  shall develop a request and notification system that,



1 in a format and language that is readily accessible  
2 and understandable, allows for expedient and swift  
3 access to information disclosed pursuant to para-  
4 graphs (5) and (6) of subsection (d).

5 “(4) UNIQUE IDENTIFIER.—The Administrator  
6 shall—

7 “(A)(i) develop a system to assign a  
8 unique identifier to each specific chemical iden-  
9 tity for which the Administrator approves a re-  
10 quest for protection from disclosure, which shall  
11 not be either the specific chemical identity or a  
12 structurally descriptive generic term; and

13 “(ii) apply that identifier consistently to all  
14 information relevant to the applicable chemical  
15 substance;

16 “(B) annually publish and update a list of  
17 chemical substances, referred to by their unique  
18 identifiers, for which claims to protect the spe-  
19 cific chemical identity from disclosure have been  
20 approved, including the expiration date for each  
21 such claim;

22 “(C) ensure that any nonconfidential infor-  
23 mation received by the Administrator with re-  
24 spect to a chemical substance included on the  
25 list published under subparagraph (B) while the

1 specific chemical identity of the chemical sub-  
2 stance is protected from disclosure under this  
3 section identifies the chemical substance using  
4 the unique identifier; and

5 “(D) for each claim for protection of a spe-  
6 cific chemical identity that has been denied by  
7 the Administrator or expired, or that has been  
8 withdrawn by the person who asserted the  
9 claim, and for which the Administrator has  
10 used a unique identifier assigned under this  
11 paragraph to protect the specific chemical iden-  
12 tity in information that the Administrator has  
13 made public, clearly link the specific chemical  
14 identity to the unique identifier in such infor-  
15 mation to the extent practicable.

16 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-  
17 SURE.—

18 “(1) INDIVIDUALS SUBJECT TO PENALTY.—

19 “(A) IN GENERAL.—Subject to subpara-  
20 graph (C) and paragraph (2), an individual de-  
21 scribed in subparagraph (B) shall be fined  
22 under title 18, United States Code, or impris-  
23 oned for not more than 1 year, or both.

1           “(B) DESCRIPTION.—An individual re-  
2           ferred to in subparagraph (A) is an individual  
3           who—

4                   “(i) pursuant to this section, obtained  
5                   possession of, or has access to, information  
6                   protected from disclosure under this sec-  
7                   tion; and

8                   “(ii) knowing that the information is  
9                   protected from disclosure under this sec-  
10                  tion, willfully discloses the information in  
11                  any manner to any person not entitled to  
12                  receive that information.

13           “(C) EXCEPTION.—This paragraph shall  
14           not apply to any medical professional (including  
15           an emergency medical technician or other first  
16           responder) who discloses any information ob-  
17           tained under paragraph (5) or (6) of subsection  
18           (d) to a patient treated by the medical profes-  
19           sional, or to a person authorized to make med-  
20           ical or health care decisions on behalf of such  
21           a patient, as needed for the diagnosis or treat-  
22           ment of the patient.

23           “(2) OTHER LAWS.—Section 1905 of title 18,  
24           United States Code, shall not apply with respect to  
25           the publishing, divulging, disclosure, or making

1 known of, or making available, information reported  
2 to or otherwise obtained by the Administrator under  
3 this Act.

4 “(i) APPLICABILITY.—

5 “(1) IN GENERAL.—Except as otherwise pro-  
6 vided in this section, section 8, or any other applica-  
7 ble Federal law, the Administrator shall have no au-  
8 thority—

9 “(A) to require the substantiation or re-  
10 substantiation of a claim for the protection  
11 from disclosure of information reported to or  
12 otherwise obtained by the Administrator under  
13 this Act prior to the date of enactment of the  
14 Frank R. Lautenberg Chemical Safety for the  
15 21st Century Act; or

16 “(B) to impose substantiation or re-  
17 substantiation requirements, with respect to the  
18 protection of information described in sub-  
19 section (a), under this Act that are more exten-  
20 sive than those required under this section.

21 “(2) ACTIONS PRIOR TO PROMULGATION OF  
22 RULES.—Nothing in this Act prevents the Adminis-  
23 trator from reviewing, requiring substantiation or re-  
24 substantiation of, or approving, approving in part, or  
25 denying any claim for the protection from disclosure

1 of information before the effective date of such rules  
2 applicable to those claims as the Administrator may  
3 promulgate after the date of enactment of the Frank  
4 R. Lautenberg Chemical Safety for the 21st Century  
5 Act.

6 “(j) ACCESS BY CONGRESS.—Notwithstanding any  
7 limitation contained in this section or any other provision  
8 of law, all information reported to or otherwise obtained  
9 by the Administrator (or any representative of the Admin-  
10 istrator) under this Act shall be made available, upon writ-  
11 ten request of any duly authorized committee of the Con-  
12 gress, to such committee.”.

13 **SEC. 12. PENALTIES.**

14 Section 16 of the Toxic Substances Control Act (15  
15 U.S.C. 2615) is amended—

16 (1) in subsection (a)(1), by striking “\$25,000”  
17 and inserting “\$37,500”; and

18 (2) in subsection (b)—

19 (A) by striking “Any person” and inserting  
20 the following:

21 “(1) IN GENERAL.—Any person”;

22 (B) by striking “\$25,000” and inserting  
23 “\$50,000”; and

24 (C) by adding at the end the following:

1           “(2) IMMINENT DANGER OF DEATH OR SERIOUS  
2           BODILY INJURY.—

3           “(A) IN GENERAL.—Any person who  
4           knowingly and willfully violates any provision of  
5           section 15 or 409, and who knows at the time  
6           of the violation that the violation places an indi-  
7           vidual in imminent danger of death or serious  
8           bodily injury, shall be subject on conviction to  
9           a fine of not more than \$250,000, or imprison-  
10          ment for not more than 15 years, or both.

11          “(B) ORGANIZATIONS.—Notwithstanding  
12          the penalties described in subparagraph (A), an  
13          organization that commits a knowing violation  
14          described in subparagraph (A) shall be subject  
15          on conviction to a fine of not more than  
16          \$1,000,000 for each violation.

17          “(C) INCORPORATION OF CORRESPONDING  
18          PROVISIONS.—Subparagraphs (B) through (F)  
19          of section 113(c)(5) of the Clean Air Act (42  
20          U.S.C. 7413(c)(5)(B)–(F)) shall apply to the  
21          prosecution of a violation under this para-  
22          graph.”.

23   **SEC. 13. STATE-FEDERAL RELATIONSHIP.**

24          Section 18 of the Toxic Substances Control Act (15  
25   U.S.C. 2617) is amended—

1 (1) by amending subsection (a) to read as fol-  
2 lows:

3 “(a) IN GENERAL.—

4 “(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-  
5 cept as otherwise provided in subsections (c), (d),  
6 (e), (f), and (g), and subject to paragraph (2), no  
7 State or political subdivision of a State may estab-  
8 lish or continue to enforce any of the following:

9 “(A) DEVELOPMENT OF INFORMATION.—A  
10 statute or administrative action to require the  
11 development of information about a chemical  
12 substance or category of chemical substances  
13 that is reasonably likely to produce the same in-  
14 formation required under section 4, 5, or 6 in—

15 “(i) a rule promulgated by the Admin-  
16 istrator;

17 “(ii) a consent agreement entered into  
18 by the Administrator; or

19 “(iii) an order issued by the Adminis-  
20 trator.

21 “(B) CHEMICAL SUBSTANCES FOUND NOT  
22 TO PRESENT AN UNREASONABLE RISK OR RE-  
23 STRICTED.—A statute, criminal penalty, or ad-  
24 ministrative action to prohibit or otherwise re-  
25 strict the manufacture, processing, or distribu-

1           tion in commerce or use of a chemical sub-  
2           stance—

3                   “(i) for which the determination de-  
4                   scribed in section 6(i)(1) is made, con-  
5                   sistent with the scope of the risk evalua-  
6                   tion under section (6)(b)(4)(D); or

7                   “(ii) for which a final rule is promul-  
8                   gated under section 6(a), after the effective  
9                   date of the rule issued under section 6(a)  
10                  for the chemical substance, consistent with  
11                  the scope of the risk evaluation under sec-  
12                  tion (6)(b)(4)(D).

13                  “(C) SIGNIFICANT NEW USE.—A statute or  
14                  administrative action requiring the notification  
15                  of a use of a chemical substance that the Ad-  
16                  ministrator has specified as a significant new  
17                  use and for which the Administrator has re-  
18                  quired notification pursuant to a rule promul-  
19                  gated under section 5.

