Review of Contaminants of Emerging Concern

Under the Health and Safety Code (HSC) (Article 3.5, Chapter 6.5 § 25135 (b)(5)(C)), DTSC is required to conduct "an assessment of additional contaminants, chemical constituents, or hazard characteristics or traits that are not currently included in the hazardous waste identification criteria, and the additional public health or environmental protections that could be achieved if those additional contaminants, chemical constituents, or hazard characteristics or traits were to be added to the hazardous waste identification criteria in the state."

DTSC conducted a review of contaminants of emerging concern, public health and environmental impacts, associated data gaps and the latest efforts of multiple agencies to address Contaminants of Emerging Concern (CECs). This review is intended to inform future planning and policy discussions regarding the identification of contaminants of emerging concern as hazardous waste.

CECs are emerging chemical or material contaminants characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards. Some have been recently discovered in waste streams and environmental media – because of improved analytical determination techniques and other factors¹ – that have the potential to cause deleterious effects to public health, aquatic life, and the environment if improperly managed. They are not currently included in routine monitoring programs and can be candidates for future regulation depending on the intrinsic physical and chemical characteristics of a substance(e.g., boiling point, volatility, water solubility etc.), potential health effects, ecotoxicity, public perception and frequency of occurrence in environmental media. CECs are not necessarily new chemicals and contaminants, as there may be some chemicals that have been present in the environment but whose presence and significance are only now being detected and evaluated. In other words, CECs can be described as contaminants for which environmental or public health risks are yet to be identified.

CECs can be naturally occurring, but they can also be sourced from many products – including antibiotics, pesticides, pharmaceuticals, and personal care products – and can be found in effluents. More recently, CECs include micro- and nanomaterials. Due to limited available information on their interaction and toxicological impact, CECs are a becoming a major area for regulatory investigation.

¹ Other factors may include modification in empirical observations of exposure in drinking water systems, in serum/biota, and of morbidity/mortality of sentinel receptors in the environment (e.g., 6PPD in coho salmon)

CECs are referred to as "Emerging Contaminants (ECs)" by U.S. EPA,² and are described as newly evaluated and/or identified contaminants with a potential of localized accumulation with a likelihood of exposure. According to the United States Geological Survey (USGS),³ emerging contaminants can refer to many different kinds of chemicals, including, as noted above, medicines, personal care or household cleaning products, lawn care and agricultural products that pose potential risk to human health and/or ecology.

U.S. EPA has developed a list of technical fact sheets for some CECs in order to illustrate physical and chemical properties, environmental and health impacts, existing federal and state guidelines, and detection and treatment methods for associated chemicals/contaminants. Some of these listed CECs are already considered and included in RCRA and state regulations. In 2020, U.S. EPA released an Action Plan⁴ to address per- and polyfluoroalkyl substances (PFASs) - including the two most studied and problematic PFAS chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). Previously, U.S. EPA also launched a PFOA Stewardship Program,⁵ which asked the eight major companies⁶ in the PFAS industry to commit to the reduction of PFOA from facility emissions and product content by 95 percent by 2010 and to work toward eliminating PFOA and its precursor chemicals from emissions and product content by 2015. As part of their commitment to the 2010/2015 PFOA Stewardship Program, the eight participating companies agreed to submit annual progress reports on their reductions of emissions and on the amount of PFASs in their products.⁷ The U.S. EPA website illustrates that most of these companies have stopped manufacturing and importing long-chain PFASs and have transitioned to alternative chemicals. Other companies exited the PFAS industry altogether to meet the program goals.⁸ U.S. EPA is currently working on a program to work cooperatively with companies to voluntarily withdraw all previously granted Low Volume Exemptions

² EPA Emerging Contaminants and Federal Facility Contaminants of Concern

³ United States Geological Survey (USGS): Emerging Contaminants: Accessed March 2, 2019. Available at: <u>Website Link</u>

⁴ U.S. EPA PFAS Action Plan (2020): Program Update. Available at:

https://www.epa.gov/sites/default/files/2020-01/documents/pfas_action_plan_feb2020.pdf

⁵ U.S. EPA Fact Sheet: 2010/2015 PFOA Stewardship Program. Available at: Website Link

⁶ The companies participating in the PFOA Stewardship Program were global companies with business operations in the U.S. and other countries, including Arkema, Asahi, BASF Corporation (successor to Ciba), Clariant, Daikin, 3M/Dyneon, DuPont, and Solvay Solexis. Under the PFOA Stewardship Program, each company committed to work toward a global phaseout of PFOA and related chemicals, both for U.S. operations and for the company's global business. UPDATE: All participating companies state that they have met the PFOA Stewardship Program goals. Website Link

