

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**NOTICE OF AUGMENTATION OF RECORD AND 2ND MODIFICATION OF
TEXT OF PROPOSED REGULATION**

**TITLE 22, CALIFORNIA CODE OF REGULATIONS,
SECTIONS 69401 THROUGH 69407**

**GREEN CHEMISTRY HAZARD TRAITS FOR CALIFORNIA'S TOXICS
INFORMATION CLEARINGHOUSE**

OCTOBER 7, 2011

The Office of Environmental Health Hazard Assessment (OEHHA) is providing a notice of changes made to the proposed regulation: Title 22, California Code of Regulations, sections 69401 through 69407. A Notice of Proposed Rulemaking was issued for this proposed regulation on December 17, 2010 and published in the California Regulatory Notice Register (Register 2010, No 51-Z). The proposed regulation is related to the specification of hazard traits by OEHHA as required by Senate Bill 509 (Simitian, Chapter 560, Statutes of 2008). A public hearing on this regulatory proposal was held on January 31, 2011. Written comments from the public were received during a 45-day comment period which closed on February 15, 2011. Pursuant to Health and Safety Code section 57004, the University of California coordinated an external scientific peer review of the proposed regulation. OEHHA received the peer review in June 2011. Subsequently, a Notice of Modification of Text was published on July 29, 2011 in the California Regulatory Notice Register (Register 2011, No 30-Z) and on OEHHA's website with a new 45-day comment period ending September 12, 2011. The comments received are posted on the OEHHA website at <http://www.oehha.ca.gov/multimedia/green/gc092211.html> and hard copies may be obtained from Monet Vela at the OEHHA Legal Office at (916) 323-2517.

OEHHA has reviewed the comments it received in this second comment period and is now proposing amendments to the modified proposed regulation and is augmenting the administrative record. A copy of the text of the amended proposed regulation is attached. The additions and deletions from the first modifications are shown in single strike-out and underline. The new modifications are shown in double-underline and double-strike-out. The page numbers have changed to reflect the document shifts caused by the text modifications. The changes to the proposed text, which were made in response to comments received, are as follows:

- Amended the title of Chapter 54 by inserting after Green Chemistry Hazard Traits the words "for California's Toxics Information Clearinghouse"

- Inserted the word “other” in front of “Toxicological Hazard Traits” in the title of Section 69403.17 to be consistent with that section.
- Reworded a sentence under Section 69401.1 to clarify the intent of the regulation.
- Corrected a typographical error in subsection 69405.2(b) evidence for the bioaccumulation hazard trait by inserting the corrected value for the log octanol water partition coefficient. In the previous version the number 5 was struck out and the number 4 should have been inserted in its place but was not.
- Added to Section 69405.3 that evidence for environmental persistence includes “the identification of a substance to be persistent by an authoritative body.” Many authoritative organizations have reviewed the scientific evidence and identified substances that are persistent.
- Fixed various punctuation and grammatical errors

The record is being augmented to include the following additional material supporting the amended modified proposed regulation:

- 29 CFR, Part 1910, Occupational Safety and Health Standards, Subpart 2, Toxic Hazardous Substances, Standard #1910.1200
- Gobas FAPC, W de Wolf, LP Burkhard, E Verbruggen, K Potzke, Revisiting bioaccumulation criteria for POPs and PBT assessments, Integrated Environmental Assessment and Management, Volume 5, Number 4, pages 624-637, 2009.

OEHHA will accept written comments on these amendments to the modified proposed regulation between October 7, 2011, and October 24, 2011. All written comments must be submitted to OEHHA by mail, fax, courier, e-mail, or hand-delivery by no later than 5:00 p.m. on **October 24, 2011**. Comments should be addressed to:

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Inquiries concerning the action described in this notice may be directed to Fran Kammerer, in writing at the address given above, or by telephone at (916) 445-4693. Monet Vela is a back-up contact person and is available at (916) 323-2517.

**MODIFIED AMENDED TEXT OF MODIFIED PROPOSED REGULATIONS
JULY 2011-OCTOBER 2011**

**DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS
CHAPTER 54. GREEN CHEMISTRY HAZARD TRAITS FOR CALIFORNIA'S TOXICS
INFORMATION CLEARINGHOUSE**

Table of Contents

Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data

Article 1. General	3
§ 69401 Purpose and Applicability	3
§ 69401.1 Hazard Trait Framework.....	3
§ 69401.2 Definitions.....	4
Article 2. Toxicological Hazard Traits – Carcinogenicity, Developmental Toxicity, and Reproductive Toxicity	5
§ 69402 General.....	5
§ 69402.1 Carcinogenicity	5
§ 69402.2 Evidence for Carcinogenicity Hazard Trait.....	6
§ 69402.3 Developmental Toxicity	7
§ 69402.4 Evidence for Developmental Toxicity Hazard Trait.....	8
§ 69402.5 Reproductive Toxicity	9
§ 69402.6 Evidence for Reproductive Toxicity Hazard Trait.....	9
Article 3. Other Toxicological Hazard Traits	11
§ 69403 General.....	11
§ 69403.1 Cardiovascular Toxicity	11
§ 69403.2 Dermatotoxicity.....	11
§ 69403.3 Endocrine Toxicity	12
§ 69403.4 Epigenetic Toxicity	12
§ 69403.5 Genotoxicity.....	13
§ 69403.6 Hematotoxicity.....	13
§ 69403.7 Hepatotoxicity and Digestive System Toxicity	13
§ 69403.8 Immunotoxicity	14
§ 69403.9 Musculoskeletal ¶ <u>T</u> oxicity.....	14
§ 69403.10 Nephrotoxicity and Other Toxicity to the Urinary System	15
§ 69403.11 <u>Neurodevelopmental Toxicity</u>	15
§ 69403.11— <u>12</u> Neurotoxicity.....	15

§ 69403.12—13	Ocular Toxicity.....	16
§ 69403.13—14	Ototoxicity.....	16
§ 69403.14—15	Reactivity in Biological Systems.....	17
§ 69403.15—16	Respiratory Toxicity.....	17
§ 69403.16—17	Evidence for <u>Other</u> Toxicological Hazard Traits.....	17
Article 4.	Environmental Hazard Traits.....	18
§ 69404	General.....	18
§ 69404.1	<u>Domesticated</u> Animal Toxicity.....	18
§ 69404.2	Eutrophication.....	19
§ 69404.3	Impairment of Waste Management Organisms.....	19
§ 69404.4	Loss of Genetic Diversity, Including Biodiversity.....	19
§ 69404.5	Phytotoxicity.....	20
§ 69404.6	Wildlife Developmental Impairment.....	20
§ 69404.7	Wildlife Growth Impairment.....	20
§ 69404.8	Wildlife Reproductive Impairment.....	21
§ 69404.9	Wildlife Survival Impairment.....	21
§ 69404.10	Evidence for the Environmental Hazard Traits.....	22
Article 5.	Exposure Potential Hazard Traits.....	23
§ 69405	General.....	23
§ 69405.1	Ambient Ozone Formation.....	23
§ 69405.2	Bioaccumulation.....	23
§ 69405.3	Environmental Persistence.....	24
§ 69405.4	Global Warming Potential.....	24
§ 69405.5	Lactational or Transplacental Transfer.....	24
§ 69405.6	Mobility in Environmental Media.....	24
§ 69405.7	Particle Size or Fiber Dimension.....	25
§ 69405.8	Stratospheric Ozone Depletion Potential.....	25
Article 6.	Physical Hazard Traits.....	25
§ 69406	General.....	25
§ 69406.1	Combustion Facilitation.....	25
§ 69406.2	Explosivity.....	25
§ 69406.3	Flammability.....	26
Article 7.	Additional Relevant Data.....	26
§ 69407	General.....	26
§ 69407.1	Exposure-Response Relationship.....	26
§ 69407.2	Physicochemical Properties.....	26

