

1 **INITIAL STATEMENT OF REASONS**

2
3 **SAFER CONSUMER PRODUCTS: CANDIDATE CHEMICAL LIST AMENDMENT**

4
5 **Department Reference Number: R-2014-02**

6
7 **Office of Administrative Law Notice File Number: Z-2015-0922-08**

8
9
10 **TABLE OF CONTENTS**

11

12 **I. SUMMARY OF PROPOSED ACTIONS & REGULATORY PROGRAM ACTIVITIES**

13 **AFFECTED.....2**

14 **II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE & RATIONALE.....2**

15 **III. ECONOMIC IMPACT ANALYSIS5**

16 **IV. REPORTS RELIED ON7**

17 **V. MANDATED USE OF SPECIFIC TECHNOLOGIES OR EQUIPMENT7**

18 **VI. REASONABLE ALTERNATIVES CONSIDERED7**

19 **VII. EVIDENCE SUPPORTING A DETERMINATION THAT THE PROPOSAL WILL**

20 **HAVE NO ADVERSE ECONOMIC IMPACT ON BUSINESS8**

21 **VIII.DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS.....8**

22

1 **I. SUMMARY OF PROPOSED ACTIONS & REGULATORY PROGRAM**
2 **ACTIVITIES AFFECTED**
3

4 The Department of Toxic Substances Control (DTSC) proposes to amend Title 22,
5 California Code of Regulations (22 CCR) section 69502.2(a)(1) to correct or update the
6 citations for three of the lists included in the Candidate Chemicals list. The proposed
7 amendments will result in three additions to the current Candidate Chemical list. This
8 action will have no adverse economic impacts on the private sector because it does not
9 impose regulatory requirements on businesses or individuals.
10

11 **II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE & RATIONALE**
12

13 *Statutory Intent & Requirements*
14

15 The Green Chemistry statutes (Health and Safety Code [HSC] sections 25251-25257.1)
16 are intended to significantly reduce adverse health and environmental impacts of
17 chemicals used in commerce, as well as the overall costs of those impacts to the State
18 of California, by encouraging the redesign of consumer products, manufacturing
19 processes, and approaches.
20

21 HSC sections 25252 and 25253 require DTSC to adopt regulations to:

- 22 • establish a process to identify and prioritize chemicals or chemical ingredients in
23 consumer products based on the volume of the chemical in commerce in
24 California, the potential for exposure to the chemical in consumer products, and
25 the potential for effects on sensitive subpopulations—including infants and
26 children, pregnant women, elderly individuals and workers;
- 27 • use, to the maximum extent feasible, available information from other nations,
28 governments, and authoritative bodies that have undertaken similar chemical
29 prioritization processes; and
- 30 • establish a process for evaluating Chemicals of Concern in consumer products,
31 and their potential alternatives, in order to determine how best to limit exposure
32 or reduce the level of hazard posed by these chemicals.
33

34 The Safer Consumer Products regulations (22 CCR sections 69501, et seq.), adopted in
35 2013, established science-based processes to identify Candidate Chemicals¹; to identify
36 and prioritize product-chemical combinations that include Chemicals of Concern; and to

¹ 22CCR section 69501.1(a)(19) defines a “Candidate Chemical” as a chemical that is a candidate for designation as a Chemical of Concern and that is identified as a Candidate Chemical in section 69502.2.

1 analyze alternatives for improving the safety of consumer products. The regulations
2 further authorize DTSC to require implementation of regulatory responses, following an
3 alternatives analysis, that are necessary to protect public health or the environment.
4 Stakeholders are also allowed to petition DTSC to add or remove chemicals, chemical
5 lists, or product-chemical combinations.

6
7 HSC section 25252(b)(2) required DTSC to use—to the maximum extent feasible—
8 available information from other authoritative organizations that have undertaken similar
9 chemical prioritization processes. DTSC elected to rely on information produced by
10 authoritative organizations whose primary goals were the protection of human health or
11 the environment, and whose work was well respected both nationally and
12 internationally. Using information that was developed and maintained by other
13 organizations allowed DTSC to rapidly assemble a robust list of Candidate Chemicals
14 and initiate the identification of consumer products that could contain Chemicals of
15 Concern.