20                  “(2) EFFECTIVE DATE OF PREEMPTION.—  
21                  Under this subsection, Federal preemption of stat-  
22                  utes and administrative actions applicable to specific  
23                  chemical substances shall not occur until the effec-  
24                  tive date of the applicable action described in para-  
25                  graph (1) taken by the Administrator.”;



1           (2) by amending subsection (b) to read as fol-  
2           lows:

3           “(b) NEW STATUTES, CRIMINAL PENALTIES, OR AD-  
4           MINISTRATIVE ACTIONS CREATING PROHIBITIONS OR  
5           OTHER RESTRICTIONS.—

6           “(1) IN GENERAL.—Except as provided in sub-  
7           sections (c), (d), (e), (f), and (g), beginning on the  
8           date on which the Administrator defines the scope of  
9           a risk evaluation for a chemical substance under sec-  
10          tion 6(b)(4)(D) and ending on the date on which the  
11          deadline established pursuant to section 6(b)(4)(G)  
12          for completion of the risk evaluation expires, or on  
13          the date on which the Administrator publishes the  
14          risk evaluation under section 6(b)(4)(C), whichever  
15          is earlier, no State or political subdivision of a State  
16          may establish a statute, criminal penalty, or admin-  
17          istrative action prohibiting or otherwise restricting  
18          the manufacture, processing, distribution in com-  
19          merce, or use of such chemical substance that is a  
20          high-priority substance designated under  
21          6(b)(1)(B)(i), such chemical substance that has been  
22          identified under section 6(b)(2)(A) (except for the  
23          first 10 chemical substances so identified), or such  
24          chemical substance that has been selected for risk  
25          evaluation under section 6(b)(4)(E)(iv)(II).

1           “(2) EFFECT OF SUBSECTION.—This sub-  
2           section does not restrict the authority of a State or  
3           political subdivision of a State to continue to enforce  
4           any statute enacted, or administrative action taken,  
5           prior to the date on which the Administrator defines  
6           and publishes the scope of a risk evaluation under  
7           section 6(b)(4)(D).”; and

8           (3) by adding at the end the following:

9           “(c) SCOPE OF PREEMPTION.—Federal preemption  
10          under subsections (a) and (b) of statutes, criminal pen-  
11          alties, and administrative actions applicable to specific  
12          chemical substances shall apply only to—

13           “(1) with respect to subsection (a)(1)(A), the  
14          chemical substances or category of chemical sub-  
15          stances subject to a rule, order, or consent agree-  
16          ment under section 4;

17           “(2) with respect to subsections (a)(1)(B) and  
18          (b), the hazards, exposures, risks, and uses or condi-  
19          tions of use of such chemical substances consistent  
20          with the scope of the risk evaluation under  
21          6(b)(4)(D); or

22           “(3) with respect to subsection (a)(1)(C), the  
23          uses of such chemical substances that the Adminis-  
24          trator has specified as significant new uses and for

1 which the Administrator has required notification  
2 pursuant to a rule promulgated under section 5.

3 “(d) EXCEPTIONS.—

4 “(1) NO PREEMPTION OF STATUTES AND AD-  
5 MINISTRATIVE ACTIONS.—

6 “(A) IN GENERAL.—Nothing in this Act,  
7 nor any amendment made by the Frank R.  
8 Lautenberg Chemical Safety for the 21st Cen-  
9 tury Act, nor any rule, standard of perform-  
10 ance, risk evaluation, or scientific assessment  
11 implemented pursuant to this Act, shall affect  
12 the right of a State or a political subdivision of  
13 a State to adopt or enforce any rule, standard  
14 of performance, risk evaluation, scientific as-  
15 sessment, or any other protection for public  
16 health or the environment that—

17 “(i) is adopted or authorized under  
18 the authority of any other Federal law or  
19 adopted to satisfy or obtain authorization  
20 or approval under any other Federal law;

21 “(ii) implements a reporting, moni-  
22 toring, or other information obligation for  
23 the chemical substance not otherwise re-  
24 quired by the Administrator under this Act  
25 or required under any other Federal law;

1           “(iii) is adopted pursuant to authority  
2           under a law of the State or political sub-  
3           division of the State related to water qual-  
4           ity, air quality, or waste treatment or dis-  
5           posal, except to the extent that the ac-  
6           tion—

7                       “(I) imposes a restriction on the  
8                       manufacture, processing, distribution  
9                       in commerce, or use of a chemical  
10                      substance; and

11                     “(II)(aa) addresses the same haz-  
12                     ards and exposures, with respect to  
13                     the same conditions of use as are in-  
14                     cluded in the scope of the risk evalua-  
15                     tion published pursuant to section  
16                     6(b)(4)(D), but is inconsistent with  
17                     the action of the Administrator; or

18                     “(bb) would cause a violation of  
19                     the applicable action by the Adminis-  
20                     trator under section 5 or 6; or

21                     “(iv) subject to subparagraph (B), is  
22                     identical to a requirement prescribed by  
23                     the Administrator.

24                     “(B) IDENTICAL REQUIREMENTS.—

1                   “(i) IN GENERAL.—The penalties and  
2                   other sanctions applicable under a law of a  
3                   State or political subdivision of a State in  
4                   the event of noncompliance with the iden-  
5                   tical requirement shall be no more strin-  
6                   gent than the penalties and other sanctions  
7                   available to the Administrator under sec-  
8                   tion 16 of this Act.

9                   “(ii) PENALTIES.—In the case of an  
10                  identical requirement—

11                   “(I) a State or political subdivi-  
12                  sion of a State may not assess a pen-  
13                  alty for a specific violation for which  
14                  the Administrator has assessed an  
15                  adequate penalty under section 16;  
16                  and

17                   “(II) if a State or political sub-  
18                  division of a State has assessed a pen-  
19                  alty for a specific violation, the Ad-  
20                  ministrator may not assess a penalty  
21                  for that violation in an amount that  
22                  would cause the total of the penalties  
23                  assessed for the violation by the State  
24                  or political subdivision of a State and  
25                  the Administrator combined to exceed

1                   the maximum amount that may be as-  
2                   sessed for that violation by the Ad-  
3                   ministrator under section 16.

4                   “(2) APPLICABILITY TO CERTAIN RULES OR OR-  
5                   DERS.—

6                   “(A) PRIOR RULES AND ORDERS.—Noth-  
7                   ing in this section shall be construed as modi-  
8                   fying the preemptive effect under this section,  
9                   as in effect on the day before the effective date  
10                  of the Frank R. Lautenberg Chemical Safety  
11                  for the 21st Century Act, of any rule or order  
12                  promulgated or issued under this Act prior to  
13                  that effective date.

14                  “(B) CERTAIN CHEMICAL SUBSTANCES  
15                  AND MIXTURES.—With respect to a chemical  
16                  substance or mixture for which any rule or  
17                  order was promulgated or issued under section  
18                  6 prior to the effective date of the Frank R.  
19                  Lautenberg Chemical Safety for the 21st Cen-  
20                  tury Act with respect to manufacturing, proc-  
21                  essing, distribution in commerce, use, or dis-  
22                  posal of the chemical substance or mixture,  
23                  nothing in this section shall be construed as  
24                  modifying the preemptive effect of this section  
25                  as in effect prior to the enactment of the Frank

1 R. Lautenberg Chemical Safety for the 21st  
2 Century Act of any rule or order that is pro-  
3 mulgated or issued with respect to such chem-  
4 ical substance or mixture under section 6 after  
5 that effective date, unless the latter rule or  
6 order is with respect to a chemical substance or  
7 mixture containing a chemical substance and  
8 follows a designation of that chemical substance  
9 as a high-priority substance under section  
10 6(b)(1)(B)(i), the identification of that chemical  
11 substance under section 6(b)(2)(A), or the se-  
12 lection of that chemical substance for risk eval-  
13 uation under section 6(b)(4)(E)(iv)(II).

14 “(e) PRESERVATION OF CERTAIN LAWS.—

15 “(1) IN GENERAL.—Nothing in this Act, sub-  
16 ject to subsection (g) of this section, shall—

17 “(A) be construed to preempt or otherwise  
18 affect the authority of a State or political sub-  
19 division of a State to continue to enforce any  
20 action taken or requirement imposed or require-  
21 ment enacted relating to a specific chemical  
22 substance before April 22, 2016, under the au-  
23 thority of a law of the State or political subdivi-  
24 sion of the State that prohibits or otherwise re-  
25 stricts manufacturing, processing, distribution

1 in commerce, use, or disposal of a chemical sub-  
2 stance; or

3 “(B) be construed to preempt or otherwise  
4 affect any action taken pursuant to a State law  
5 that was in effect on August 31, 2003.