Amend division 4.5 of California Code of Regulations, title 22, by adding chapter 54 to read:

Article 1. General

§ 69401 Purpose and Applicability

Health and Safety Code section 25256.1 requires the Office of Environmental Health Hazard Assessment (hereafter referred to as "OEHHA") "to evaluate and specify the hazard traits, toxicological and environmental endpoints, and any other relevant data to be included" in the Toxics Information Clearinghouse ("Clearinghouse") mandated under Health and Safety Code section 25252 *et seq.* The law envisions that the Clearinghouse will "provide a decentralized, Web-based system for the collection, maintenance and distribution of specific chemical hazard trait and environmental and toxicological endpoint data." As such, it will provide basic scientific information that will be available to agencies, the public, and industry and government scientists and engineers evaluating chemicals in consumer products. Health and Safety Code section 25252 requires the Department of Toxic Substances Control (hereafter referred to as "Department" or "DTSC") to ~~evaluate chemicals by developing criteria~~ develop criteria for chemical evaluations that include but are not limited to traits, characteristics and endpoints ~~for~~ in the Toxics Information Clearinghouse.

Chapter 54 specifies hazard traits, toxicological and environmental endpoints, and other relevant data to be included in the Clearinghouse as required by Health and Safety Code section 25256.1. This information is intended for use pursuant to Health and Safety Code sections 25252 *et seq.*, chapter 53 to division 4.5 of California Code of Regulations, ~~title~~ Title 22.

§ 69401.1 Hazard Trait Framework

This Chapter and its components reflect a framework for organizing information on chemical hazards for use by the Department in implementing Health and Safety Code section 25252 *et seq.* This chapter provides a structure for relating scientific information to the hazard traits, and ~~for deciding general guidance on whether or not a given~~ chemical exhibits a hazard trait based on the scientific evidence. The framework is organized around four major categories of hazard traits: toxicological, environmental, exposure potential and physical. Beneath each of these are specific hazard traits, the major toxicities and adverse characteristics of chemical substances. The toxicological and environmental hazard traits are manifested as endpoints, which are the kinds of adverse health and environmental effects observed in scientific studies. Other relevant data are also included for the toxicological and environmental hazard traits. These data

can be observed through scientific study and provide less-direct but useful evidence of the potential presence of a hazard trait. For exposure potential and physical hazard traits, data from scientific studies can also be used to determine the presence or absence of the hazard trait. A non-exclusive list of additional relevant data that may be useful in evaluating chemicals is provided in Article 7. ~~This chapter provides a structure for relating scientific information to the hazard traits, and for deciding whether or not a given chemical exhibits a hazard trait based on the scientific evidence.~~

§ 69401.2 Definitions

- (a) “Adverse effect” for toxicological hazard traits and endpoints means a biochemical change, functional impairment, or pathologic lesion that negatively affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge. “Adverse effect” for environmental hazard traits and endpoints means a change that negatively affects an ecosystem, community, assemblage, population, species, or individual level of biological organization.
- (b) “Authoritative organization” means a state, national, international or non-governmental entity whose scientific findings on the safety, risks or hazards of chemical agents are relied upon by state, national or international governments and their supporting public health or environmental entities in regulating or otherwise protecting human health or the environment from threats posed by those chemical agents. Authoritative organizations include the following:
- (1) OEHHA, DTSC and other State of California Boards, Departments, Offices or Agencies
 - (2) The National Academy of Sciences, including the National Research Council and the Institute of Medicine
 - (3) Departments or Agencies of the United States government, including but not limited to: the Consumer Product Safety Commission, Environmental Protection Agency, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health, National Institute of Occupational Safety and Health, the Occupational Safety and Health Administration, and the Department of Transportation
 - (4) Environmental and public health regulatory agencies of other states
 - ~~(4)(5)~~ Canadian government agencies including Environment Canada and Health Canada
 - ~~(5)(6)~~ Governmental bodies within the European Union, including the European Chemicals Agency and national governments
 - ~~(6)(7)~~ Any agency or program within the United Nations including the World Health Organization and its International Agency for Research on Cancer.

- (c) A “chemical substance” is a chemical, chemical compound, chemical mixture, elemental material, particulate matter, fiber, or radioactive agent, its metabolites or degradation by-products.
- (d) An “Environmental endpoints” for a specific hazard trait are is a measured or otherwise observed adverse environmental effects in ecological systems, or in components of ecological systems, or in non-human organisms within ecological systems that indicates the presence of the hazard trait.
- (e) “Hazard traits” are properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential and physical hazards that may contribute to adverse effects in exposed humans, domesticated animals, wildlife, or in ecological communities, populations or ecosystems.
- (f) “Mechanistic similarity” means that a chemical substance acts on a biological system in a manner similar to other chemicals that induce toxicological or environmental effects associated with a specific hazard trait.
- (g) “Other relevant data” for a specific toxicological or environmental hazard trait means non-endpoint data, including chemical, physical, biochemical, biological or other data, that may indicate a chemical substance may have the hazard trait.
- (h) A “toxicological endpoint” for a specific hazard trait is a measured or otherwise observed adverse effect in a biological system that indicates the presence of the hazard trait.
- (i) “Well-conducted scientific studies” means studies published in the open literature or conducted by or submitted to a local, state, national or international government agency, using methods and analyses which are scientifically valid according to generally accepted principles.
- (j) “Wildlife” means undomesticated animals including but not limited to aquatic and terrestrial vertebrate and invertebrate organisms.

Article 2. Toxicological Hazard Traits – Carcinogenicity, Developmental Toxicity, and Reproductive Toxicity

§ 69402 General

This article specifies carcinogenicity, developmental toxicity and reproductive toxicity hazard traits, endpoints and other relevant data for these three traits.

§ 69402.1 Carcinogenicity

- (a) The carcinogenicity hazard trait is defined as the occurrence of increased incidence, reduced latency, or increased severity or multiplicity in neoplasia following exposure to a chemical substance.
- (b) Toxicological eEndpoints for carcinogenicity include, but are not limited to those indicating malignant or benign neoplasia or pre-neoplasia of alimentary,

cardiovascular, endocrine, genital, hematopoietic, integumentary, musculoskeletal, nervous, respiratory, special senses, ~~and or~~ urinary systems as well as any other systemic neoplastic lesions observed in human or animal studies.