16
17 The Candidate Chemicals list is composed of chemicals that exhibit specified hazard
18 traits and/or environmental or toxicological endpoints and are included in one or more of
19 the 23 authoritative organizations' lists cited in section 69502.2(a). The following
20 chemicals will not be identified as a Candidate Chemicals: chemicals in products that
21 are exempted under HSC section 25251 (e.g., pesticides and prescription drugs) and
22 chemicals that are not known to exhibit a Chapter 54 hazard trait or environmental or
23 toxicological endpoint.

24
25 Organizations responsible for the authoritative lists cited in section 69502.2(a) may
26 amend them according to their regulatory or procedural requirements. As a result, the
27 Candidate Chemicals list is not static. Per section 69502.3(a), to ensure that all
28 stakeholders—including responsible entities and other interested parties—are
29 adequately informed, DTSC periodically updates the informational Candidate Chemicals
30 list to reflect changes to the underlying lists and sources and posts this information to its
31 website. Per section 69502.3(b), to add or delete entire lists or individual chemicals, or
32 update references to current lists, DTSC must follow the formal procedures specified in
33 the Administrative Procedure Act (commencing with Government Code section 11340).

34
35 Following the adoption of the Safer Consumer Products regulations in October 2013,
36 DTSC noted that the lists in sections 69502.2(a)(1)(C) and 69502.2(a)(1)(G) were cited
37 incorrectly. Recently, DTSC also became aware that a more current edition of the
38 report cited in 69502.2(a)(1)(F) had been published. Timely corrections and updates to
39 the Candidate Chemicals list are necessary to:

- 40 • ensure full implementation of HSC section 25252(b)(2);

- 1 • gain the maximum benefit of using information developed by authoritative
- 2 organizations;
- 3 • accurately identify all appropriate Candidate Chemicals; and
- 4 • provide clear documentation of the sources from which the Candidate Chemicals
- 5 are drawn.

6
7 DTSC is proposing to amend the sections noted below to correct or update the names
8 of the lists or report:

- 9
10 1) **Amend Section 69502.2(a)(1)(C).** This section currently specifies, “chemicals
11 included as Category 1 endocrine disruptors by the European Commission in the
12 candidate list of Substances of Very High Concern in accordance with Article 59
13 of Regulation (EC) 1907/2006.”

14
15 The references to “chemicals included as Category 1 endocrine disruptors” and
16 the “European Commission” are incorrect. Chemicals with endocrine disrupting
17 properties are included in the European Union candidate list of Substances of
18 Very High Concern on the basis of Article 57(f) for endocrine disrupting
19 properties. The European Union does not use a numerical system to categorize
20 chemicals with endocrine disrupting properties; therefore, the currently cited list
21 does not exist. As a result, DTSC was unable to properly incorporate this list into
22 the Candidate Chemical list. By correcting the original drafting errors, DTSC will
23 be able to incorporate chemicals identified as endocrine disruptors on the list of
24 Substances of Very High Concern into the Candidate Chemical list and also to
25 associate them with the hazard trait of endocrine toxicity for the purposes of the
26 informational Candidate Chemical list.

27
28 Many of the chemicals on the candidate list of Substances of Very High Concern
29 for endocrine disrupting properties are already incorporated into the Candidate
30 Chemicals list because they appear on one or more of the currently identified
31 authoritative lists. As a result of this correction, DTSC will add the following to
32 the Candidate Chemical list: 1) 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated,
33 2) 4-nonylphenol, branched and linear, and 3) 4-nonylphenol, branched and
34 linear, ethoxylated, as described on the European Union candidate list of
35 Substances of Very High Concern.

- 36
37 2) **Amend Section 69502.2(a)(1)(F).** This section currently specifies “chemicals
38 that are identified as ‘known to be’ or ‘reasonably anticipated to be’ a human
39 carcinogen in the 12th Report on Carcinogens, United States Department of

1 Health and Human Services (DHHS), Public Health Service, National Toxicology
2 Program.”

3
4 On October 2, 2014, DHHS published the 13th Report on Carcinogens. Each
5 biennial report is cumulative, and every new edition replaces the previous report
6 in its entirety.