6 “(2) EFFECT OF SUBSECTION.—This sub-  
7 section does not affect, modify, or alter the relation-  
8 ship between Federal law and laws of a State or po-  
9 litical subdivision of a State pursuant to any other  
10 Federal law.

11 “(f) WAIVERS.—

12 “(1) DISCRETIONARY EXEMPTIONS.—Upon ap-  
13 plication of a State or political subdivision of a  
14 State, the Administrator may, by rule, exempt from  
15 subsection (a), under such conditions as may be pre-  
16 scribed in the rule, a statute, criminal penalty, or  
17 administrative action of that State or political sub-  
18 division of the State that relates to the effects of ex-  
19 posure to a chemical substance under the conditions  
20 of use if the Administrator determines that—

21 “(A) compelling conditions warrant grant-  
22 ing the waiver to protect health or the environ-  
23 ment;

24 “(B) compliance with the proposed require-  
25 ment of the State or political subdivision of the



1 State would not unduly burden interstate com-  
2 merce in the manufacture, processing, distribu-  
3 tion in commerce, or use of a chemical sub-  
4 stance;

5 “(C) compliance with the proposed require-  
6 ment of the State or political subdivision of the  
7 State would not cause a violation of any appli-  
8 cable Federal law, rule, or order; and

9 “(D) in the judgment of the Adminis-  
10 trator, the proposed requirement of the State or  
11 political subdivision of the State is designed to  
12 address a risk of a chemical substance, under  
13 the conditions of use, that was identified—

14 “(i) consistent with the best available  
15 science;

16 “(ii) using supporting studies con-  
17 ducted in accordance with sound and ob-  
18 jective scientific practices; and

19 “(iii) based on the weight of the sci-  
20 entific evidence.

21 “(2) REQUIRED EXEMPTIONS.—Upon applica-  
22 tion of a State or political subdivision of a State, the  
23 Administrator shall exempt from subsection (b) a  
24 statute or administrative action of a State or polit-  
25 ical subdivision of a State that relates to the effects

1 of exposure to a chemical substance under the condi-  
2 tions of use if the Administrator determines that—

3 “(A)(i) compliance with the proposed re-  
4 quirement of the State or political subdivision  
5 of the State would not unduly burden interstate  
6 commerce in the manufacture, processing, dis-  
7 tribution in commerce, or use of a chemical  
8 substance;

9 “(ii) compliance with the proposed require-  
10 ment of the State or political subdivision of the  
11 State would not cause a violation of any appli-  
12 cable Federal law, rule, or order; and

13 “(iii) the State or political subdivision of  
14 the State has a concern about the chemical sub-  
15 stance or use of the chemical substance based  
16 in peer-reviewed science; or

17 “(B) no later than the date that is 18  
18 months after the date on which the Adminis-  
19 trator has initiated the prioritization process for  
20 a chemical substance under the rule promul-  
21 gated pursuant to section 6(b)(1)(A), or the  
22 date on which the Administrator publishes the  
23 scope of the risk evaluation for a chemical sub-  
24 stance under section 6(b)(4)(D), whichever is  
25 sooner, the State or political subdivision of the

1 State has enacted a statute or proposed or fi-  
2 nalized an administrative action intended to  
3 prohibit or otherwise restrict the manufacture,  
4 processing, distribution in commerce, or use of  
5 the chemical substance.

6 “(3) DETERMINATION OF A WAIVER RE-  
7 QUEST.—The duty of the Administrator to grant or  
8 deny a waiver application shall be nondelegable and  
9 shall be exercised—

10 “(A) not later than 180 days after the date  
11 on which an application under paragraph (1) is  
12 submitted; and

13 “(B) not later than 110 days after the  
14 date on which an application under paragraph  
15 (2) is submitted.

16 “(4) FAILURE TO MAKE A DETERMINATION.—  
17 If the Administrator fails to make a determination  
18 under paragraph (3)(B) during the 110-day period  
19 beginning on the date on which an application under  
20 paragraph (2) is submitted, the statute or adminis-  
21 trative action of the State or political subdivision of  
22 the State that was the subject of the application  
23 shall not be considered to be an existing statute or  
24 administrative action for purposes of subsection (b)

1 by reason of the failure of the Administrator to  
2 make a determination.

3 “(5) NOTICE AND COMMENT.—Except in the  
4 case of an application approved under paragraph  
5 (9), the application of a State or political subdivision  
6 of a State under this subsection shall be subject to  
7 public notice and comment.

8 “(6) FINAL AGENCY ACTION.—The decision of  
9 the Administrator on the application of a State or  
10 political subdivision of a State shall be—

11 “(A) considered to be a final agency ac-  
12 tion; and

13 “(B) subject to judicial review.

14 “(7) DURATION OF WAIVERS.—A waiver grant-  
15 ed under paragraph (2) or approved under para-  
16 graph (9) shall remain in effect until such time as  
17 the Administrator publishes the risk evaluation  
18 under section 6(b).

19 “(8) JUDICIAL REVIEW OF WAIVERS.—Not later  
20 than 60 days after the date on which the Adminis-  
21 trator makes a determination on an application of a  
22 State or political subdivision of a State under para-  
23 graph (1) or (2), any person may file a petition for  
24 judicial review in the United States Court of Appeals

1 for the District of Columbia Circuit, which shall  
2 have exclusive jurisdiction over the determination.

3 “(9) APPROVAL.—

4 “(A) AUTOMATIC APPROVAL.—If the Ad-  
5 ministrator fails to meet the deadline estab-  
6 lished under paragraph (3)(B), the application  
7 of a State or political subdivision of a State  
8 under paragraph (2) shall be automatically ap-  
9 proved, effective on the date that is 10 days  
10 after the deadline.

11 “(B) REQUIREMENTS.—Notwithstanding  
12 paragraph (6), approval of a waiver application  
13 under subparagraph (A) for failure to meet the  
14 deadline under paragraph (3)(B) shall not be  
15 considered final agency action or be subject to  
16 judicial review or public notice and comment.

17 “(g) SAVINGS.—

18 “(1) NO PREEMPTION OF COMMON LAW OR  
19 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF  
20 OR CRIMINAL CONDUCT.—

21 “(A) IN GENERAL.—Nothing in this Act,  
22 nor any amendment made by the Frank R.  
23 Lautenberg Chemical Safety for the 21st Cen-  
24 tury Act, nor any standard, rule, requirement,  
25 standard of performance, risk evaluation, or sci-

1           entific assessment implemented pursuant to this  
2           Act, shall be construed to preempt, displace, or  
3           supplant any State or Federal common law  
4           rights or any State or Federal statute creating  
5           a remedy for civil relief, including those for civil  
6           damage, or a penalty for a criminal conduct.

7           “(B) CLARIFICATION OF NO PREEMP-  
8           TION.—Notwithstanding any other provision of  
9           this Act, nothing in this Act, nor any amend-  
10          ments made by the Frank R. Lautenberg  
11          Chemical Safety for the 21st Century Act, shall  
12          preempt or preclude any cause of action for  
13          personal injury, wrongful death, property dam-  
14          age, or other injury based on negligence, strict  
15          liability, products liability, failure to warn, or  
16          any other legal theory of liability under any  
17          State law, maritime law, or Federal common  
18          law or statutory theory.

19          “(2) NO EFFECT ON PRIVATE REMEDIES.—

20          “(A) IN GENERAL.—Nothing in this Act,  
21          nor any amendments made by the Frank R.  
22          Lautenberg Chemical Safety for the 21st Cen-  
23          tury Act, nor any rules, regulations, require-  
24          ments, risk evaluations, scientific assessments,  
25          or orders issued pursuant to this Act shall be

1 interpreted as, in either the plaintiff's or de-  
2 fendant's favor, dispositive in any civil action.

3 “(B) AUTHORITY OF COURTS.—This Act  
4 does not affect the authority of any court to  
5 make a determination in an adjudicatory pro-  
6 ceeding under applicable State or Federal law  
7 with respect to the admission into evidence or  
8 any other use of this Act or rules, regulations,  
9 requirements, standards of performance, risk  
10 evaluations, scientific assessments, or orders  
11 issued pursuant to this Act.”.

12 **SEC. 14. JUDICIAL REVIEW.**

13 Section 19(a) of the Toxic Substances Control Act  
14 (15 U.S.C. 2618(a)) is amended—

15 (1) in paragraph (1), by adding at the end the  
16 following:

17 “(C)(i) Not later than 60 days after the publi-  
18 cation of a designation under section 6(b)(1)(B)(ii)  
19 or (iii), any person may commence a civil action to  
20 challenge the designation.

21 “(ii) The United States Court of Appeals for  
22 the District of Columbia Circuit shall have exclusive  
23 jurisdiction over a civil action filed under this sub-  
24 paragraph.”; and

25 (2) by striking paragraph (3).

