

FINAL STATEMENT OF REASONS

SAFER CONSUMER PRODUCTS REGULATIONS – Listing Nail Products Containing Toluene as a Priority Product

Department of Toxic Substances Control Reference Number: R-2019-04
Office of Administrative Law Notice Reference Number: Z2021-0921-06

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UPDATED INFORMATIVE DIGEST

Changes to Existing Statutes or Regulations

There have been no changes in applicable laws from the laws described in the Notice of Proposed Action dated October 1, 2021, or the 15-Day Notice of Modified Text and Availability of Additional Documents and Information dated January 20, 2023. The proposed regulations described in the Notice of Proposed Action dated October 1, 2021, and the 30-Day Notice of Modified Text and Availability of Additional Documents and Information dated July 8, 2022, were partially approved by the Office of Administrative Law (OAL) on November 14, 2022. There have been no other changes to the effect of the proposed regulations from the effects described in the 15-Day Notice of Modified Text and Availability of Additional Documents and Information dated May 15, 2023.

GENERAL INFORMATION

Update to the Initial Statement of Reasons

As authorized by Government Code section 11346.9, subsection (d), the Department of Toxic Substances Control (DTSC) incorporates by reference the complete rulemaking package for OAL Regulatory Number 2022-0930-02, including the Final Statement of

Reasons and the Form 399 signed by the Department of Finance on September 29, 2022.

Changes to the Proposed Regulatory Text

Changes to the proposed regulatory text, along with documents relied upon, were released for public comment from January 20, 2023, through February 6, 2023, and again from May 15, 2023, through May 30, 2023. The detailed statement of specific purpose and rationale for the changes in the proposed regulatory text are described below.

DETAILED STATEMENT OF SPECIFIC PURPOSE AND RATIONALE

Add Section 69511.6(h).

Purpose. This section specifies that a manufacturer submitting an Alternatives Analysis Threshold Notification (AATN) must demonstrate and certify that the concentration of toluene in a Priority Product does not exceed the Alternatives Analysis Threshold (AAT). Further, this section also clearly states the timeframe in which a manufacturer must notify DTSC if their Alternatives Analysis (AA) exemption status changes.

Necessity. This section is necessary to ensure that manufacturers who assert that they are exempt from AA requirements understand the reporting requirements.

Add Section 69511.6(h)(1).

Purpose. This section specifies that there are two ways for a manufacturer to demonstrate that their Priority Product meets the exemption from completing an AA by submitting the following with an AATN:

- certificates of analyses from ingredient suppliers as well as calculations of toluene in the final product; or
- laboratory testing results from analysis conducted by a testing laboratory which meets the method performance criteria specified in the regulation.

Necessity. This section is necessary to ensure that manufacturers who assert that they are exempt from AA requirements understand what is acceptable to demonstrate and certify that the concentration of toluene in a Priority Product does not exceed the AAT of 100 ppm.

Add Section 69511.6(h)(2).

Purpose. This section specifies the information that manufacturers must provide to DTSC when they submit laboratory testing results to certify and demonstrate that their product(s) meet AATN requirements.

Necessity. This section is necessary to ensure that manufacturers understand what they must submit to DTSC when they conduct lab testing to demonstrate that toluene does not exceed the AAT in a Priority Product they manufacture.

Add Section 69511.6(h)(3).

Purpose. This section specifies that when laboratory analysis is conducted to demonstrate and certify that toluene concentration in a Priority Product does not exceed the AAT, the laboratory conducting the analyses must meet the method performance criteria specified in this regulation and take corrective action until the method performance criteria are met.

Necessity. This section is necessary to ensure that laboratory analytical testing and data meets specified criteria to ensure that their analysis of toluene in a Priority Product is both accurate and precise.

Add Section 69511.6(h)(3)(A)1.

Purpose. This section specifies the sample preparation criteria requirements that a laboratory must meet when a manufacturer submits laboratory testing data with an AATN to demonstrate and certify that the concentration of toluene in a product does not exceed the AAT. These criteria are based best laboratory management practices to ensure sample uniformity and the DTSC Environmental Chemistry Laboratory's (ECL) standard operating procedures.

Necessity. This section is necessary to ensure that manufacturers and the laboratories who analyze the concentration of toluene in a nail product understand the sample preparation requirements when a manufacturer submits an AATN to demonstrate and certify that the concentration of toluene in a product does not exceed the AAT.

Add Section 69511.6(h)(3)(A)2.

Purpose. This section specifies the techniques for sample introduction into the analytical instrument used to measure the concentration of toluene in a nail product. These criteria are based on United States Environmental Protection Agency (EPA) Method 8260D section 1.2.