⁷ 2010/2015 PFOA Stewardship Program - 2014 Annual Progress Reports: Available at: Website Link

⁸ U.S. EPA. 2010/2015 <u>PFOA Stewardship Program</u>. All participating companies state that met the PFOA Stewardship Program goals. Read the latest progress reports, available at: <u>Website Link</u>

(LVEs) for PFASs.⁹ This outreach effort has resulted in companies withdrawing more than half of the 82 long-chain PFAS LVEs targeted for withdrawal when the program was launched in 2016. More recently, U.S. EPA issued a proposal in August 2022¹⁰ to designate PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). If this proposed designation is finalized, releases of PFOA and PFOS that meet or exceed the reportable quantity would have to be reported to responsible entities.¹¹ U.S. EPA anticipates that action (final rule) would encourage facilities handling PFOA or PFOS to adopt better waste management and treatment practices.

CECs include many different compounds with potential significant impacts on human health and the environment and can be broadly classed into several categories of chemicals,¹² such as:

- Per- and poly-fluoroalkyl substances, including:
 - Perfluorooctanoic acid (PFOA)
 - Perfluorooctane sulfonic acid (PFOS)
 - Polyfluorinated and perfluorinated (PFAS)
- Brominated flame retardants (BFRs), including:
 - Polybrominated diphenylethers (PBDEs)
- Organophosphate flame retardants (OPFRs), including:
 - Triphenyl phosphate, TDCIPP, TCEP etc.
- Nitrosodimethylamine
- Phthalates
- Nonylphenols
- Nanoparticles
- Synthetic musks
- Personal care product ingredients
- Perchlorate
- Nitrates
- Pharmaceuticals
- Industrial chemicals, including:
 - o Additives

⁹ U.S. EPA. PFAS Low Volume Exemption Stewardship Program. Details are available at:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption

¹⁰ Further details can be accessed at: https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund

¹¹ Including National Response Center, state, or Tribal emergency response commissions, and the local or Tribal emergency planning committees

¹² See for more details: Chemicals of Emerging Concern. Available at: https://dtsc.ca.gov/emergingchemicals-of-concern/

- o Stabilizers
- o Adjuvants
- Hormonally active compounds

Several CECs are carcinogenic, and some can also act as endocrine disruptors or reproductive toxicants.¹³ Such CECs can include:

- Pharmaceuticals and pharmaceutical wastes
- Bis-phenol-A and its substitutes
- Phthalates
- Nonylphenols and other compounds

Because of their frequent use and environmental persistence, some CECs are pervasive and transport far from their point of generation. For example, flame retardants such as polybrominated diphenyl ethers (PBDEs) are widely used in furniture and electronics. PBDEs undergo long-range atmospheric transport and are known to accumulate in household dust.¹⁴ PBDEs are usually detected in human blood in industrialized countries at concentrations of concern to environmental toxicologists.¹⁵ Use of PBDEs has been restricted in some states, including California.¹⁶ The chemical structure of some CECs is shown in Figure 1.

¹³ <u>Gore et al., (2015)</u>, EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. PMID: 26544531 PMCID: PMC4702494 DOI: 10.1210/er.2015-1010

¹⁴ Hites, R.A. (2004). Polybrominated diphenyl ethers in the environment and in people: a meta-analysis of concentrations. Environ Sci Technol. 2004; 38:945–956. [PubMed] [Google Scholar]

¹⁵ Johnson et al. (2010). Relationships between polybrominated diphenyl ether concentrations in house dust and serum. Environ Sci Technol. 2010; 44:5627–5632. [PMC free article] [PubMed] [Google Scholar] [Ref list]

¹⁶ Assembly Bill 302 (2008). Polybrominated diphenyl ether. This bill would prohibit, on and after January 1, 2008, a person from manufacturing, processing, or distributing in commerce a product, or a flame-retarded part of a product, containing more than 1/10 of 1% pentaBDE or octaBDE, by mass. Available at: <u>Website Link</u>



Appendix E Figure 1: Structural representation of some CECs: Abbreviations: D4, octamethylcyclotetrasiloxane; DBDE, decabromodiphenyl ether; HMDS, hexamethyldisiloxane; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate. Source: Ela et al., 2011¹⁷

¹⁷ Ela et al. (2011). Toward identifying the next generation of superfund and hazardous waste site contaminants. Environ Health Perspect. 2011 Jan;119(1):6-10. doi: 10.1289/ehp.1002497. PMID: 21205582; PMCID: PMC3018501.