7
8 The proposed language updates the reference to the most current version of this
9 report. This proposal does not add new chemicals to DTSC’s Candidate
10 Chemicals list. Three of the four new chemicals added to the 13th edition of this
11 report are already included in DTSC’s Candidate Chemicals list. Two of these
12 chemicals are already associated with the hazard trait of carcinogenicity and the
13 third chemical, 1-bromopropane, will now also be associated with the hazard trait
14 of carcinogenicity in addition to the previously identified hazard traits. The fourth
15 new chemical added to this report is not within the scope of the Safer Consumer
16 Products program because it is solely used as a pesticide.

- 17
18 3) **Amend Section 69502.2(a)(1)(G)**. This section currently specifies, “chemicals
19 included as persistent, bioaccumulative and toxic, or very persistent and very
20 bioaccumulative by the European Commission in the candidate list of
21 Substances of Very High Concern in accordance with Article 59 of Regulation
22 (EC) 1907/2006.”

23
24 The references to “chemicals included as persistent, bioaccumulative and toxic,
25 or very persistent and very bioaccumulative” and the “European Commission” are
26 incorrect. Persistent, bioaccumulative and toxic, or very persistent and very
27 bioaccumulative chemicals are included in the European Union candidate list of
28 Substances of Very High Concern on the basis of Article 57 (d-f) for persistent,
29 bioaccumulative and toxic, or very persistent and very bioaccumulative
30 properties.

31
32 The proposed language corrects the original drafting errors. This proposal does
33 not add new chemicals to DTSC’s Candidate Chemicals list or change the way
34 they are listed in the informational list of Candidate Chemicals.

35 36 **III. ECONOMIC IMPACT ANALYSIS**

37
38 The Candidate Chemical list is an inventory of chemicals that DTSC can consider for
39 designation as a Chemical of Concern in a Priority Product. The intent of this proposed
40 regulatory action is to correct or update citations to the existing Candidate Chemicals

1 list to ensure that the regulations are accurate and up to date. This proposal is not a
2 directed action to capture specific chemicals on the Candidate Chemical list. The
3 proposed amendments will result in three additions to the current Candidate Chemical
4 list, currently comprised of thousands of chemicals, which will be evaluated when DTSC
5 considers new Priority Products with Chemicals of Concern.
6

7 This action will have no adverse economic impacts on the private sector because it
8 does not impose regulatory requirements on businesses or individuals. Businesses and
9 individuals are not required to take specific actions because DTSC is not identifying
10 specific product-chemical combinations in the proposed amendments to these
11 regulations. Given the intent of this regulatory proposal and the very small number of
12 additions relative to the rest of the Candidate Chemical list we do not anticipate any
13 businesses taking action as a result of these regulations. Future regulations from DTSC
14 will specify product-chemical combinations as they are identified.
15

16 In accordance with Government Code §11346.3(b), DTSC has made the following
17 assessments regarding the proposed regulation:
18

19 **Creation or Elimination of Jobs within California**

20 DTSC has determined that this proposed regulation will not create or eliminate jobs.
21

22 **Creation of New Businesses or Elimination of Existing Businesses within**
23 **California**

24 DTSC has determined that this proposed regulation will not result in the creation of new
25 businesses.
26

27 **Expansion of Current California Businesses**

28 DTSC has determined that this proposed regulation will not result in opportunities for
29 growth of California businesses.
30

31 **Anticipated Benefits**

32 The broad objective of the Safer Consumer Products regulations is a comprehensive,
33 state-level effort to find safer alternatives to hazardous chemicals. The use of fewer
34 hazardous chemicals reduces the potential for adverse impacts to the people of
35 California and the environment.
36

37 HSC section 25252 requires DTSC to reference and use—to the maximum extent
38 feasible—available information from other nations, governments, and authoritative
39 bodies that have undertaken similar chemical prioritizations processes, so as to
40 leverage the work and costs already incurred by those entities. By basing the