1 **SEC. 15. CITIZENS' CIVIL ACTIONS.**

2 Section 20(b) of the Toxic Substances Control Act  
3 (15 U.S.C. 2619(b)) is amended—

4 (1) in paragraph (1)(B), by striking “or” at the  
5 end; and

6 (2) in paragraph (2), by striking the period at  
7 the end and inserting the following: “, except that  
8 no prior notification shall be required in the case of  
9 a civil action brought to compel a decision by the  
10 Administrator pursuant to section 18(f)(3)(B); or

11 “(3) in the case of a civil action brought to  
12 compel a decision by the Administrator pursuant to  
13 section 18(f)(3)(B), after the date that is 60 days  
14 after the deadline specified in section 18(f)(3)(B).”.

15 **SEC. 16. STUDIES.**

16 Section 25 of the Toxic Substances Control Act (15  
17 U.S.C. 2624) is repealed.

18 **SEC. 17. ADMINISTRATION OF THE ACT.**

19 Section 26 of the Toxic Substances Control Act (15  
20 U.S.C. 2625) is amended—

21 (1) in subsection (b)(1)—

22 (A) by striking “of a reasonable fee”;

23 (B) by striking “data under section 4 or 5  
24 to defray the cost of administering this Act”  
25 and inserting “information under section 4 or a  
26 notice or other information to be reviewed by



1 the Administrator under section 5, or who man-  
2 ufactures or processes a chemical substance  
3 that is the subject of a risk evaluation under  
4 section 6(b), of a fee that is sufficient and not  
5 more than reasonably necessary to defray the  
6 cost related to such chemical substance of ad-  
7 ministering sections 4, 5, and 6, and collecting,  
8 processing, reviewing, and providing access to  
9 and protecting from disclosure as appropriate  
10 under section 14 information on chemical sub-  
11 stances under this title, including contractor  
12 costs incurred by the Administrator”;

13 (C) by striking “Such rules shall not pro-  
14 vide for any fee in excess of \$2,500 or, in the  
15 case of a small business concern, any fee in ex-  
16 cess of \$100.”; and

17 (D) by striking “submit the data and the  
18 cost to the Administrator of reviewing such  
19 data” and inserting “pay such fee and the cost  
20 to the Administrator of carrying out the activi-  
21 ties described in this paragraph”;

22 (2) in subsection (b)—

23 (A) in paragraph (2), by striking “para-  
24 graph (1)” and inserting “paragraph (4)”;

25 (B) by adding at the end the following:

1 “(3) FUND.—

2 “(A) ESTABLISHMENT.—There is established in  
3 the Treasury of the United States a fund, to be  
4 known as the TSCA Service Fee Fund (in this para-  
5 graph referred to as the ‘Fund’), consisting of such  
6 amounts as are deposited in the Fund under this  
7 paragraph.

8 “(B) COLLECTION AND DEPOSIT OF FEES.—  
9 Subject to the conditions of subparagraph (C), the  
10 Administrator shall collect the fees described in this  
11 subsection and deposit those fees in the Fund.

12 “(C) USE OF FUNDS BY ADMINISTRATOR.—  
13 Fees authorized under this section shall be collected  
14 and available for obligation only to the extent and in  
15 the amount provided in advance in appropriations  
16 Acts, and shall be available without fiscal year limi-  
17 tation for use in defraying the costs of the activities  
18 described in paragraph (1).

19 “(D) ACCOUNTING AND AUDITING.—

20 “(i) ACCOUNTING.—The Administrator  
21 shall biennially prepare and submit to the Com-  
22 mittee on Environment and Public Works of the  
23 Senate and the Committee on Energy and Com-  
24 merce of the House of Representatives a report  
25 that includes an accounting of the fees paid to

1 the Administrator under this paragraph and  
2 amounts disbursed from the Fund for the pe-  
3 riod covered by the report, as reflected by fi-  
4 nancial statements provided in accordance with  
5 sections 3515 and 3521 of title 31, United  
6 States Code.

7 “(ii) AUDITING.—

8 “(I) IN GENERAL.—For the purpose  
9 of section 3515(c) of title 31, United  
10 States Code, the Fund shall be considered  
11 a component of a covered executive agency.

12 “(II) COMPONENTS OF AUDIT.—The  
13 annual audit required in accordance with  
14 sections 3515 and 3521 of title 31, United  
15 States Code, of the financial statements of  
16 activities carried out using amounts from  
17 the Fund shall include an analysis of—

18 “(aa) the fees collected and  
19 amounts disbursed under this sub-  
20 section;

21 “(bb) the reasonableness of the  
22 fees in place as of the date of the  
23 audit to meet current and projected  
24 costs of administering the provisions

1 of this title for which the fees may be  
2 used; and

3 “(cc) the number of requests for  
4 a risk evaluation made by manufac-  
5 turers under section 6(b)(4)(C)(ii).

6 “(III) FEDERAL RESPONSIBILITY.—  
7 The Inspector General of the Environ-  
8 mental Protection Agency shall conduct  
9 the annual audit described in subclause  
10 (II) and submit to the Administrator a re-  
11 port that describes the findings and any  
12 recommendations of the Inspector General  
13 resulting from the audit.

14 “(4) AMOUNT AND ADJUSTMENT OF FEES; RE-  
15 FUNDS.—In setting fees under this section, the Adminis-  
16 trator shall—

17 “(A) prescribe lower fees for small business  
18 concerns, after consultation with the Administrator  
19 of the Small Business Administration;

20 “(B) set the fees established under paragraph  
21 (1) at levels such that the fees will, in aggregate,  
22 provide a sustainable source of funds to annually de-  
23 fray—

24 “(i) the lower of—

1           “(I) 25 percent of the costs to the Ad-  
2           ministrators of carrying out sections 4, 5,  
3           and 6, and of collecting, processing, re-  
4           viewing, and providing access to and pro-  
5           tecting from disclosure as appropriate  
6           under section 14 information on chemical  
7           substances under this title, other than the  
8           costs to conduct and complete risk evalua-  
9           tions under section 6(b); or

10           “(II) \$25,000,000 (subject to adjust-  
11           ment pursuant to subparagraph (F)); and

12           “(ii) the costs of risk evaluations specified  
13           in subparagraph (D);

14           “(C) reflect an appropriate balance in the as-  
15           sessment of fees between manufacturers and proc-  
16           essors, and allow the payment of fees by consortia  
17           of manufacturers or processors;

18           “(D) notwithstanding subparagraph (B)—

19           “(i) except as provided in clause (ii), for  
20           chemical substances for which the Adminis-  
21           trator has granted a request from a manufac-  
22           turer pursuant to section 6(b)(4)(C)(ii), estab-  
23           lish the fee at a level sufficient to defray the  
24           full costs to the Administrator of conducting  
25           the risk evaluation under section 6(b);

1           “(ii) for chemical substances for which the  
2 Administrator has granted a request from a  
3 manufacturer pursuant to section  
4 6(b)(4)(C)(ii), and which are included in the  
5 2014 update of the TSCA Work Plan for  
6 Chemical Assessments, establish the fee at a  
7 level sufficient to defray 50 percent of the costs  
8 to the Administrator of conducting the risk  
9 evaluation under section 6(b); and

10           “(iii) apply fees collected pursuant to  
11 clauses (i) and (ii) only to defray the costs de-  
12 scribed in those clauses;

13           “(E) prior to the establishment or amendment  
14 of any fees under paragraph (1), consult and meet  
15 with parties potentially subject to the fees or their  
16 representatives, subject to the condition that no obli-  
17 gation under the Federal Advisory Committee Act (5  
18 U.S.C. App.) or subchapter II of chapter 5 of title  
19 5, United States Code, is applicable with respect to  
20 such meetings;

21           “(F) beginning with the fiscal year that is 3  
22 years after the date of enactment of the Frank R.  
23 Lautenberg Chemical Safety for the 21st Century  
24 Act, and every 3 years thereafter, after consultation  
25 with parties potentially subject to the fees and their

1 representatives pursuant to subparagraph (E), in-  
2 crease or decrease the fees established under para-  
3 graph (1) as necessary to adjust for inflation and to  
4 ensure that funds deposited in the Fund are suffi-  
5 cient to defray—

6 “(i) approximately but not more than 25  
7 percent of the costs to the Administrator of car-  
8 rying out sections 4, 5, and 6, and of collecting,  
9 processing, reviewing, and providing access to  
10 and protecting from disclosure as appropriate  
11 under section 14 information on chemical sub-  
12 stances under this title, other than the costs to  
13 conduct and complete risk evaluations requested  
14 under section 6(b)(4)(C)(ii); and

15 “(ii) the costs of risk evaluations specified  
16 in subparagraph (D); and

17 “(G) if a notice submitted under section 5 is  
18 not reviewed or such a notice is withdrawn, refund  
19 the fee or a portion of the fee if no substantial work  
20 was performed on the notice.