- (c) Other relevant carcinogenicity data include but are not limited to: data on: mechanisms of carcinogenesis such as exposure-related modifications to the physiology or response of cells, tissues and organs (such as for example, mitogenesis, compensatory cell division, hyperplasia, ~~or in the~~ signaling pathways used by cells to manage critical processes related to increased risk for cancer); changes in key cellular structures at the molecular level such as mutation and other genotoxicity endpoints; ~~or~~ epigenetic changes associated with increased cancer risk; structural similarity to other carcinogenic chemical substances ~~with the carcinogenicity hazard trait.~~

§ 69402.2 Evidence for Carcinogenicity Hazard Trait

- a) Each of the following constitutes strong evidence of carcinogenicity for a given chemical substance:
- (1) Identification as known to the state to cause cancer in Title 27, California Code of Regulations, section 27001.
 - (2) Meeting the U.S. Environmental Protection Agency's criteria for being identified as "Carcinogenic to Humans" or "Likely to Be Carcinogenic to Humans" or as a Group A, B1 or B2 carcinogen.
 - (3) Meeting the International Agency for Research on Cancer criteria for Group 1, 2A, or 2B classification.
 - (4) Meeting the criteria for classification as "known to be" or "reasonably anticipated to be" a human carcinogen by the U.S. National Toxicology Program.
 - (5) Meeting the criteria for being classified as a "Category 1 Known or Presumed Carcinogen" under the United Nation's Globally Harmonized System for Classification and Labeling of Chemicals.
 - (6) Identification as or other recognition that the chemical substance is a known or potential carcinogen in a report by the National Academy of Sciences' National Research Council or Institute of Medicine.
 - (7) Recognition as a known or potential carcinogen by ~~California, other states,~~ the United States or other nations an authoritative organization.
- (b) Each of the following constitutes suggestive evidence of carcinogenicity for a given chemical substance:

- (1) Identification by the U.S. Environmental Protection Agency as having “Suggestive Evidence of Carcinogenic Potential,” or as being in Group C, ~~or the equivalent.~~
- (2) Meeting the International Agency for Research on Cancer criteria for limited evidence of carcinogenicity in animals.
- (3) Recognition as a suspected carcinogen, ~~or the equivalent,~~ by California, ~~other states, the United States or other nations~~ an authoritative organization.
- (4) Possessing strong evidence for the Genotoxicity Hazard Trait as defined in Article 3 subsection 69403.5 of this Chapter.
- (5) Mechanistic evidence that is suggestive of carcinogenic potential, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in carcinogenesis, such as described by the International Agency for Research on Cancer in the current Preamble to its Monographs on the Evaluation of Carcinogenic Risks to Humans.
- (6) Strong indications of carcinogenicity from structure activity relationships, including but not limited to those from ~~validated~~ Quantitative Structure Activity Relationship models.

§ 69402.3 Developmental Toxicity

- (a) The developmental toxicity hazard trait is defined as the occurrence of adverse effects on the developing organism following exposure to a chemical substance prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Developmental toxicity occurs during the postnatal period only if the developing organism shows greater quantitative or qualitative susceptibility to the chemical substance than does the adult organism.
- (b) Toxicological Endpoints for developmental toxicity include but are not limited to those indicating: death of the developing organism, structural abnormality, altered growth, functional deficiency or other adverse effect on the developing organism. These observations in animals or humans can be manifested at any point in the lifespan of the organism or its offspring.
- (c) Other relevant data include, but are not limited to: mechanistic data at the molecular level such as genotoxicity or epigenetic toxicity, or at the cellular, organ, or organism level; structural or mechanistic similarity to other chemical substances that are toxic to developing organisms ~~with the developmental toxicity hazard trait.~~

§ 69402.4 Evidence for Developmental Toxicity Hazard Trait

- (a) Each of the following constitutes strong evidence of developmental toxicity for a given chemical substance:
- (1) Identification as known to the state to cause reproductive toxicity with developmental toxicity denoted as an endpoint in Title 27, California Code of Regulations, section 27001.
 - (2) Meeting the National Toxicology Program criteria as having clear or sufficient evidence of adverse effects for developmental toxicity, ~~or the equivalent.~~
 - (3) Meeting the criteria for being classified as Category 1, known or presumed human reproductive toxicant based on developmental toxicity data, under the United Nation's Globally Harmonized System for Classification and Labeling.
 - (4) Identification in the National Institute for Occupational Safety and Health's Pocket Guide to Chemical Hazards as having teratogenic or other developmental effect.
 - (5) Identification as a known or potential developmental toxicant or having the capacity to cause developmental toxicity, ~~or the equivalent,~~ in a report published by the National Academy of Sciences' National Research Council or Institute of Medicine.
 - (6) Identification as having sufficient evidence of carcinogenicity by the International Agency for Research on Cancer, with a clear statement that the chemical substance induces transplacental carcinogenesis noted in an International Agency for Research on Cancer IARC Monograph on the Evaluation of Carcinogenic Risks to Humans.
 - (7) Recognition as a developmental toxicant by an authoritative organization by California, other states, the United States or other nations of the chemical substance posing a developmental toxicity hazard.
- (b) Each of the following constitutes suggestive evidence of developmental toxicity for a given chemical substance:
- (1) Meeting National Toxicology Program criteria as "some or limited evidence of adverse effects," ~~"limited evidence of adverse effects," or the equivalent~~ for developmental toxicity.
 - (2) Identification as having limited evidence of carcinogenicity by the International Agency for Research on Cancer, with a clear statement that the chemical substance may induce transplacental carcinogenesis noted in an International Agency for Research on Cancer IARC Monograph on the Evaluation of Carcinogenic Risks to Humans.

- (3) Recognition as a suspected developmental toxicant, ~~or the equivalent,~~ by California, other states, the Federal government or other nations an authoritative organization.
- (4) Strong evidence for the Genotoxicity Hazard Trait ~~per~~ pursuant to Article 3 subsection 69403.5 of this Chapter or the Endocrine Toxicity Hazard Trait ~~per~~ pursuant to Article 3 subsection 69403.3 of this Chapter with mechanisms of genotoxicity or endocrine ~~disruption~~ toxicity likely to be involved in developmental toxicity.
- (5) Strong indications from “supportive studies,” as described by the National Toxicology Program, indicating possible developmental toxicity.
- (6) Mechanistic evidence that is suggestive of developmental toxicity potential, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in developmental toxicity.
- (7) Strong indications of developmental toxicity from structure activity relationships, including but not limited to those from ~~validated~~ Quantitative Structure Activity Relationship models.

§ 69402.5 Reproductive Toxicity

- (a) The reproductive toxicity hazard trait is defined as the occurrence of adverse effects on the reproductive system or reproductive function of females or males following exposure to a chemical substance.
- (b) Toxicological Endpoints ~~of~~ for reproductive toxicity include, but are not limited to ~~the~~ adverse alterations to the female or male reproductive organs, the related endocrine system, or pregnancy outcomes; adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, gestation, parturition, or lactation; developmental toxicity, premature reproductive senescence, or other modifications that compromise the integrity of the reproductive system or reproductive function in animals or humans.
- (c) Other relevant data include but are not limited to: data on endocrine disruption, genotoxicity, *in vitro* measures of the capacity of a chemical to damage the function or structure of germ cells such as sperm or oocytes or cells critical for reproductive function, such as Sertoli and Leydig cells in males; structural or mechanistic similarity to other substances ~~exhibiting the reproductive hazard trait~~ that are toxic to reproductive systems.