Importance of Identification and Evaluation of CECs

The risks posed by CECs are currently not assessed or regulated. Several CECs have been found to be building up in the environment, have been noticed to be stored in the bodies of humans, aquatic life, and wildlife, and may have the potential to cause adverse effects. Surveys of natural and synthetic chemicals in urban watersheds¹⁸ have shown that CECs are prevalent in the environment and may adversely affect humans, aquatic species, and the environment.

There are many past examples of regulatory attention being given to CECs only after their adverse effects occurred and were noticed. For example, in the 19th and early 20th centuries, asbestos¹⁹ was a commonly used substance in many products worldwide and was not recognized as a threat to human health or the environment. Though deaths and lung problems caused by asbestos were noticed and documented in the early 20th century,²⁰ the first regulations of the asbestos industry were not published in the United States until the 1980s.²¹ Another serious issue arose in 1970s, involving water treatment infrastructure in several states. A notable example was Southern California, where water from the Sacramento-San Joaquin River Delta was being disinfected through chlorine treatment, and the treated chemicals reacted with runoff chemicals and organic matter to form trihalomethanes (THMs).²² Later, thorough research identified the carcinogenic and harmful nature of this category of compounds. In 1979, U.S. EPA issued its first standard for THMs²³ applicable to public water systems and later updated it with more stringent standards in 1998 and 2006. A more recent example involves 1,4-Dioxane,²⁴ a constituent present in certain beauty, personal care, hygiene, and cleaning products. After carcinogenic impacts were noticed,

²¹ U.S. EPA. Asbestos Laws and Regulations. Available at: Website Link

²³ Federal Register (1979). "National Interim Primary Drinking Water Regulations; Control of

¹⁸ Bai et al. (2018). Occurrence, distribution, and seasonality of emerging contaminants in urban watersheds. <u>https</u>://doi.org/10.1016/j.chemosphere.2018.02.106

¹⁹ Asbestos is a naturally occurring fibrous silicate mineral that was widely used in construction and other industries until the late 1990s. The fiber is composed of many microscopic "fibrils" that can be released into the atmosphere. Inhalation of asbestos fibers can lead to various dangerous lung conditions, including mesothelioma, asbestosis, and lung cancer, so it is now notorious as a serious health and safety hazard. (British Lung Foundation. 28 September 2015. Available at: https://www.blf.org.uk/supportfor-you/asbestos-related-conditions/what-is-asbestos)

²⁰ American Cancer Society (2015). Asbestos and Cancer Risk. cancer.org | 1.800.227.2345. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/603.00.pdf

²² Hutton et al. (2022). The Municipal Water Quality Investigations Program: A Retrospective Overview of the Program's First Three Decades. Available at: <u>Website Link</u>

Trihalomethanes in Drinking Water; Final rule." Federal Register, 44 FR 68624. Available at:

https://www.govinfo.gov/content/pkg/FR-1979-11-29/pdf/FR-1979-11-29.pdf

²⁴ 1,4-Dioxane is a likely human carcinogen that is highly mobile and persistent in water and is not removed by most standard forms of wastewater and drinking water treatment. Refer to EPA Technical Fact Sheet- 1,4-Dioxane for further details, accessible at: <u>Website Link</u>

DTSC released a background document in 2019²⁵ regarding adverse impacts from exposure to products containing 1,4-Dioxane and drinking water containing 1,4-Dioxane. DTSC's Safer Consumer Products program (SCP) and Environmental Chemistry Laboratory (ECL)²⁶ have worked with the New York Department of Environmental Conservation (DEC)²⁷ to develop draft Method Performance Criteria (MPC) for 1,4-Dioxane,²⁸ and guidance on the Alternatives Analysis Threshold (AAT).²⁹ 1,4-Dioxane is not regulated at the federal level; however, the New York State Legislature recently passed legislation to restrict the level of 1,4-Dioxane in household cleaning and personal care products to below 2 ppm by the end of December 2022 and below 1 ppm by the end of 2023.³⁰

Unfortunately, the environmental effects and human toxicology of many CECs have not yet been studied,³¹ so many waste streams and environmental systems are not, or cannot be, tested for their presence. In addition, the endocrine disrupting nature of exposure to many CECs and pharmaceuticals and personal care products (PPCPs) can cause the alteration of the normal functions of hormones, resulting in a variety of health effects including impacts on reproductive systems. The evaluation of these effects may require testing methodologies not typically available, along with endpoints not previously evaluated using current guidelines, because these CECs have not been previously assessed or are newly discovered.