21 “(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees  
22 may not be assessed for a fiscal year under this section  
23 unless the amount of appropriations for the Chemical Risk  
24 Review and Reduction program project of the Environ-  
25 mental Protection Agency for the fiscal year (excluding

1 the amount of any fees appropriated for the fiscal year)  
2 are equal to or greater than the amount of appropriations  
3 for that program project for fiscal year 2014.

4 “(6) TERMINATION.—The authority provided by this  
5 subsection shall terminate at the conclusion of the fiscal  
6 year that is 10 years after the date of enactment of the  
7 Frank R. Lautenberg Chemical Safety for the 21st Cen-  
8 tury Act unless otherwise reauthorized or modified by  
9 Congress.”; and

10 (3) by adding at the end the following:

11 “(h) SCIENTIFIC STANDARDS.—In carrying out sec-  
12 tions 4, 5, and 6, to the extent that the Administrator  
13 makes a decision based on science, the Administrator shall  
14 use scientific information, technical procedures, measures,  
15 methods, protocols, methodologies, or models, employed in  
16 a manner consistent with the best available science, and  
17 shall consider as applicable—

18 “(1) the extent to which the scientific informa-  
19 tion, technical procedures, measures, methods, proto-  
20 cols, methodologies, or models employed to generate  
21 the information are reasonable for and consistent  
22 with the intended use of the information;

23 “(2) the extent to which the information is rel-  
24 evant for the Administrator’s use in making a deci-  
25 sion about a chemical substance or mixture;



1           “(3) the degree of clarity and completeness with  
2           which the data, assumptions, methods, quality assur-  
3           ance, and analyses employed to generate the infor-  
4           mation are documented;

5           “(4) the extent to which the variability and un-  
6           certainty in the information, or in the procedures,  
7           measures, methods, protocols, methodologies, or  
8           models, are evaluated and characterized; and

9           “(5) the extent of independent verification or  
10          peer review of the information or of the procedures,  
11          measures, methods, protocols, methodologies, or  
12          models.

13          “(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-  
14          ministrators shall make decisions under sections 4, 5, and  
15          6 based on the weight of the scientific evidence.

16          “(j) AVAILABILITY OF INFORMATION.—Subject to  
17          section 14, the Administrator shall make available to the  
18          public—

19                 “(1) all notices, determinations, findings, rules,  
20                 consent agreements, and orders of the Administrator  
21                 under this title;

22                 “(2) any information required to be provided to  
23                 the Administrator under section 4;

24                 “(3) a nontechnical summary of each risk eval-  
25                 uation conducted under section 6(b);

1           “(4) a list of the studies considered by the Ad-  
2           ministrator in carrying out each such risk evalua-  
3           tion, along with the results of those studies; and

4           “(5) each designation of a chemical substance  
5           under section 6(b), along with an identification of  
6           the information, analysis, and basis used to make  
7           the designations.

8           “(k) REASONABLY AVAILABLE INFORMATION.—In  
9           carrying out sections 4, 5, and 6, the Administrator shall  
10          take into consideration information relating to a chemical  
11          substance or mixture, including hazard and exposure in-  
12          formation, under the conditions of use, that is reasonably  
13          available to the Administrator.

14          “(l) POLICIES, PROCEDURES, AND GUIDANCE.—

15                 “(1) DEVELOPMENT.—Not later than 2 years  
16                 after the date of enactment of the Frank R. Lauten-  
17                 berg Chemical Safety for the 21st Century Act, the  
18                 Administrator shall develop any policies, procedures,  
19                 and guidance the Administrator determines are nec-  
20                 essary to carry out the amendments to this Act  
21                 made by the Frank R. Lautenberg Chemical Safety  
22                 for the 21st Century Act.

23                 “(2) REVIEW.—Not later than 5 years after the  
24                 date of enactment of the Frank R. Lautenberg  
25                 Chemical Safety for the 21st Century Act, and not

1 less frequently than once every 5 years thereafter,  
2 the Administrator shall—

3 “(A) review the adequacy of the policies,  
4 procedures, and guidance developed under para-  
5 graph (1), including with respect to animal,  
6 nonanimal, and epidemiological test methods  
7 and procedures for assessing and determining  
8 risk under this title; and

9 “(B) revise such policies, procedures, and  
10 guidance as the Administrator determines nec-  
11 essary to reflect new scientific developments or  
12 understandings.

13 “(3) TESTING OF CHEMICAL SUBSTANCES AND  
14 MIXTURES.—The policies, procedures, and guidance  
15 developed under paragraph (1) applicable to testing  
16 chemical substances and mixtures shall—

17 “(A) address how and when the exposure  
18 level or exposure potential of a chemical sub-  
19 stance or mixture would factor into decisions to  
20 require new testing, subject to the condition  
21 that the Administrator shall not interpret the  
22 lack of exposure information as a lack of expo-  
23 sure or exposure potential; and

24 “(B) describe the manner in which the Ad-  
25 ministrator will determine that additional infor-

1           mation is necessary to carry out this title, in-  
2           cluding information relating to potentially ex-  
3           posed or susceptible populations.

4           “(4) CHEMICAL SUBSTANCES WITH COMPLETED  
5           RISK ASSESSMENTS.—With respect to a chemical  
6           substance listed in the 2014 update to the TSCA  
7           Work Plan for Chemical Assessments for which the  
8           Administrator has published a completed risk assess-  
9           ment prior to the date of enactment of the Frank  
10          R. Lautenberg Chemical Safety for the 21st Century  
11          Act, the Administrator may publish proposed and  
12          final rules under section 6(a) that are consistent  
13          with the scope of the completed risk assessment for  
14          the chemical substance and consistent with other ap-  
15          plicable requirements of section 6.

16          “(5) GUIDANCE.—Not later than 1 year after  
17          the date of enactment of the Frank R. Lautenberg  
18          Chemical Safety for the 21st Century Act, the Ad-  
19          ministrator shall develop guidance to assist inter-  
20          ested persons in developing and submitting draft  
21          risk evaluations which shall be considered by the Ad-  
22          ministrator. The guidance shall, at a minimum, ad-  
23          dress the quality of the information submitted and  
24          the process to be followed in developing draft risk  
25          evaluations for consideration by the Administrator.

1 “(m) REPORT TO CONGRESS.—

2 “(1) INITIAL REPORT.—Not later than 6  
3 months after the date of enactment of the Frank R.  
4 Lautenberg Chemical Safety for the 21st Century  
5 Act, the Administrator shall submit to the Commit-  
6 tees on Energy and Commerce and Appropriations  
7 of the House of Representatives and the Committees  
8 on Environment and Public Works and Appropria-  
9 tions of the Senate a report containing an estimation  
10 of—

11 “(A) the capacity of the Environmental  
12 Protection Agency to conduct and publish risk  
13 evaluations under section 6(b)(4)(C)(i) and(ii),  
14 and the resources necessary to conduct the min-  
15 imum number of risk evaluations required  
16 under section 6(b)(2);

17 “(B) the capacity of the Environmental  
18 Protection Agency to conduct and publish risk  
19 evaluations under section 6(b)(4)(A)(ii), the  
20 likely demand for such risk evaluations, and the  
21 anticipated schedule for accommodating that  
22 demand;

23 “(C) the capacity of the Environmental  
24 Protection Agency to promulgate rules under  
25 section 6(a) as required based on risk evalua-

1           tions conducted and published under section  
2           6(b); and

3                   “(D) the actual and anticipated efforts of  
4           the Environmental Protection Agency to in-  
5           crease the Agency’s capacity to conduct and  
6           publish risk evaluations under section 6(b).

7                   “(2) SUBSEQUENT REPORTS.—The Adminis-  
8           trator shall update and resubmit the report de-  
9           scribed in paragraph (1) not less frequently than  
10          once every 5 years.

11          “(n) ANNUAL PLAN.—

12                   “(1) IN GENERAL.—The Administrator shall in-  
13          form the public regarding the schedule and the re-  
14          sources necessary for the completion of each risk  
15          evaluation as soon as practicable after initiating the  
16          risk evaluation.

17                   “(2) PUBLICATION OF PLAN.—At the beginning  
18          of each calendar year, the Administrator shall pub-  
19          lish an annual plan that—

20                           “(A) identifies the chemical substances for  
21                           which risk evaluations are expected to be initi-  
22                           ated or completed that year and the resources  
23                           necessary for their completion;

1           “(B) describes the status of each risk eval-  
2           uation that has been initiated but not yet com-  
3           pleted; and

4           “(C) if the schedule for completion of a  
5           risk evaluation has changed, includes an up-  
6           dated schedule for that risk evaluation.