§ 69402.6 Evidence for Reproductive Toxicity Hazard Trait

- (a) Each of the following constitutes strong evidence of reproductive toxicity for a given chemical substance:

- (1) Identification as known to the state to cause reproductive toxicity with male or female reproductive toxicity or both denoted as an endpoint in Title 27, California Code of Regulations, section 27001.
 - (2) Meeting the National Toxicology Program criteria as having clear or sufficient evidence of adverse effects for reproductive toxicity, ~~or the equivalent.~~
 - (3) Meeting the criteria for being classified as Category 1 for “known or presumed effects on human reproduction or on development” based on male or female reproductive toxicity data under the United Nations’ Globally Harmonized System for Classification and Labeling of Chemicals.
 - (4) Identification as a known or potential male or female reproductive toxicant or both or having the capacity to cause reproductive toxicity in a report by the National Academy of Sciences’ National Research Council or Institute of Medicine.
 - (5) Identification in the National Institute for Occupational Safety and Health (“NIOSH”) Pocket Guide to Chemical Hazards with having reproductive organs as the target organ or as having sterility or other reproductive effects.
 - (6) ~~The chemical substance is recognized as a~~ Recognition as a male or female reproductive hazard by California, other states, the United States or other nations toxicant by an authoritative organization.
- (b) Each of the following constitutes suggestive evidence of reproductive toxicity for a given chemical substance:
- (1) Meeting the National Toxicology Program criteria as having “some or limited evidence of adverse effects” ~~“limited evidence of adverse effects,” or the equivalent,~~ for reproductive toxicity.
 - (2) Recognition as a suspected reproductive toxicant, ~~or the equivalent,~~ by ~~California, other states, the United States or other nations;~~ an authoritative organization.
 - (3) Strong evidence for the Genotoxicity Hazard Trait ~~per~~ pursuant to Article 3 subsection 69403.5 of this Chapter or the Endocrine Toxicity Hazard Trait ~~per~~ pursuant to Article 3 subsection 69403.3 of this Chapter with mechanisms of genotoxicity or endocrine ~~disruption~~ toxicity likely to be involved in reproductive toxicity.
 - (4) Supportive studies, as defined by the National Toxicology Program, indicating possible male or female reproductive toxicity.
 - (5) Mechanistic evidence that is suggestive of reproductive toxicity potential, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in reproductive toxicity.

- (6) Strong indications of reproductive toxicity from structure activity relationships, including but not limited to those from ~~validated~~ Quantitative Structure Activity Relationship models.

Article 3. Other Toxicological Hazard Traits

§ 69403 General

This article specifies toxicological hazard traits and endpoints and other relevant data for toxicological hazard traits that are not otherwise addressed in Article 2 of this Chapter.

§ 69403.1 Cardiovascular Toxicity

- (a) The cardiovascular toxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the heart or the vascular system following exposure to a chemical substance.
- (b) Toxicological endpoints for cCardiovascular toxicity ~~endpoints~~ include but are not limited to observations indicating: structural effects associated with cell necrosis, cellular degeneration, proliferation, fibrosis, or inflammation of the heart or vasculature, atherosclerosis, thickening of arterial walls, or cardiac hypertrophy; functional effects such as arrhythmia or changes in rhythmicity or contractility of the heart, hypo- or hyper- tension, decreased cardiac output, alteration of vascular reactivity or vessel dilation or contraction; outcomes of structural or functional impairment including high blood pressure, myocardial infarct; or cardiac failure; epidemiological or laboratory animal observations of cardiovascular morbidity or mortality in association with chemical substance exposure.
- (c) Other relevant cardiovascular toxicity data include but are not limited to: markers of systemic inflammation; alteration of the electrophysiology of isolated cardiomyocytes; dysregulation of cytokines; platelet activation and aggregation; perturbation of clotting; changes in cardiomyocytes gene expression involved in heart disease; alterations of cell signaling related to vascular or heart disease; *in vitro* measures of cardiovascular toxicity such as cytotoxicity to isolated vascular endothelial cells; structural or mechanistic similarity to other chemical substances ~~with the cardiovascular toxicity hazard trait~~ that are toxic to the cardiovascular system.

§ 69403.2 Dermatotoxicity

- (a) The dermatotoxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the skin including its barrier properties and its ability to maintain heat, fluid, or electrolyte homeostasis following exposure to a chemical substance.

- (b) Toxicological endpoints for dermatotoxicity include but are not limited to those indicating: allergic sensitization, allergic reactions, acute or subacute irritation, photosensitivity, or corrosivity measured in *in vivo* and *in vitro* skin models.
- (c) Other relevant dermatotoxicity data include, but are not limited to: *in vitro* measures of dermatotoxicity such as toxicity in cell-based models; ~~and~~ structural or mechanistic similarity to other chemical substances ~~with the dermatotoxicity hazard trait~~ that are dermatotoxic.

§ 69403.3 Endocrine Toxicity

- (a) The endocrine toxicity hazard trait is defined as the occurrence of adverse effects following exposure to a chemical substance on the structure or function of the endocrine system, including endocrine disruption and metabolic syndrome.
- (b) Toxicological endpoints for endocrine toxicity endpoints include but are not limited to those indicating: adverse effects on endocrine organs; adverse perturbations of the synthesis, secretion, transport, binding, action, or elimination of natural hormones or their receptors in the body that are responsible for the maintenance of homeostasis, metabolism, reproduction, development or behavior.
- (c) Other relevant data include but are not limited to: binding of a chemical substance or its metabolites to hormones or hormonal receptors or inhibition of hormone synthesis *in vitro* experimental models; induction of hormone metabolic enzymes; modulation of genes involved in metabolic syndrome; structural or mechanistic similarity to other chemical substances ~~with the endocrine toxicity hazard trait~~ that are toxic to endocrine systems.

§ 69403.4 Epigenetic Toxicity

- (a) The epigenetic toxicity hazard trait is defined as changes, at the cellular or organism level, in gene expression or gene function that do not involve changes in the DNA sequence and contribute to adverse effects in an organism, following exposure to a chemical substance.
- (b) Toxicological endpoints for epigenetic toxicity endpoints include, but are not limited to those indicating: toxicity in humans or animals associated with epigenetic mechanisms such as chemically induced DNA methylation, histone modification, nucleosome remodeling, or non-coding RNA. Chemically induced epigenetic endpoints may be observed in an exposed ~~individual~~ organism or its offspring.
- (c) Other relevant epigenetic toxicity data include but are not limited to: *in vitro* or other data using biological models indicative of chemically induced epigenetic toxicity in an exposed ~~individual~~ organism or its offspring; or structural or

mechanistic similarity to other chemical substances that induce adverse epigenetic effects.

§ 69403.5 Genotoxicity

- (a) Genotoxicity is defined as the occurrence of a chemical substance-induced change, either direct or indirect, to the cellular genome, including DNA sequences or chromosomes.
- (b) Toxicological endpoints for gGenotoxicity-endpoints include but are not limited to those indicating: DNA damage, mutations in genes, chromosomal aberrations, micronuclei, sister chromatid exchange, aneuploidy, polyploidy, DNA adduct formation, or unscheduled DNA synthesis in humans, animals, other organisms or cell lines.
- (c) Other relevant data include but are not limited to: data on protein-adduct formation; electrophilic potential; abasic sites; protein-DNA crosslinks; structural or mechanistic similarity to other chemical substances ~~with the genotoxicity hazard trait~~ that are genotoxic.