https://www.dec.ny.gov/chemical/121658.html

²⁵ Background Document on 1,4-Dioxane in personal care and cleaning products can be accessed at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/10/Background-Document_14dioxane_accessible.pdf

²⁶ ECL has identified several analytical methods for measuring 1,4-Dioxane in various sample matrices. U.S. EPA has a well-established method for quantifying 1,4-Ddioxane in water at parts per trillion (ppt) levels (<u>EPA Method 522</u>), but it cannot accommodate the complex matrices associated with viscous and foaming products like detergents and gels.

²⁷ For more information on DEC actions on 1,4-Dioxane, visit its website:

https://www.dec.ny.gov/chemical/121658.html

²⁸ Details available at: <u>https://dtsc.ca.gov/scp/1-4-dioxane/</u>

²⁹ To establish an Alternatives Analysis Threshold (AAT) for 1,4-dioxane, <u>DTSC</u> must understand how completely 1,4-dioxane can be removed from products, or from ethoxylated ingredients, using available removal technologies. DTSC's Safer Consumer Products regulations require DTSC to set an Alternatives Analysis Threshold (AAT) for contaminants such as 1,4-dioxane in proposed Priority Products [§69503.5(c)]. A manufacturers must file an Alternatives Analysis Threshold Notification (AATN) documenting that a contaminant is present at a concentration below a set threshold level or indicating that it will reformulate the product or remove the product from the marketplace.

³⁰ For more information on DEC actions on 1,4-Dioxane, visit its website:

³¹ Rosenfeld and Lydia (2011). Risks of Hazardous Wastes. ISBN 9781437778427, https://doi.org/10.1016/B978-1-4377-7842-7.00016-7



Appendix E Figure 2: Overview of the sources, environmental fate, and elimination/transformation of pharmaceuticals, personal care products and other emerging contaminants in the aquatic environment³²

CECs enter the environment every day and remain in waste streams because treatment plants are not designed to eliminate these chemicals. Improper waste management and lack of regulatory pathways for these CECs eventually allow them to accumulate in the nation's lakes and rivers.

DTSC's Human and Ecological Risk Office (HERO) reports that more than 80,000 chemicals are present in United States current commerce.³³ Further, about 2,500 new chemicals are introduced into commerce annually, a rate of about seven new chemicals per day. Most of the 80,000+ chemicals registered for use in the United States today have not been tested for safety or toxicity by any government agency. HERO reports that approximately 2,500 of these 80,000 chemicals are considered high production volume (HPV) chemicals,³⁴ and nearly 45 percent of these HPV chemicals lack adequate toxicological studies.³⁵

³² Source: Wilkinson et al., 2017. Occurrence, fate and transformation of emerging contaminants in water: An overarching review of the field. <u>https://doi.org/10.1016/j.envpol.2017.08.032</u>.

³³ Human and Ecological Risk Office (HERO). Chemicals of Emerging Concern. Available at: <u>Website</u> <u>Link</u>

³⁴ High production volume (HPV) chemicals are those manufactured at a rate of more than one million pounds annually

³⁵ Toxicological studies are conducted to evaluate health effects on humans and on wildlife.

Current Regulatory Efforts to Address Issues Associated with CECs

CECs are examples of instances in which communities may be left vulnerable to adverse health effects while regulations have not been established or are in the process of development. Many states have assessed CECs as a serious issue nationwide, but only a few have specific risk management programs.

U.S. EPA is authorized to conduct pre-release risk assessments of all chemicals used in the United States, through the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The same is true of the U.S. Food and Drug Administration (FDA) – through the Federal Food, Drug, and Cosmetics Act (FFDCA) and the Food Quality Protection Act (FQPA) – and all federal agencies, through the National Environmental Policy Act (NEPA).

The European Union³⁶ adopted a chemical regulation policy in 2006. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). REACH is based on the "Precautionary Principle" of addressing the safety of the environment and public health. The primary focus of the policy is to ensure that no action is taken unless it can be proven to be safe. REACH requires manufacturers that produce or import more than 1,000 kilograms of a chemical to undergo a registration process and disclose the hazard and exposure information related to their industrial chemicals. Chemical manufacturers must also gain government authorization to use certain substances of very high concern. The manufacturer is responsible for conducting a risk assessment of a chemical's adverse environmental effects, and unless the chemical has been registered in accordance with REACH, the company is not allowed to place its product on the market. The REACH regulation requires a review after every 5 years to monitor progress: the first and second REACH reviews were published in 2013 and 2017, respectively. To gain compliance with REACH, manufacturers in the European Union, as well as foreign importers, have created a seismic change in the chemical industry by following the standards of a unified market. REACH compliance is also prompting change at the international level,³⁷ as chemical and product manufacturers around the world are compelled to comply with REACH in order to do business in the chemical industry.