7           “(o) CONSULTATION WITH SCIENCE ADVISORY COM-  
8           MITTEE ON CHEMICALS.—

9           “(1) ESTABLISHMENT.—Not later than 1 year  
10          after the date of enactment of the Frank R. Lauten-  
11          berg Chemical Safety for the 21st Century Act, the  
12          Administrator shall establish an advisory committee,  
13          to be known as the Science Advisory Committee on  
14          Chemicals (referred to in this subsection as the  
15          ‘Committee’).

16          “(2) PURPOSE.—The purpose of the Committee  
17          shall be to provide independent advice and expert  
18          consultation, at the request of the Administrator,  
19          with respect to the scientific and technical aspects of  
20          issues relating to the implementation of this title.

21          “(3) COMPOSITION.—The Committee shall be  
22          composed of representatives of such science, govern-  
23          ment, labor, public health, public interest, animal  
24          protection, industry, and other groups as the Admin-  
25          istrator determines to be advisable, including rep-

1       representatives that have specific scientific expertise in  
2       the relationship of chemical exposures to women,  
3       children, and other potentially exposed or susceptible  
4       subpopulations.

5               “(4) SCHEDULE.—The Administrator shall con-  
6       vene the Committee in accordance with such sched-  
7       ule as the Administrator determines to be appro-  
8       priate, but not less frequently than once every 2  
9       years.

10       “(p) PRIOR ACTIONS.—

11               “(1) RULES, ORDERS, AND EXEMPTIONS.—  
12       Nothing in the Frank R. Lautenberg Chemical Safe-  
13       ty for the 21st Century Act eliminates, modifies, or  
14       withdraws any rule promulgated, order issued, or ex-  
15       emption established pursuant to this Act before the  
16       date of enactment of the Frank R. Lautenberg  
17       Chemical Safety for the 21st Century Act.

18               “(2) PRIOR-INITIATED EVALUATIONS.—Nothing  
19       in this Act prevents the Administrator from initi-  
20       ating a risk evaluation regarding a chemical sub-  
21       stance, or from continuing or completing such risk  
22       evaluation, prior to the effective date of the policies,  
23       procedures, and guidance required to be developed  
24       by the Administrator pursuant to the amendments



1 made by the Frank R. Lautenberg Chemical Safety  
2 for the 21st Century Act.

3 “(3) ACTIONS COMPLETED PRIOR TO COMPLE-  
4 TION OF POLICIES, PROCEDURES, AND GUIDANCE.—  
5 Nothing in this Act requires the Administrator to re-  
6 vise or withdraw a completed risk evaluation, deter-  
7 mination, or rule under this Act solely because the  
8 action was completed prior to the development of a  
9 policy, procedure, or guidance pursuant to the  
10 amendments made by the Frank R. Lautenberg  
11 Chemical Safety for the 21st Century Act.”.

12 **SEC. 18. STATE PROGRAMS.**

13 Section 28 of the Toxic Substances Control Act (15  
14 U.S.C. 2627) is amended by striking subsections (c) and  
15 (d).

16 **SEC. 19. CONFORMING AMENDMENTS.**

17 (a) TABLE OF CONTENTS.—The table of contents in  
18 section 1 of the Toxic Substances Control Act is amend-  
19 ed—

20 (1) by striking the item relating to section 6  
21 and inserting the following:

“Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances  
and mixtures.”;

22 (2) by striking the item relating to section 10  
23 and inserting the following:

“Sec. 10. Research, development, collection, dissemination, and utilization of in-  
formation.”;

1           (3) by striking the item relating to section 14  
2           and inserting the following:

“Sec. 14. Confidential information.”; and

3           (4) by striking the item relating to section 25.

4           (b) SECTION 2.—Section 2(b)(1) of the Toxic Sub-  
5 stances Control Act (15 U.S.C. 2601(b)(1)) is amended  
6 by striking “data” both places it appears and inserting  
7 “information”.

8           (c) SECTION 3.—Section 3 of the Toxic Substances  
9 Control Act (15 U.S.C. 2602) is amended—

10           (1) in paragraph (8) (as redesignated by section  
11 3 of this Act), by striking “data” and inserting “in-  
12 formation”; and

13           (2) in paragraph (15) (as redesignated by sec-  
14 tion 3 of this Act)—

15                   (A) by striking “standards” and inserting  
16 “protocols and methodologies”;

17                   (B) by striking “test data” both places it  
18 appears and inserting “information”; and

19                   (C) by striking “data” each place it ap-  
20 pears and inserting “information”.

21           (d) SECTION 4.—Section 4 of the Toxic Substances  
22 Control Act (15 U.S.C. 2603) is amended—

23           (1) in subsection (b)—

24                   (A) in paragraph (1)—

1 (i) in the paragraph heading, by add-  
2 ing “, ORDER, OR CONSENT AGREEMENT”  
3 at the end; and

4 (ii) by striking “rule” each place it  
5 appears and inserting “rule, order, or con-  
6 sent agreement”;

7 (B) in paragraph (2)(B), by striking  
8 “rules” and inserting “rules, orders, and con-  
9 sent agreements”;

10 (C) in paragraph (3)(A), by striking “rule”  
11 and inserting “rule or order”; and

12 (D) in paragraph (4)—

13 (i) by striking “rule under subsection  
14 (a)” each place it appears and inserting  
15 “rule, order, or consent agreement under  
16 subsection (a)”;

17 (ii) by striking “repeals the rule” each  
18 place it appears and inserting “repeals the  
19 rule or order or modifies the consent  
20 agreement to terminate the requirement”;  
21 and

22 (iii) by striking “repeals the applica-  
23 tion of the rule” and inserting “repeals or  
24 modifies the application of the rule, order,  
25 or consent agreement”;

1 (2) in subsection (c)—

2 (A) in paragraph (1), by striking “rule”  
3 and inserting “rule or order”;

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by striking  
6 “a rule under subsection (a) or for which  
7 data is being developed pursuant to such a  
8 rule” and inserting “a rule, order, or con-  
9 sent agreement under subsection (a) or for  
10 which information is being developed pur-  
11 suant to such a rule, order, or consent  
12 agreement”;

13 (ii) in subparagraph (B), by striking  
14 “such rule or which is being developed pur-  
15 suant to such rule” and inserting “such  
16 rule, order, or consent agreement or which  
17 is being developed pursuant to such rule,  
18 order, or consent agreement”; and

19 (iii) in the matter following subpara-  
20 graph (B), by striking “the rule” and in-  
21 serting “the rule or order”;

22 (C) in paragraph (3)(B)(i), by striking  
23 “rule promulgated” and inserting “rule, order,  
24 or consent agreement”; and

25 (D) in paragraph (4)—

1 (i) by striking “rule promulgated”  
2 each place it appears and inserting “rule,  
3 order, or consent agreement”;

4 (ii) by striking “such rule” each place  
5 it appears and inserting “such rule, order,  
6 or consent agreement”; and

7 (iii) in subparagraph (B), by striking  
8 “the rule” and inserting “the rule or  
9 order”;

10 (3) in subsection (d), by striking “rule” and in-  
11 serting “rule, order, or consent agreement”; and

12 (4) in subsection (g), by striking “rule” and in-  
13 serting “rule, order, or consent agreement”.

14 (e) SECTION 5.—Section 5 of the Toxic Substances  
15 Control Act (15 U.S.C. 2604) is amended—

16 (1) in subsection (b)—

17 (A) in paragraph (1)(A)—

18 (i) by striking “rule promulgated”  
19 and inserting “rule, order, or consent  
20 agreement”; and

21 (ii) by striking “such rule” and insert-  
22 ing “such rule, order, or consent agree-  
23 ment”;

1 (B) in paragraph (1)(B), by striking “rule  
2 promulgated” and inserting “rule or order”;  
3 and

4 (C) in paragraph (2)(A)(ii), by striking  
5 “rule promulgated” and inserting “rule, order,  
6 or consent agreement”; and

7 (2) in subsection (d)(2)(C), by striking “rule”  
8 and inserting “rule, order, or consent agreement”.

9 (f) SECTION 7.—Section 7(a) of the Toxic Substances  
10 Control Act (15 U.S.C. 2606(a)) is amended—

11 (1) in paragraph (1), in the matter following  
12 subparagraph (C), by striking “a rule under section  
13 4, 5, 6, or title IV or an order under section 5 or  
14 title IV” and inserting “a determination under sec-  
15 tion 5 or 6, a rule under section 4, 5, or 6 or title  
16 IV, an order under section 4, 5, or 6 or title IV, or  
17 a consent agreement under section 4”; and

18 (2) in paragraph (2), by striking “subsection  
19 6(d)(2)(A)(i)” and inserting “section 6(d)(3)(A)(i)”.