§ 69403.6 Hematotoxicity

- (a) The hematotoxicity hazard trait is defined as the occurrence of adverse effects on blood or blood-forming tissues following exposure to a chemical substance.
- (b) Toxicological endpoints for hHematotoxicity-endpoints include, but are not limited to those indicating: alterations in the number, types or lifetime of circulating blood cells, or in the ratio of cell types; decrease in the oxygen transporting capacity of hemoglobin or red blood cells; increase or decrease in blood clotting activity resulting from interference in platelet response or function or other causes; bone marrow toxicity; aplastic, hemolytic or myelodysplastic anemia.
- (c) Other relevant data include but are not limited to: *in vitro* measures of toxicity in isolated blood cells or blood-forming tissues; structural or mechanistic similarity to other chemical substances ~~with the hematotoxicity hazard trait~~ that are hematotoxic.

§ 69403.7 Hepatotoxicity and Digestive System Toxicity

- (a) The hepatotoxicity and digestive system toxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the liver, gall bladder, or gastrointestinal tract following exposure to a chemical substance.
- (b) Toxicological eEndpoints for hepatotoxicity and digestive system toxicity include, but are not limited to those indicating: liver damage; fatty liver; hepatitis; canicular cholestasis; vascular changes; steatosis; bile duct damage; gall bladder disease; gastrointestinal tract dysfunction including emesis and acid reflux disorder;

sinusoidal damage; cirrhosis; or inflammation or hyperplasia of the gastrointestinal epithelium.

- (c) Other relevant hepatotoxicity and gastrointestinal toxicity data include but are not limited to those indicating: elevated pro-inflammatory cytokines, induction or inhibition of xenobiotic metabolizing enzymes; generation of reactive metabolites; disruption of glucose or glycogen metabolism; impaired or unbalanced serum protein production; *in vitro* indicators of hepatotoxicity; structural or mechanistic similarity to other chemical substances ~~with the hepatotoxicity and digestive system toxicity hazard trait~~ that are hepatotoxic or cause digestive system toxicity.

§ 69403.8 Immunotoxicity

- (a) Immunotoxicity is defined as the occurrence of adverse effects on the components or function of the immune system following exposure to a chemical substance.
- (b) Toxicological eEndpoints for immunotoxicity include but are not limited to those indicating: allergic sensitization, those indicating hypersensitivity (types I-IV); changes in circulating immune cell numbers; gross and histopathological changes in lymphoid organs; alterations in cytokine production and release; changes in number or behavior of regulatory effector cells; *in vivo* suppression or enhancement of the immune response; changes in specific immunoglobulins; changes in immune organ weights; *in vitro* or *ex vivo* indicators of heightened or suppressed immune response; initiation or exacerbation of autoimmunity.
- (c) Other relevant immunotoxicity data include but are not limited to: high antigenicity; structural or mechanistic similarity to other chemical substances ~~with the immunotoxicity hazard trait~~ that are immunotoxic.

§ 69403.9 Musculoskeletal Toxicity

- (a) The musculoskeletal toxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the musculoskeletal system following exposure to a chemical substance. The musculoskeletal system includes bones, muscles, cartilage, tendons, ligaments, joints and connective tissue.
- (b) Toxicological eEndpoints for musculoskeletal toxicity include, but are not limited to those indicating: necrosis, inflammation, discomfort or pain of the musculoskeletal system; arthritis; decreased joint movement; changes in mineral content of bone including tooth mottling; osteomalacia; osteoporosis; bone malformation or other skeletal growth disorders; abnormal bone mass or density indices; tooth loss; cell proliferation or altered ratio of musculoskeletal cells; fibromyalgia; adverse muscle or neuromuscular function.

- (c) Other relevant musculoskeletal toxicity data include, but are not limited to: *in vitro* indicators of musculoskeletal toxicity; structural or mechanistic similarity to other chemical substances ~~with the musculoskeletal toxicity hazard trait~~ that are toxic to the musculoskeletal systems.

§ 69403.10 Nephrotoxicity and Other Toxicity to the Urinary System

- (a) The nephrotoxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the kidney and other components of the urinary system following exposure to a chemical substance.
- (b) Toxicological endpoints for nephrotoxicity and other urinary system toxicity include, but are not limited to those indicating: abnormal urine volume or chemistry; abnormal blood chemistry; alterations in glomerular filtration rate or tubular re-absorptive capacity; pathological changes to the kidney; formation of calculi in the ureter or bladder; muscular or epithelial damage in the urinary bladder.
- (c) Other relevant data include, but are not limited to: *in vitro* indicators of nephrotoxicity; structural or mechanistic similarity to other chemical substances with this hazard trait that are nephrotoxic.

§ 69403.11 Neurodevelopmental Toxicity

- (a) The neurodevelopmental toxicity hazard trait is defined as the occurrence of adverse effects on development of the nervous system resulting from exposure to a chemical substance during the developmental period, including effects on the structure or function of the central or peripheral nervous system, such as neurochemical, neurophysiological, neuroanatomical, or behavioral alterations.
- (b) Toxicological endpoints for neurodevelopmental toxicity include but are not limited to: alterations in neuromuscular, sensory, cognitive (learning and memory), integrative or autonomic functions; neuropathological changes including gross change in size or shape of the brain or brain regions, death of neuronal precursors, abnormal proliferation, migration, differentiation, or alterations in transient developmental structures, or hydrocephalus.
- (c) Other relevant developmental neurotoxicity data include but are not limited to evidence of neurotoxicity in adult animals; in vitro indicators of toxicity such as in isolated neuronal precursor cells or stem cells, or neurosphere models; structural or mechanistic similarity to chemicals that are toxic to the developing nervous system.

§ 69403.11—12 Neurotoxicity

- (a) The neurotoxicity hazard trait is defined as the occurrence of adverse effects, following exposure to a chemical substance, on the structure or function of the

central or peripheral nervous system, such as neurochemical, neurophysiological, or behavioral effects, ~~and includes developmental neurotoxicity.~~

- (b) Toxicological eEndpoints for neurotoxicity include, but are not limited to those indicating: pathological changes in the central or peripheral nervous systems; abnormal electrical activity of the central or peripheral nervous systems; altered neurochemical synthesis, storage, secretion or uptake; impairments in neuromuscular control; mood disorders; behavioral changes; impaired cognition including IQ decrements.
- (c) Other relevant neurotoxicity data include but are not limited to: *in vitro* indicators of neurotoxicity in isolated nervous system cells; structural or mechanistic similarity to other chemical substances ~~with the neurotoxicity hazard trait~~ that are neurotoxic.