• U.S. EPA

 ³⁶ E.U. OSHA (2006). Regulation (EC) No 1907/2006 - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). Latest update: 27/04/2021. Available at: <u>Website Link</u>
 ³⁷ Mark Schapiro (2007). Exposed: The Toxic Chemistry of Everyday Products and What's at Stake for American Power. White River Junction, VT:Chelsea Green, 2007. 224 pp. ISBN: 978-1-933392-15-8. Article

Americans might expect that the government carefully evaluates the safety of every chemical before allowing it on the market, but most of the 80,000+ registered chemicals have not been assessed and tested for safety. At the federal level, U.S. EPA has constantly implemented several mechanisms to identify and evaluate emerging chemicals, but there is no clear guidance or consensus on how states should evaluate or manage this information. 1,4-Dioxane and PFAS are two examples of this challenge.

U.S. EPA has various monitoring programs – including the Unregulated Contaminant Monitoring Rule (UCMR)³⁸ program under the Safe Drinking Water Act (SDWA)³⁹ – that generate data that can be useful for identifying emerging chemicals. The United States established TSCA in the late 1970s as the nation's primary chemicals management law. Under TSCA,⁴⁰ U.S. EPA requires reporting and record-keeping, and sets testing requirements and restrictions relating to chemical substances/mixtures. TSCA also requires U.S. EPA to compile, keep current, and publish a list of each chemical substance manufactured or processed in the United States. This list is called the TSCA Inventory,⁴¹ and it plays a central role in the regulation of most industrial chemicals in the United States. The first TSCA Inventory was published in 1979 and a second version, containing about 62,000 chemical substances, was published in 1982. Currently, the TSCA Inventory lists more than 86,000 chemicals and is continuously updated. TSCA also contains restrictions on the production, importation, use, and disposal of specific chemicals, including polychlorinated biphenyls (PCBs), asbestos, radon, and lead-based paint.⁴² However, exclusions that apply to food, drugs, cosmetics, pesticides, and other categories of chemicals have added a layer of challenge. Because of these TSCA exemptions, fewer than 200 chemicals have ever undergone any risk assessment.⁴³

³⁸ U.S. EPA. Learn About the Unregulated Contaminant Monitoring Rule. Information available at: <u>Website Link</u>

³⁹ The Safe Drinking Water Act (SDWA) requires that once every five years EPA issue a list of unregulated contaminants to be monitored by public water systems (PWSs). More information is available at: <u>Website Link</u>

⁴⁰ 15 U.S.C. 2601 et seq Section (8)(b). TSCA provides U.S. EPA with authority to require reporting, record-keeping, and testing and to enforce restrictions relating to chemical substances and/or mixtures. Available at: <u>Website Link</u>

⁴¹ TSCA Inventory is updated approximately every six months. It can be searched in multiple ways. The link provides ways to download the non-confidential Inventory and offers help in using these downloaded files. The February 2022 update is available below. The Inventory contains 86,631 chemicals, 42,039 of which are active. Link to access the TSCA Inventory: <u>Website Link</u>

 ⁴² U.S. EPA. Summary of the Toxic Substances Control Act (TSCA). Available at: Website Link
 ⁴³ Mark Schapiro (2007). Toxic Inaction. Article can be accessed at:

https://harpers.org/archive/2007/10/toxic-inaction/ . 224 pp. ISBN: 978-1-933392-15-8. Article

On June 22, 2016, the Lautenberg Chemical Safety Act⁴⁴ was signed into law to amend TSCA by expanding U.S. EPA's authority to obtain testing information from manufacturers on existing chemicals. The law established clear and enforceable deadlines for U.S. EPA to evaluate existing chemicals and gave it the authority to review risk-based chemical assessments and to promote increased public transparency for chemical information.