20 (g) SECTION 8.—Section 8(a) of the Toxic Sub-  
21 stances Control Act (15 U.S.C. 2607(a)) is amended—

22 (1) in paragraph (2)(E), by striking “data” and  
23 inserting “information”; and

24 (2) in paragraph (3)(A)(ii)(I), by striking “or  
25 an order in effect under section 5(e)” and inserting

1 “, an order in effect under section 4 or 5(e), or a  
2 consent agreement under section 4”.

3 (h) SECTION 9.—Section 9 of the Toxic Substances  
4 Control Act (15 U.S.C. 2608) is amended—

5 (1) in subsection (a), by striking “section 6”  
6 each place it appears and inserting “section 6(a)”;  
7 and

8 (2) in subsection (d), by striking “Health, Edu-  
9 cation, and Welfare” and inserting “Health and  
10 Human Services”.

11 (i) SECTION 10.—Section 10 of the Toxic Substances  
12 Control Act (15 U.S.C. 2609) is amended—

13 (1) in the section heading, by striking “**DATA**”  
14 and inserting “**INFORMATION**”;

15 (2) by striking “Health, Education, and Wel-  
16 fare” each place it appears and inserting “Health  
17 and Human Services”;

18 (3) in subsection (b)—

19 (A) in the subsection heading, by striking  
20 “DATA” and inserting “INFORMATION”;

21 (B) by striking “data” and inserting “in-  
22 formation” in paragraph (1);

23 (C) by striking “data” and inserting “in-  
24 formation” in paragraph (2)(A); and

1 (D) by striking “a data” and inserting “an  
2 information” in paragraph (2)(B); and  
3 (4) in subsection (g), by striking “data” and in-  
4 serting “information”.

5 (j) SECTION 11.—Section 11(b)(2) of the Toxic Sub-  
6 stances Control Act (15 U.S.C. 2610(b)(2)) is amended—

7 (1) by striking “data” each place it appears  
8 and inserting “information”; and

9 (2) in subparagraph (E), by striking “rule pro-  
10 mulgated” and inserting “rule promulgated, order  
11 issued, or consent agreement entered into”.

12 (k) SECTION 12.—Section 12(b)(1) of the Toxic Sub-  
13 stances Control Act (15 U.S.C. 2611(b)(1)) is amended  
14 by striking “data” both places it appears and inserting  
15 “information”.

16 (l) SECTION 15.—Section 15(1) of the Toxic Sub-  
17 stances Control Act (15 U.S.C. 2614(1)) is amended by  
18 striking “(A) any rule” and all that follows through “or  
19 (D)” and inserting “any requirement of this title or any  
20 rule promulgated, order issued, or consent agreement en-  
21 tered into under this title, or”.

22 (m) SECTION 19.—Section 19 of the Toxic Sub-  
23 stances Control Act (15 U.S.C. 2618) is amended—

24 (1) in subsection (a)—

25 (A) in paragraph (1)(A)—



1 (i) by striking “Not later than 60  
2 days after the date of the promulgation of  
3 a rule under section 4(a), 5(a)(2), 5(b)(4),  
4 6(a), 6(e), or 8, or under title II or IV”  
5 and inserting “Except as otherwise pro-  
6 vided in this title, not later than 60 days  
7 after the date on which a rule is promul-  
8 gated under this title, title II, or title IV,  
9 or the date on which an order is issued  
10 under section 4, 5(e), 5(f), or 6(i)(1),”;

11 (ii) by striking “such rule” and insert-  
12 ing “such rule or order”; and

13 (iii) by striking “such a rule” and in-  
14 serting “such a rule or order”;

15 (B) in paragraph (1)(B)—

16 (i) by striking “Courts” and inserting  
17 “Except as otherwise provided in this title,  
18 courts”; and

19 (ii) by striking “subparagraph (A) or  
20 (B) of section 6(b)(1)” and inserting “this  
21 title, other than an order under section 4,  
22 5(e), 5(f), or 6(i)(1),”;

23 (C) in paragraph (2)—

24 (i) by striking “rulemaking record”  
25 and inserting “record”; and

- 1 (ii) by striking “based the rule” and  
2 inserting “based the rule or order”;
- 3 (2) in subsection (b)—
- 4 (A) by striking “review a rule” and insert-  
5 ing “review a rule, or an order under section 4,  
6 5(e), 5(f), or 6(i)(1),”;
- 7 (B) by striking “such rule” and inserting  
8 “such rule or order”;
- 9 (C) by striking “the rule” and inserting  
10 “the rule or order”;
- 11 (D) by striking “new rule” each place it  
12 appears and inserting “new rule or order”; and
- 13 (E) by striking “modified rule” and insert-  
14 ing “modified rule or order”; and
- 15 (3) in subsection (c)—
- 16 (A) in paragraph (1)—
- 17 (i) in subparagraph (A)—
- 18 (I) by striking “a rule” and in-  
19 serting “a rule or order”; and
- 20 (II) by striking “such rule” and  
21 inserting “such rule or order”;
- 22 (ii) in subparagraph (B)—
- 23 (I) in the matter preceding clause  
24 (i), by striking “a rule” and inserting  
25 “a rule or order”;

1 (II) by amending clause (i) to  
2 read as follows:

3 “(i) in the case of review of—

4 “(I) a rule under section 4(a), 5(b)(4),  
5 6(a) (including review of the associated deter-  
6 mination under section 6(b)(4)(A)), or 6(e), the  
7 standard for review prescribed by paragraph  
8 (2)(E) of such section 706 shall not apply and  
9 the court shall hold unlawful and set aside such  
10 rule if the court finds that the rule is not sup-  
11 ported by substantial evidence in the rule-  
12 making record taken as a whole; and

13 “(II) an order under section 4, 5(e), 5(f),  
14 or 6(i)(1), the standard for review prescribed by  
15 paragraph (2)(E) of such section 706 shall not  
16 apply and the court shall hold unlawful and set  
17 aside such order if the court finds that the  
18 order is not supported by substantial evidence  
19 in the record taken as a whole; and”;

20 (III) by striking clauses (ii) and  
21 (iii) and the matter after clause (iii)  
22 and inserting the following:

23 “(ii) the court may not review the contents and  
24 adequacy of any statement of basis and purpose re-  
25 quired by section 553(c) of title 5, United States

1 Code, to be incorporated in the rule or order, except  
2 as part of the record, taken as a whole.”; and

3 (iii) by striking subparagraph (C);

4 and

5 (B) in paragraph (2), by striking “any  
6 rule” and inserting “any rule or order”.

7 (n) SECTION 20.—Section 20(a)(1) of the Toxic Sub-  
8 stances Control Act (15 U.S.C. 2619(a)(1)) is amended  
9 by striking “order issued under section 5” and inserting  
10 “order issued under section 4 or 5”.

11 (o) SECTION 21.—Section 21 of the Toxic Substances  
12 Control Act (15 U.S.C. 2620) is amended—

13 (1) in subsection (a), by striking “order under  
14 section 5(e) or (6)(b)(2)” and inserting “order  
15 under section 4 or 5(e) or (f)”; and

16 (2) in subsection (b)—

17 (A) in paragraph (1), by striking “order  
18 under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)”  
19 and inserting “order under section 4 or 5(e) or  
20 (f)”; and

21 (B) in paragraph (4)(B)—

22 (i) in the matter preceding clause (i),  
23 by striking “order under section 5(e) or  
24 6(b)(2)” and inserting “order under sec-  
25 tion 4 or 5(e) or (f)”; and

1 (ii) in clause (i), by striking “order  
2 under section 5(e)” and inserting “order  
3 under section 4 or 5(e) or (f)”;

4 (iii) in clause (ii), by striking “section  
5 6 or 8 or an order under section 6(b)(2)”  
6 and inserting “section 6(a) or 8 or an  
7 order under section 5(f)”.

8 (p) SECTION 24.—Section 24(b)(2)(B) of the Toxic  
9 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is  
10 amended—

11 (1) by inserting “and” at the end of clause (i);

12 (2) by striking clause (ii); and

13 (3) by redesignating clause (iii) as clause (ii).

14 (q) SECTION 26.—Section 26 of the Toxic Substances  
15 Control Act (15 U.S.C. 2625) is amended—

16 (1) in subsection (e), by striking “Health, Edu-  
17 cation, and Welfare” each place it appears and in-  
18 serting “Health and Human Services”; and

19 (2) in subsection (g)(1), by striking “data” and  
20 inserting “information”.