1 Candidate Chemicals list on externally produced information, DTSC maximized benefits
2 for the state's economy while minimizing program implementation costs. The proposed
3 amendments to sections 69502.2(a)(1)(C), (F), and (G) leverage the European Union's
4 work on the Candidate List of Substances of Very High Concern for Authorization, as
5 well as the National Toxicology Program's work on the biennial Report on Carcinogens.
6

7 Ensuring that authoritative lists used to identify Candidate Chemicals are current and
8 cited correctly minimizes potential confusion as to which chemicals may be identified by
9 DTSC as a Chemical of Concern in a Priority Product. DTSC's actions to ensure
10 accurate, reliable information will encourage manufacturers to use the Candidate
11 Chemicals list to identify potentially hazardous ingredients in their products, avoid
12 regrettable substitutions, and proactively improve the safety of the products sold to
13 California's consumers.
14

15 **IV. REPORTS RELIED ON**

16
17 DTSC relied on the following documents in this rulemaking:
18

- 19 a. European Commission Candidate List of Substances of Very High
20 Concern for Authorisation published in accordance with Article 59(10) of
21 the REACH Regulation. [http://echa.europa.eu/web/guest/candidate-list-](http://echa.europa.eu/web/guest/candidate-list-table)
22 [table](http://echa.europa.eu/web/guest/candidate-list-table). Last updated: June, 15, 2015;
23
- 24 b. 13th Report on Carcinogens, United States Department of Health and
25 Human Services, Public Health Service, National Toxicology Program.
26 <http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html>. Released:
27 October 2, 2014; and
28
- 29 c. Economic Analysis/Assessment (STD 399) for DTSC's amendment to
30 Title 22 section 69502.2(a).
31

32 **V. MANDATED USE OF SPECIFIC TECHNOLOGIES OR EQUIPMENT**

33
34 The proposed regulatory action does not mandate the use of specific technologies or
35 equipment, nor does it prescribe specific actions or procedures.
36

37 **VI. REASONABLE ALTERNATIVES CONSIDERED**

38
39 The proposed amendments will have no adverse economic because they do not impose
40 regulatory requirements on business or individuals. Since there are no impacts, there

1 are no alternatives which would have fewer impacts to businesses or individuals or be
2 more effective in carrying out the purpose of these regulation changes. Taking no
3 action was not considered a viable alternative for this proposed regulatory action due to
4 the critical nature of correcting and updating citations in the Safer Consumer Products
5 regulations.

6
7 **VII. EVIDENCE SUPPORTING A DETERMINATION THAT THE PROPOSAL WILL**
8 **HAVE NO ADVERSE ECONOMIC IMPACT ON BUSINESS**

9
10 The proposed regulatory action seeks to correct or update citations to the existing
11 Candidate Chemicals lists. The proposed amendments will result in three additions to
12 the current Candidate Chemical list which will be evaluated when DTSC considers new
13 Priority Products with Chemicals of Concern.

14
15 This action will have no adverse economic impacts on the private sector because it
16 does not impose regulatory requirements on businesses or individuals. Although
17 businesses and individuals are not required to take action as a result of this
18 amendment, they may opt to use this information when they evaluate their product
19 manufacturing processes

20
21 **VIII. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS**

22
23 The proposed regulation does not duplicate or conflict with existing federal law. DTSC
24 identified existing lists to leverage resources and achieve results benefiting common
25 goals—preventing exposures to harmful chemicals in consumer products. The
26 chemicals identified as Candidate Chemicals with hazard traits are based on
27 deliberative work conducted by authoritative organizations, and compiled from lists of
28 chemicals created by the authoritative organizations identified in section 69502.2(a).

29
30 Building on the work done by authoritative bodies will allow DTSC to speed up the
31 implementation of these regulations by reducing the need to duplicate work already
32 completed to construct the lists. It is also consistent with the statutory directive to
33 leverage the work of other “nations, governments, and authoritative bodies that have
34 undertaken similar chemical prioritization processes, so as to leverage the work and
35 costs already incurred by those entities and to minimize costs and maximize benefits for
36 the state’s economy” (HSC section 25252(b)(2)).