§ 69403.12—13 Ocular Toxicity

- (a) The ocular toxicity hazard trait is defined as the occurrence of adverse changes to the components or function of the visual system following exposure to a chemical substance.
- (b) Toxicological eEndpoints for ocular toxicity include but are not limited to those indicating: damage to the iris, conjunctiva, lens or cornea; abnormal reaction to light; damage to the eye lids or nictitating membranes; functional or structural damage to the retina; damage to or induction of functional abnormalities to the ocular portions of the central nervous system.
- (c) Other relevant ocular toxicity data include, but are not limited to physicochemical properties such as pH and chemical reactivity; data on dermal irritancy or corrosivity; structural or mechanistic similarity to other chemical substances ~~with the ocular toxicity hazard trait~~ that induce ocular toxicity.

§ 69403.13—14 Ototoxicity

- (a) The ototoxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the inner ear or the vestibulo-cochlear nerve, or auditory portions of the central nervous system, which could result in temporary or permanent disturbances of hearing, balance, or both following exposure to a chemical substance.
- (b) Toxicological eEndpoints for ototoxicity include, but are not limited to those indicating: hearing impairment; abnormal balance; changes to cellular components of the inner ear; change in auditory response or electrical activity in the ~~vestibule~~ vestibulo-cochlear nerve or auditory areas of the brain.
- (c) Other relevant ototoxicity data include but are not limited to: *in vitro* indications of ototoxicity; structural or mechanistic similarity to other chemical substances ~~with~~

~~the ototoxicity hazard trait that are ototoxic.~~

§ 69403.14—15 Reactivity in Biological Systems

- (a) The reactivity in biological systems hazard trait is defined as the occurrence of rapid reactions with molecules in the body that lead to alterations in critical molecular function and ultimately adverse health outcomes.
- (b) Toxicological endpoints for reactivity in biological systems include, but are not limited to: covalent binding to or oxidation of cellular macromolecules; *in vivo* generation of reactive oxygen species or oxidative stress; catalytic generation of hydroxyl radicals *in vivo*.
- (c) Other relevant data include, but are not limited to: *in vitro* measurements of covalent binding to or oxidation of DNA, lipids or proteins; detection of reactive species in cell culture; structural or mechanistic similarity to other chemical substances ~~with the reactivity in biological systems hazard trait~~ that are reactive in biological systems.

§ 69403.15—16 Respiratory Toxicity

- (a) The respiratory toxicity hazard trait is defined as the occurrence of adverse effects on an adverse change in the structure or function of the respiratory tract following exposure to a chemical substance, including respiratory tract injury or decreased ability of the lungs to function in gas exchange.
- (b) Toxicological endpoints for respiratory toxicity include, but are not limited to those indicating: respiratory irritation; pathological changes to the airway or other lung structures; inflammation; fibrosis; hypersensitivity pneumonitis; airways hyperresponsiveness; altered lung function; asthma; airways remodeling; increased respiratory infections; altered composition of bronchoalveolar lavage fluid.
- (c) Other relevant data include but are not limited to: *in vitro* evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers; long half-life in the lung; chemical reactivity; redox potential; structural or mechanistic similarity to other chemical substances ~~with the respiratory toxicity hazard trait~~ that are toxic to the respiratory system.

§ 69403.16—17 Evidence for Other Toxicological Hazard Traits

- (a) For a given chemical substance, either of the following constitutes strong evidence of any of the hazard traits identified in this article:
 - (1) An authoritative organization identifies or otherwise indicates that the chemical substance has the hazard trait by:
 - (A) concluding based on well-conducted scientific studies that the chemical has the hazard trait.

- (B) using the hazard trait in a hazard identification, dose-response assessment or risk assessment.
 - (C) including the chemical substance on a list of substances identified as having, or being regulated based on, the hazard trait.
- (2) ~~Two or more~~The available data from well-conducted scientific studies that show that exposure to the chemical substance induces a toxicological endpoint or endpoints for the hazard trait.
- (b) For a given chemical substance, each of the following constitutes suggestive evidence of any of the hazard traits identified in this article:
- (1) An authoritative organization identifies or discusses the chemical substance as possibly having the hazard trait.
 - (2) ~~A~~The available data from well-conducted scientific studies ~~sy indicates~~ suggest exposure to the chemical substance induces a toxicological endpoint or endpoints for the hazard trait.
 - (3) Mechanistic evidence that is suggestive of the hazard trait, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in causing the hazard trait.
 - (4) Strong indications of the hazard trait from structure activity relationships, including but not limited to those from ~~validated~~ Quantitative Structure Activity Relationship models.

Article 4. Environmental Hazard Traits

§ 69404 General

This article specifies environmental hazard traits and endpoints and other relevant data for these traits.

§ 69404.1 Domesticated Animal Toxicity

- (a) The domesticated animal toxicity hazard trait is defined as the occurrence of adverse health effects on pets or livestock from exposure to a chemical substance.
- (b) Environmental endpoints for domesticated animal toxicity include but are not limited to: observations of reproductive or developmental toxicity, morbidity or mortality of pets or livestock following exposure to a chemical substance.
- (c) Other relevant data include but are not limited to endpoint data described in Articles 2 or and 3 or and Article 4 subsections 69404.6, 69404.7, 69404.8, or and 69404.9 of this Chapter, showing the potential for effects in a pet or livestock species.

§ 69404.2 Eutrophication

- (a) The eutrophication hazard trait is defined as contributing to adverse changes in aquatic or soil ecosystems resulting from the release of excess chemical nutrients or substances increasing the availability of nutrients. Observed adverse changes typically include excessive plant growth, hypoxia in aquatic systems and changes in species composition.
- (b) Environmental endpoints for eutrophication include, but are not limited to those indicating: excessive plant growth, hypoxia, or changes in species composition following the release of excess nutrients or substances increasing the availability of nutrients.
- (c) Other relevant data include but are not limited to modeling to predict the impact of chemicals on nutrient levels and plant growth in aquatic and terrestrial ecosystems.

§ 69404.3 Impairment of Waste Management Organisms

- (a) The impairment of waste management organisms hazard trait is defined as adverse changes to biota relied upon in aerobic and anaerobic sewage treatment, and waste recycling.
- (b) Environmental endpoints for impairment of waste management organisms include but are not limited to: toxicity to microorganisms, such as bacteria and algae, used in sewage treatment processes, or respiration inhibition of activated sludge following exposure to a chemical substance.
- (c) Other relevant data include but are not limited to mechanistic or structural similarity to other chemicals that impair waste management organisms.