In 1998, U.S. EPA initiated the Endocrine Disruptor Screening Program (EDSP)⁴⁵ due to concerns raised by some scientists in the 1990sthat certain chemicals were suspected to disrupt the endocrine systems of humans and wildlife. The EDSP screens pesticides, chemicals, and environmental contaminants for their potential effect on estrogen, androgen, and thyroid hormone systems. As a result of this screening, some CECs have been recognized as endocrine disrupting chemicals, which have been shown to exert epigenetic effects.⁴⁶

In 2007, U.S. EPA initiated the development of the Toxicity Forecaster (ToxCast) program⁴⁷ to develop new methodologies for assessing the rapidly expanding number of environmental chemicals. ToxCast uses automated chemical screening technologies to rank and prioritize chemicals. U.S. EPA expects the ToxCast program to assist in developing the ability to forecast the toxicity of compounds based on their bioactivity and then to prioritize these chemicals for further screening and testing. In fact, EDSP is currently working to use ToxCast to identify priority chemicals. This information may further assist in the management and regulation of these chemicals at a national level.

In 2008, U.S. EPA developed a white paper entitled Aquatic Life Criteria for Contaminants of Emerging Concern⁴⁸ to better address CECs and to develop ambient water quality criteria for protection of aquatic life.

Since 2004, multiple federal agencies have been investigating nanoparticles or nanomaterials (NMs) – tiny particles that are measured in nanometers, or one millionth of a millimeter, which is approximately 100,000 times smaller than the thickness of a sheet of paper. The National Institute for Occupational Safety and Health (NIOSH) – the

⁴⁸ U. S. EPA (2008). White Paper Aquatic Life Criteria for Contaminants of Emerging Concern Part I General Challenges and Recommendations. Prepared by the OW/ORD Emerging Contaminants Workgroup June 03, 2008. Available at: https://www.epa.gov/sites/default/files/2015-08/documents/white_paper_aquatic_life_criteria_for_contaminants_of_emerging_concern_part_i_general _challenges_and_recommendations_1.pdf

⁴⁴ Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016). Public Law 114–182—June 22, 2016. Available at: <u>Website Link</u>

 ⁴⁵ U.S. EPA. Endocrine Disruptor Screening Program (EDSP) Overview. Available at: Website Link
 ⁴⁶ Depending on the chemical and timing of exposure, epigenetic effects of endocrine disrupting chemicals include changes in the structure of chromatin and DNA methylation that result in long-term changes in gene expression and cell growth and changes in susceptibility to maladies including diabetes, breast cancer, and prostate cancer.

⁴⁷ U.S. EPA Toxicity Forecasting Program (ToxCast). Available at: Website Link

federal agency responsible for preventing work-related injury, illness, and death – established the Nanotechnology Research Center (NTRC) in 2004 to assess the hazards of various nanoparticles.⁴⁹ In 2017, U.S. EPA published a nanomaterials technical fact sheet to provide a summary of NMs, including their physical and chemical properties, potential environmental and health impacts, existing federal and state guidelines, detection and treatment methods, and additional sources of information.⁵⁰

• State of California

The State of California has embarked on a process of identifying CECs in products, promoting and evaluating safer alternatives, and implementing regulations when needed to reduce exposure. For example, the state currently regulates perchlorate, 1,2,3-trichloropropane, NDMA and other nitrosamines, and 1,4-dioxane. There are several programs under CalEPA that are working individually and in collaboration with other agencies to identify and evaluate CECs. Some of the programs, discussed below, are actively involved in CEC determination and evaluation.

Under DTSC, Safer Consumer Products (SCP) is actively involved in the process of identifying and prioritizing products that contain chemicals known to be potentially hazardous products (not hazardous waste). If a chemical in a product raises concern regarding its adverse impacts and exposures, SCP proposes the product as a Priority Product.⁵¹ SCP also focuses on the identification of alternatives in an effort to eliminate or reduce potential exposures to CECs in Priority Products. SCP evaluates specific product categories to identify Priority Products, issuing a Work Plan every three years identifying the categories it will evaluate during that three-year period. The current Priority Product Work Plan (for 2021-2023) includes a general explanation of DTSC's decision-making process for the selection of product categories.⁵²

SCP has developed an informational list of Candidate Chemicals,⁵³ which is primarily based on established authoritative lists.⁵⁴ Provisions regarding Candidate Chemicals

⁴⁹NIOSH. Nanotechnology. Information is available at: <u>Website Link</u>

⁵⁰ U.S.EPA (2017). Technical Fact Sheet. Information available at: Website Link

⁵¹ A Priority Product is a product-chemical combination identified and listed as a Priority Product by SCP under section 69503.5. Priority Products must include a chemical from the <u>Candidate Chemicals List</u>. Details are available at: <u>Website Link</u>