21 (r) SECTION 27.—Section 27(a) of the Toxic Sub-  
22 stances Control Act (15 U.S.C. 2626(a)) is amended—

23 (1) by striking “Health, Education, and Wel-  
24 fare” and inserting “Health and Human Services”;

1           (2) by striking “test data” both places it ap-  
2           pears and inserting “information”;

3           (3) by striking “rules promulgated” and insert-  
4           ing “rules, orders, or consent agreements”; and

5           (4) by striking “standards” and inserting “pro-  
6           tocols and methodologies”.

7           (s) SECTION 30.—Section 30(2) of the Toxic Sub-  
8           stances Control Act (15 U.S.C. 2629(2)) is amended by  
9           striking “rule” and inserting “rule, order, or consent  
10          agreement”.

11   **SEC. 20. NO RETROACTIVITY.**

12          Nothing in sections 1 through 19, or the amendments  
13          made by sections 1 through 19, shall be interpreted to  
14          apply retroactively to any State, Federal, or maritime legal  
15          action filed before the date of enactment of this Act.

16   **SEC. 21. TREVOR’S LAW.**

17          (a) PURPOSES.—The purposes of this section are—

18               (1) to provide the appropriate Federal agencies  
19               with the authority to help conduct investigations into  
20               potential cancer clusters;

21               (2) to ensure that Federal agencies have the  
22               authority to undertake actions to help address can-  
23               cer clusters and factors that may contribute to the  
24               creation of potential cancer clusters; and

1           (3) to enable Federal agencies to coordinate  
2           with other Federal, State, and local agencies, insti-  
3           tutes of higher education, and the public in inves-  
4           tigating and addressing cancer clusters.

5           (b) DESIGNATION AND INVESTIGATION OF POTEN-  
6           TIAL CANCER CLUSTERS.—Part P of title III of the Pub-  
7           lic Health Service Act (42 U.S.C. 280g et seq.) is amended  
8           by adding at the end the following:

9           **“SEC. 399V-6. DESIGNATION AND INVESTIGATION OF PO-**  
10           **TENTIAL CANCER CLUSTERS.**

11           “(a) DEFINITIONS.—In this section:

12           “(1) CANCER CLUSTER.—The term ‘cancer  
13           cluster’ means the incidence of a particular cancer  
14           within a population group, a geographical area, and  
15           a period of time that is greater than expected for  
16           such group, area, and period.

17           “(2) PARTICULAR CANCER.—The term ‘par-  
18           ticular cancer’ means one specific type of cancer or  
19           a type of cancers scientifically proven to have the  
20           same cause.

21           “(3) POPULATION GROUP.—The term ‘popu-  
22           lation group’ means a group, for purposes of calcu-  
23           lating cancer rates, defined by factors such as race,  
24           ethnicity, age, or gender.

1           “(b) CRITERIA FOR DESIGNATION OF POTENTIAL  
2 CANCER CLUSTERS.—

3           “(1) DEVELOPMENT OF CRITERIA.—The Sec-  
4 retary shall develop criteria for the designation of  
5 potential cancer clusters.

6           “(2) REQUIREMENTS.—The criteria developed  
7 under paragraph (1) shall consider, as appropriate—

8           “(A) a standard for cancer cluster identi-  
9 fication and reporting protocols used to deter-  
10 mine when cancer incidence is greater than  
11 would be typically observed;

12           “(B) scientific screening standards that  
13 ensure that a cluster of a particular cancer in-  
14 volves the same type of cancer, or types of can-  
15 cers;

16           “(C) the population in which the cluster of  
17 a particular cancer occurs by factors such as  
18 race, ethnicity, age, and gender, for purposes of  
19 calculating cancer rates;

20           “(D) the boundaries of a geographic area  
21 in which a cluster of a particular cancer occurs  
22 so as not to create or obscure a potential clus-  
23 ter by selection of a specific area; and



1           “(E) the time period over which the num-  
2           ber of cases of a particular cancer, or the cal-  
3           culation of an expected number of cases, occurs.

4           “(c) GUIDELINES FOR INVESTIGATION OF POTEN-  
5 TIAL CANCER CLUSTERS.—The Secretary, in consultation  
6 with the Council of State and Territorial Epidemiologists  
7 and representatives of State and local health departments,  
8 shall develop, publish, and periodically update guidelines  
9 for investigating potential cancer clusters. The guidelines  
10 shall—

11           “(1) recommend that investigations of cancer  
12           clusters—

13           “(A) use the criteria developed under sub-  
14           section (b);

15           “(B) use the best available science; and

16           “(C) rely on a weight of the scientific evi-  
17           dence;

18           “(2) provide standardized methods of reviewing  
19           and categorizing data, including from health surveil-  
20           lance systems and reports of potential cancer clus-  
21           ters; and

22           “(3) provide guidance for using appropriate epi-  
23           demiological and other approaches for investigations.

24           “(d) INVESTIGATION OF CANCER CLUSTERS.—

1           “(1) SECRETARY DISCRETION.—The Sec-  
2     retary—

3           “(A) in consultation with representatives of  
4     the relevant State and local health departments,  
5     shall consider whether it is appropriate to con-  
6     duct an investigation of a potential cancer clus-  
7     ter; and

8           “(B) in conducting investigations shall  
9     have the discretion to prioritize certain poten-  
10    tial cancer clusters, based on the availability of  
11    resources.

12          “(2) COORDINATION.—In investigating poten-  
13    tial cancer clusters, the Secretary shall coordinate  
14    with agencies within the Department of Health and  
15    Human Services and other Federal agencies, such as  
16    the Environmental Protection Agency.

17          “(3) BIOMONITORING.—In investigating poten-  
18    tial cancer clusters, the Secretary shall rely on all  
19    appropriate biomonitoring information collected  
20    under other Federal programs, such as the National  
21    Health and Nutrition Examination Survey. The Sec-  
22    retary may provide technical assistance for relevant  
23    biomonitoring studies of other Federal agencies.

24          “(e) DUTIES.—The Secretary shall—

1           “(1) ensure that appropriate staff of agencies  
2           within the Department of Health and Human Serv-  
3           ices are prepared to provide timely assistance, to the  
4           extent practicable, upon receiving a request to inves-  
5           tigate a potential cancer cluster from a State or  
6           local health authority;

7           “(2) maintain staff expertise in epidemiology,  
8           toxicology, data analysis, environmental health and  
9           cancer surveillance, exposure assessment, pediatric  
10          health, pollution control, community outreach, health  
11          education, laboratory sampling and analysis, spatial  
12          mapping, and informatics;

13          “(3) consult with community members as inves-  
14          tigations into potential cancer clusters are con-  
15          ducted, as the Secretary determines appropriate;

16          “(4) collect, store, and disseminate reports on  
17          investigations of potential cancer clusters, the pos-  
18          sible causes of such clusters, and the actions taken  
19          to address such clusters; and

20          “(5) provide technical assistance for inves-  
21          tigating cancer clusters to State and local health de-  
22          partments through existing programs, such as the  
23          Epi-Aids program of the Centers for Disease Control  
24          and Prevention and the Assessments of Chemical

1       Exposures Program of the Agency for Toxic Sub-  
2       stances and Disease Registry.”.

3       **TITLE II—RURAL HEALTHCARE**  
4       **CONNECTIVITY**

5       **SEC. 201. SHORT TITLE.**

6       This title may be cited as the “Rural Healthcare  
7       Connectivity Act of 2016”.

8       **SEC. 202. TELECOMMUNICATIONS SERVICES FOR SKILLED**  
9       **NURSING FACILITIES.**

10       (a) IN GENERAL.—Section 254(h)(7)(B) of the Com-  
11       munications Act of 1934 (47 U.S.C. 254(h)(7)(B)) is  
12       amended—

13               (1) in clause (vi), by striking “and” at the end;

14               (2) by redesignating clause (vii) as clause (viii);

15               (3) by inserting after clause (vi) the following:

16                       “(vii) skilled nursing facilities (as de-

17                       fined in section 1819(a) of the Social Secu-

18                       rity Act (42 U.S.C. 1395i–3(a))); and”;

19                       and

20               (4) in clause (viii), as redesignated, by striking

21       “clauses (i) through (vi)” and inserting “clauses (i)

22       through (vii)”.

23       (b) SAVINGS CLAUSE.—Nothing in subsection (a)

24       shall be construed to affect the aggregate annual cap on

25       Federal universal service support for health care providers

1 under section 54.675 of title 47, Code of Federal Regula-  
2 tions, or any successor regulation.

3 (c) EFFECTIVE DATE.—The amendments made by  
4 subsection (a) shall apply beginning on the date that is  
5 180 days after the date of the enactment of this Act.