§ 69404.4 Loss of Genetic Diversity, Including Biodiversity

- (a) The loss of genetic diversity hazard trait is defined as contributing to adverse change in the genetic make-up of a species, community, assemblage or ecosystem following exposure to a chemical substance.
- (b) Environmental endpoints for loss of genetic diversity, including biodiversity include, but are not limited to those indicating: reduction in the abundance of species within a community, assemblage or ecosystem, or the genetic make-up of local populations in aquatic or terrestrial ecosystems.
- (c) Other relevant data include but are not limited to in silico predictions of changes in genetic diversity. ~~Associative data from field studies linking exposure to a chemical substance with changes in genetic diversity or biodiversity are also considered relevant.~~

§ 69404.5 Phytotoxicity

- (a) The phytotoxicity hazard trait is defined as the occurrence of adverse effects on the reproduction, development, growth, function or survival of plants following exposure to a chemical substance. For the purpose of this hazard trait, “plants” mean vascular and nonvascular plants, algae, fungi and lichen present in the aquatic and terrestrial environment, including harvested species.
- (b) Environmental endpoints for phytotoxicity ~~Endpoints~~ include, but are not limited to those indicating: adverse effects on survival, fecundity, fertility, ~~gross developmental anomalies~~, growth, abundance, production, function or normal physiology in plants; gross developmental anomalies.
- (c) Other relevant phytotoxicity impairment data include but are not limited to: mechanistic or structural similarity to other phytotoxicants; *in vitro* evidence of exposure-related adverse impacts in plants; ~~Associative data from field studies linking exposure to a chemical substance with observed phytotoxicity are also considered relevant.~~

§ 69404.6 Wildlife Developmental Impairment

- (a) The wildlife developmental impairment hazard trait is defined as the occurrence of adverse effects on the structure or function of the developing organism, including aquatic and terrestrial organisms, following exposure to a chemical substance.
- (b) Environmental endpoints for wildlife development impairment ~~Endpoints~~ include, but are not limited to those indicating: malformations, exposure related adverse impacts on rate of development, neurodevelopment, metamorphosis, or morphometrics in animal organisms, including aquatic and terrestrial species.
- (c) Other relevant developmental impairment data include but are not limited to: mechanistic or structural similarity to other chemical substances that impair wildlife development; data on mechanisms of mammalian developmental toxicity as described for ~~human health~~ the toxicological hazard traits in Article 2 subsection 69402.3 of this Chapter; mechanistic data specific to non-mammalian wildlife; ~~Associative data from field studies linking exposure to a chemical substance with adverse changes in development are also considered relevant.~~

§ 69404.7 Wildlife Growth Impairment

- (a) The wildlife growth impairment hazard trait is defined as the occurrence of adverse changes in absolute growth, proportional growth or growth rate in organisms, including aquatic and terrestrial organisms, following exposure to a chemical substance.

- (b) Environmental endpoints for wildlife growth impairmentEndpoints include, but are not limited to those indicating ~~abnormalities~~ abnormalities in growth rates or body size indices observed in animals, including aquatic and terrestrial species.
- (c) Other relevant growth impairment data includes but are not limited to: mechanistic or structural similarity to other chemicals that impair wildlife growth; mechanistically based markers of data on growth retardation; ~~Associative data~~ Associative data from field studies linking exposure to a chemical substance with adverse changes in wildlife growth ~~are also considered relevant.~~

§ 69404.8 Wildlife Reproductive Impairment

- (a) The wildlife reproductive impairment hazard trait is defined as the occurrence of adverse effects on the reproductive system or sexual function of wildlife, including aquatic and terrestrial organisms, following exposure to a chemical substance that may reduce reproductive capacity in the environment.
- (b) Environmental endpoints for wildlife reproductive impairmentEndpoints include, but are not limited to those indicating: adverse changes in reproductive endocrine function, sexual maturation, structure and function of reproductive organs, including intersex and imposex organs, secondary sex characteristics, behavior related to reproduction such as mating and parental care, vitellogenin production, fecundity, fertility, or offspring sex ratio observed in the laboratory or in a wild population, including aquatic and terrestrial species. Endpoints of toxicity described for ~~human health~~ the toxicological hazard traits in Article 2 subsections 69402.5 and 69403.3 of this Chapter are also valid endpoints for wildlife reproductive impairment.
- (c) Other relevant reproductive impairment data include but are not limited to: mechanistic or structural similarity to other chemical substances that impair wildlife reproduction; *in vitro* evidence of exposure related perturbations of the hypothalamic-pituitary-gonadal axis; agonism of the aryl hydrocarbon receptor; binding or disruption of the function of the estrogen or androgen receptors; toxicogenomic responses associated with reproductive impairment; ~~or other relevant data as described for toxicological hazard traits in Article 2 Subsections 69402.5 and or Article 3 subsection 69403.3 of this Chapter.~~ Associative data from field studies linking exposure to a chemical substance with reductions in animal reproduction ~~are also considered relevant.~~

§ 69404.9 Wildlife Survival Impairment

- (a) The wildlife survival impairment hazard trait is defined as the occurrence of increased incidence of death, disease or other biological impairment, following exposure to a chemical substance that may decrease the potential for wildlife survival, including in aquatic and terrestrial species.

- (b) Environmental endpoints for wildlife survival impairment Endpoints include, but are not limited to, those indicating: death; aquatic or terrestrial toxicity; toxicity described for ~~human health~~ toxicological hazard traits in Articles 2 and 3 of this ~~proposed regulation chapter~~; non-specific toxicity such as narcosis, behavioral impacts, increased disease susceptibility, or changes in population viability observed in the laboratory or in wild populations, including aquatic and terrestrial species.
- (c) Other relevant survival impairment data include but are not limited to: structural or functional similarity to chemical substances shown to impair wildlife survival; *in vitro* evidence described for ~~human health~~ toxicological hazard traits in Articles 2 and 3 of this Chapter; data from *in vitro* testing designed specifically for ecotoxicological endpoints; ~~A~~ associative data from field studies suggesting a possible link between a chemical and community or ecosystem level impacts ~~are also considered relevant~~.

§ 69404.10 Evidence for Environmental Hazard Traits

- (a) For a given chemical substance, either of the following constitutes strong evidence of any of the hazard traits identified in this article:
- (1) An authoritative organization identifies or otherwise indicates that the chemical substance has the hazard trait by:
 - (A) concluding based on well-conducted scientific studies that the chemical has the hazard trait.
 - (B) using the hazard trait in a hazard identification, dose-response assessment, risk assessment, or other scientific evaluation.
 - (C) including the chemical substance on a list of substances identified as having, or being regulated based on, the hazard trait.
 - (2) ~~Two or more~~ The available data from well-conducted scientific studies that show that exposure to the chemical substance induces an environmental endpoint or endpoints for the hazard trait. Studies include, but are not limited to, standard aquatic and terrestrial toxicity testing as well as research-based investigations.
- (b) For a given chemical substance, each of the following constitutes suggestive evidence of any of the hazard traits identified in this article:
- (1) An authoritative organization identifies or discusses the chemical substance as possibly having the hazard trait.
 - (2) ~~A~~ The available data from well-conducted scientific studies suggesty ~~indicates~~ exposure to the chemical substance induces a toxicological endpoint or endpoints for the hazard trait. ~~The study~~ Studies can be, but ~~is~~ are not limited to, ~~a~~ standard aquatic and terrestrial toxicity tests or a research-based investigation.

- (3) Mechanistic evidence that is suggestive of the hazard trait, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in causing the hazard trait.
- (4) Strong indications of the hazard trait from structure activity relationships, including but not limited to those from ~~validated~~ Quantitative Structure Activity Relationship programs.

Article 5. Exposure Potential Hazard Traits

§ 69405 General

This article specifies exposure potential hazard traits.

§ 69405.1 Ambient Ozone Formation

- (a) The ambient ozone formation hazard trait is defined as the capacity for chemical substances such as volatile organic compounds to react, outdoors in the presence of ultraviolet light to generate ozone and other oxidants or indoors in the presence of visible light, to produce ozone.
- (b) Evidence for the ambient ozone formation hazard trait includes but is not limited to: measurements of reactivity of the chemical substance, such as the Maximal Reactivity Scale adopted by the California Air Resources Board pursuant to Health and Safety Code section 41712.