⁵² Safer Consumer Program (SCP). Three Year Priority Product Work Plan (2021-2023). Available at: https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/04/Final-2021-2023-Priority-Product-Work-Plan.pdf ⁵³ A <u>Candidate Chemical</u> must exhibit a hazard trait and/or an environmental or toxicological endpoint and is either 1) found on one or more of the authoritative lists specified in section 69502.2(a), or 2) it is listed by DTSC using the criteria specified in section 69502.2(b). List of Candidate Chemical is available at: <u>https://calsafer.dtsc.ca.gov/cms/search/?type=Chemical</u>

⁵⁴ The authoritative lists fall into two categories: lists based on hazard traits (15 lists), and lists based on potential exposure concerns (8 lists).

are found in Cal. Code Regs. tit. 22, § 69502.2.⁵⁵ This regulatory section defines a Candidate Chemical as a chemical that exhibits a hazard trait and/or an environmental or toxicological endpoint, meets specified carcinogenic standards,⁵⁶ or is classified as a carcinogen by the European Commission.⁵⁷ The Candidate Chemicals list includes more than 3300 chemical names and their information and is updated continually. DTSC is authorized to add or remove individual chemicals or chemical source lists to the Candidate Chemicals list by adopting new regulations using the criteria in Cal. Code Regs. tit. 22, § 69502.2. The Candidate Chemicals list includes the chemical name, the Chemical Abstracts Service Registry Number (CAS RN), the chemical's group name, the authoritative list name, and the hazard traits that demonstrate why the chemical is listed.

DTSC's Environmental Chemistry Lab (ECL)⁵⁸ is actively involved in evaluating CECs and developing methods to identify them in products, environmental samples, and waste streams. ECL research has led to significant protections for human health and the environment. For example, ECL scientists first reported a class of flame retardants (polybrominated diphenylethers (PBDEs)) in the blood of Californians. This led to the first legislative ban on the use of PBDEs in the United States. However, the phaseout of PBDEs led to the introduction of other flame retardants, some of which also pose adverse health hazards, including carcinogenic impacts. In September 2014, Governor Brown signed SB 1019 (Leno)⁵⁹ into law, requiring the labeling of upholstered furniture for the presence or absence of flame retardants. ECL is currently working on new methods to efficiently detect and measure newer flame retardants, as well as PFASs and synthetic musks and other fragrance compounds.

DTSC is part of "Biomonitoring California," a program constituted under Senate Bill (SB) 1379⁶⁰ in 2006. It is a collaborative effort of DTSC, the Office of Environmental Health

 ⁵⁵ Cal. Code Regs. Tit. 22, § 69502.2 - Candidate Chemicals Identification. Available at: <u>Website Link</u>
 ⁵⁶ Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986

⁵⁷ Chemicals classified by the European Commission as carcinogens, mutagens,

and/or reproductive toxicants Categories 1A and 1B in Annex VI to Regulation (EC) 1272/2008

⁵⁸ Environmental Chemistry Lab (ECL). Chemicals of Emerging Concern. Website: Website Link

⁵⁹ This law requires a manufacturer of upholstered furniture sold in California ("covered products") to indicate whether the product contains added flame-retardant chemicals by appropriately marking the label affixed to the product. This information is available at: <u>Website Link</u>

⁶⁰ SB 1379: This bill required the responsible entities including department of Health Services (DHS) in collaboration with the California Environmental Protection Agency (CalEPA), to establish theCalifornia Environmental Contaminant Biomonitoring Program to monitor the presence and concentration of designated chemicals, as defined, in Californians. This bill also required the DHS and CalEPA to establish a Scientific Guidance Panel (SGP) to assist the Department and the Agency. Note: DHS is reorganized into Department of Health Care Services (DHCS) and California Department of Public Health (CDPH). Further details regarding SB 1379 (105441) is available at: Website Link

Hazard Assessment (OEHHA), and the California Department of Public Health (CDPH) to identify and measure chemical contaminants that can be found in human bodies. The program focuses on chemicals of specific interest and concern to California, such as perchlorate and PFOS, flame retardants, and some heavy metals like mercury and arsenic. More than 150 chemical contaminants in the blood or urine of approximately 5,000 Californians have been measured to determine the exposures and associated risks. SB 1379⁶⁰ advised the responsible entities (DHS and CalEPA) to construct a Scientific Guidance Panel (SGP)⁶¹ to make decisions regarding designated chemicals⁶² and whether to add them to a priority list for future work. Biomonitoring California prepares scientific documents on chemicals of interest for possible biomonitoring to support the deliberations of the SGP. These documents summarize information on exposure, toxicity, analytical considerations, and public health importance in California. Based on the SGPs recommendations of priority chemicals, Biomonitoring California selects specific chemicals to measure in each of its projects.⁶³ There are 48 listed chemicals currently being measured in Biomonitoring California studies.⁶⁴

DTSC is involved in the Interstate Technology and Regulatory Council (ITRC),⁶⁵ collaborating with other states to:

- Address how states can track and identify CECs to better manage them,
- Address the properties and traits that lead to identification, and
- Provide guidance for evaluating these properties.