§ 69405.2 Bioaccumulation

- (a) The bioaccumulation hazard trait is defined as the accumulation of a chemical substance in the tissue of organisms through any route, including respiration, ingestion, or dermal, including~~or~~ direct contact with contaminated water, sediment, and pore water in the sediment, or through ~~biomagnification-transfer~~ up the food chain.
- (b) Evidence for the bioaccumulation hazard trait includes but is not limited to: the identification of a substance to be bioaccumulative by an authoritative organization; studies which show bioaccumulation in animal or human, domesticated animal, wildlife or plant tissues; inhibition of an efflux transporter; transfer of the chemical up a food web; a trophic magnification factor or biomagnification factor greater than 1 in aquatic or terrestrial systems; for organic chemicals, a bioaccumulation or bioconcentration factor greater than 1000; a log octanol water partition coefficient greater than or equal to 45, or a log octanol-air partition coefficient greater than or equal to 5; results from bioaccumulation models indicating potential for bioaccumulation; structural similarity to other bioaccumulative chemicals.

§ 69405.3 Environmental Persistence

- (a) The environmental persistence hazard trait is defined as the propensity for a chemical substance to remain in the environment for a long time period subsequent to its release, by resisting chemical and biological degradation.
- (b) Evidence for environmental persistence includes but is not limited to: the identification of a substance to be persistent by an authoritative organization; resistance to degradation in wastewater treatment processes; half-lives in marine, fresh or estuary water of greater than 40 to 60 days, in marine sediment of greater than 2 months, in ambient air of greater than 2 days, or in soil of greater than 2 months; structural similarity to other persistent chemicals.

§ 69405.4 Global Warming Potential

- (a) The global warming potential hazard trait is defined as the propensity for a chemical substance to be a greenhouse gas, that is, to absorb infra-red radiation in the atmosphere, and thereby contribute to the general warming of the planet.
- (b) Evidence for the global warming hazard trait includes but is not limited to: measures of the global warming potential which meet the criteria of the International Panel on Climate Change as a global warming substance.

§ 69405.5 Lactational or Transplacental Transfer

- (a) The lactational or transplacental transfer hazard trait is defined as the ability of a chemical substance to transfer from the mother's tissues into breast milk or across the placenta.
- (b) Evidence for lactational or transplacental transfer ~~can be indicated by~~ includes but is not limited to: studies measuring measurement of the chemical substance in mother's milk or crossing the placenta into fetal circulation, or by or the chemical substance possessing having physical-chemical or pharmacokinetic properties associated with movement into mother's milk or across the placenta.

§ 69405.6 Mobility in Environmental Media

- (a) The mobility in environmental media hazard trait is defined as the capacity of a chemical substance for rapid movement in the environment.
- (b) Evidence for environmental mobility of a chemical substance includes, but is not limited to: reports in the scientific literature of environmental mobility; evidence of widespread contamination of the food chain or global distribution or ubiquitousness in the environment; ~~volatility, water solubility, or other physico-chemical characteristics predisposing to ease of movement through~~ environmental compartments such as air, water, or soil.

§ 69405.7 Particle Size or Fiber Dimension

- (a) The particle size or fiber dimension hazard trait is defined as the existence of a chemical substance in the form of small particles or fibers or the propensity to form into such small-sized particles or fibers with use or environmental release.
- (b) Evidence for the particle size or fiber dimension hazard trait includes, but is not limited to: measures of particle size less than or equal to 10 micrometers in mass median aerodynamic diameter for inhalation exposure, or less than 10 micrometers in any dimension for dermal or ingestion exposure, or fibers with a 3:1 aspect ratio and a width less than or equal to 3 micrometers.

§ 69405.8 Stratospheric Ozone Depletion Potential

- (a) This hazard trait is defined as the capacity for a chemical substance to deplete stratospheric ozone, and thereby contribute to higher levels of ultraviolet B radiation reaching the earth's surface.
- (b) Evidence for the stratospheric ozone depletion hazard trait includes but is not limited to: listing of a chemical substance in the Montreal Protocol or by the U.S. EPA-Environmental Protection Agency pursuant to Section 612(a) of the Clean Air Act as a substance that depletes stratospheric ozone.

Article 6. Physical Hazard Traits**§ 69406 General**

This article specifies physical hazard traits.

§ 69406.1 Combustion Facilitation

- (a) The combustion facilitation hazard trait is defined as a hazard due to a substance causing or contributing to the combustion of another material.
- (b) Evidence for this hazard trait includes, but is not limited to meeting the criteria for being an oxidizing gas in section 2.4, oxidizing liquid in section 2.13, oxidizing solid in section 2.14 of the Globally Harmonized System of Classification and Labeling of Chemicals.

§ 69406.2 Explosivity

- (a) The explosivity hazard trait is defined as a hazard that results from chemical reaction that produces gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings.
- (b) Evidence for this hazard trait includes but is not limited to: meeting the criteria for being an explosive in section 2.1 or for organic peroxide type A or B in section 2.15 of the Globally Harmonized System of Classification and Labeling of Chemicals.

§ 69406.3 Flammability

- (a) The flammability hazard trait is defined as hazards due to substances that ignite or heat under certain conditions, causing burns or fire.
- (b) Evidence for this hazard trait includes, but is not limited to, meeting the criteria definition of flammable aerosol, flammable gas, flammable liquid, or flammable solid in 29 CFR, Occupational Safety and Health Standards, Part 1910, subpart Z, Toxic and Hazardous Substances, Standard number 1910.1200; meeting the criteria for being a flammable gas in section 2.3, liquid in section 2.6, solid in section 2.7, or aerosol in section 2.3; pyrophoric liquid in section 2.9 or solid in section 2.10; self-reactive substance or mixture in section 2.8; self-heating substance or mixture in section 2.11; substance or mixtures which, in contact with water, emit flammable gases in section 2.12; or types C through F organic peroxides in section 2.15 of the Globally Harmonized System of Classification and Labeling of Chemicals.

Article 7. Additional Relevant Data**§ 69407 General**

This Article identifies types of relevant data in addition to those provided in Articles 2 through 6 of this Chapter that may be included in the Toxics Information Clearinghouse and that can inform chemical evaluations under Health and Safety Code section 25252.

§ 69407.1 Exposure-Response Relationship

Data on the relationship between exposure to a given chemical substance and degree of response include but are not limited to: estimates of potency for carcinogenic effects and other non-cancer toxicity published by authoritative organizations; evidence from well-conducted scientific studies describing or quantifying the relationship between exposure concentration or dose and degree of adverse effect or biological response.

§ 69407.2 Physicochemical properties

Physicochemical properties of chemicals that can inform chemical evaluation include but are not limited to: physical state; molecular weight; density; vapor pressure and saturated vapor pressure; melting point; boiling point; water solubility; lipid solubility; octanol-water partition coefficient, octanol-air partition coefficient, organic carbon partition coefficient; diffusivity in air and water; Henry's Law constant; sorption coefficient for soil and sediment; redox potential; photolysis rates; hydrolysis rates; dissociation constants; or reactivity including electrophilicity.