ITRC intends to provide a framework⁶⁶ for anticipating and responding to emerging chemicals that can be used by state regulatory agencies to review and understand available data and to identify what additional data may be needed.

California's Office of Environmental Health Hazard Assessment (OEHHA) is involved in evaluating CECs and is participating in Biomonitoring California with DTSC and CDPH. OEHHA publishes and updates the Hazard Trait-Based Lists (Proposition 65 list).⁶⁷

⁶¹ The Scientific Guidance Panel (SGP), a panel of expert scientists from outside of state government, plays a major role in the California Environmental Contaminant Biomonitoring Program (also known as Biomonitoring California). More information is available at: <u>Website Link</u>

⁶² Information about Designated Chemicals is available at Biomonitoring California: https://biomonitoring.ca.gov/chemicals/designated-chemicals

 ⁶³ A list of Biomonitoring California projects is available at: https://biomonitoring.ca.gov/projects/archive
 ⁶⁴ A list of chemicals currently being measured in Biomonitoring California studies is available at: Website Link

⁶⁵ ITRC. Contaminants of Emerging Concern. Website: <u>https://itrcweb.org/teams/active/cec</u>

⁶⁶ 2022 ITRC Final Proposal Template. Identifying and Evaluating Chemicals of Emerging Concern. Available at:

https://connect.itrcweb.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=48dec2 ad-da17-49ca-0747-82af767c0f9a

⁶⁷ Proposition 65 protects the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects, or other reproductive harm and requires businesses to inform Californians about exposures to such chemicals. Information is available at: <u>Website Link</u>

Proposition 65 (officially known as The Safe Drinking Water and Toxic Enforcement Act of 1986) requires the governor of California to, at least once per year, revise and republish the list of chemicals known to the state to cause cancer or reproductive toxicity.⁶⁸

Regarding the assessment of CECs, a major knowledge gap at the present time is the lack of knowledge on where, how often, and to what extent humans and the environment are exposed to certain chemical mixtures and how exposure may change over time. Interactions of chemicals in mixtures are difficult to foresee, particularly when discarded and improperly managed in waste streams. Further research and assessment are needed to identify the additional contaminants, chemical constituents, or hazard characteristics or traits that are not currently included in the hazardous waste identification criteria in the state of California to protect public health and the environment.

⁶⁸ Chemicals known to cause cancer and/or reproductive toxicity are listed under Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 (22 CCR 69502.2(a)(1)(A)). List is available at: <u>Website Link</u>

Resources

Additional information on CECs can be found in the links below. These outside links are provided as sources of information and are not necessarily endorsed by DTSC:

- U.S. EPA: Analytical methods for unregulated contaminants
- U.S. EPA: Contaminants of Emerging Concern including Pharmaceuticals
 and Personal Care Products
- U.S. EPA: Per- and Polyfluoroalkyl Substances (PFAS)
- U.S. EPA: PFAS Low Volume Exemption Stewardship Program
- U.S. EPA: PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024
- U.S. EPA: Emerging Contaminants (EC) in Small or Disadvantaged Communities Grant (SDC)
- U.S. EPA: Emerging Contaminant Nanomaterials
- DTSC (SCP): Candidate Chemicals List
- DTSC (SCP): Priority Products
- DTSC (SCP): Safer Nail Products
- CalEPA: Pharmaceuticals
- CalEPA: Polybrominated Diphenyl Ethers: Recommendations to Reduce Exposure in California
- DTSC (ECL): Chemicals of Emerging Concern
- DTSC: Chemicals Biomonitored in California
- DTSC (HERO): Chemicals of Emerging Concern
- DTSC: Emerging Issues
- ITRC: Contaminants of Emerging Concern
- State Water Resources Control Board: Monitoring Strategies for Chemicals of Emerging Concern (CECs) in California's Aquatic Ecosystems
- Product Stewardship Institute: Pharmaceuticals and other product categories
- State Water Resources Control Board (Division of Drinking Water): Chemicals and contaminants in drinking water