Necessity. This section is necessary to provide guidance on sample introduction techniques to use when determining the concentration of toluene in a nail product.

Add Section 69511.6(h)(3)(B)1.

Purpose. This section specifies the suggested analytical method and instrumentation to be used to measure the concentration of toluene in a nail product. These criteria are based on EPA Method 8260D section 1.2.

Necessity. This section is necessary to ensure that manufacturers and the laboratories who conduct the analytical testing have guidance on the recommended analytical method and instrumentation to use for the analysis and determination of toluene concentrations in nail products.

Add Section 69511.6(h)(3)(B)2.

Purpose. This section specifies the internal standards and surrogates which may be used to measure the concentration of toluene in a nail product, as well as the internal standard preparation criteria. These criteria are based on EPA Method 8260D, sections 7.8, 7.9, and 17.0 Table 1A.

Necessity. This section is necessary to ensure that manufacturers and the laboratories who conduct the analytical testing understand which internal standards and surrogates are allowable, when to add internal standards to the sample aliquots, and what internal standard concentration is acceptable.

Add Section 69511.6(h)(3)(B)3.

Purpose. This section specifies the analytical method limit of quantitation required when measuring the toluene concentration in a nail product to demonstrate that concentration of toluene in the product does not exceed 100 ppm. This criterion is based on ECL's standard operating procedures.

Necessity. This section is necessary to ensure that manufacturers and the laboratories who conduct the analytical testing understand the required minimum limit of quantitation for analysis of toluene in a nail product.

Add Section 69511.6(h)(3)(C)1.

Purpose. This section specifies that the instrument used for analysis must meet manufacturer's specifications and meet acceptable requirements prior to analyzing samples. These criteria are based on EPA Method 9.0 and EPA Method 8000D section 11.4.

Necessity. This section is necessary to ensure that the instrument used for the analysis is able to generate accurate and reliable results.

Add Section 69511.6(h)(3)(C)2.

Purpose. This section specifies that the analyte of interest may be analyzed by gas chromatograph/mass spectrometer and that identification of the analyte of interest should be established by characteristic ions in a reference mass spectrum. These criteria are based on EPA Method 8260D sections 1.1, 1.2, and 11.6.1.3.

Necessity. This section is necessary to ensure that manufacturers and the laboratory conducting the analytical testing understands which instrumentation is recommended to use and the requirements of the qualifier and quantitation ions to identify and measure when testing a nail product for the concentration of toluene. During chemical analysis, toluene is separated from other chemicals in a nail product by the gas chromatograph and the mass spectrometer then accurately identifies toluene based on specific fragmented ions which are characteristic to toluene.

Add Section 69511.6(h)(3)(C)2.a.

Purpose. This section specifies the acceptable mass spectrometer scanning modes which may be used when analyzing nail products to determine toluene concentrations. These criteria are based on EPA Method 8000D section 9.8, EPA Method 8260D section 11.3.1.2, and ECL's standard operating procedures.

Necessity. This section is necessary to specify that full scan, selected ion monitoring, or multiple reaction monitoring scanning modes are acceptable for analyte analysis when testing nail products to determine the concentration of toluene.

Add Section 69511.6(h)(3)(C)2.b.

Purpose: This section specifies that there must be at least one quantitation ion and one qualifier ion for toluene when measuring the concentration of toluene in a nail product. These criteria are based on EPA Method 8260D section 11.3.1, EPA Method 8260D section 17.0 Table 1A, best laboratory management practices, and ECL's standard operating procedures.

Necessity: This section is necessary because an analyte's presence and concentration are determined based on detection and measurement of its specific quantitation and qualifier ions.

Add Section 69511.6(h)(3)(C)2.b.i.

Purpose. This section specifies the identifying mass spectrum quantitation and qualifier ions that must be used for detection and measurement of toluene. These criteria are based on EPA Method 8260D section 17.0 Table 1A.

Necessity. This section is necessary to ensure the unequivocal identification of the analyte of interest. The quantitation and qualifier ions specified in the method performance criteria are specific to identification of toluene.

Add Section 69511.6(h)(3)(C)2.c.

Purpose. This section specifies that there must be at least one quantitation ion for internal standards and surrogates. Further, the method may additionally include one or more qualifier ions for internal standards and surrogates. These criteria are based on EPA Method 8260 section 11.3.1, best laboratory management practices, and ECL's standard operating procedures.

Necessity. This section is necessary for the minimum criteria for the analyte ions used to ensure the unequivocal identification of the internal standards and surrogates based on their mass spectrum quantitation ions characteristic to toluene-d₈ and chlorobenzene-d₅.

Add Section 69511.6(h)(3)(C)2.c.i. and 69511.6(h)(3)(C)2.c.ii.

Purpose. These sections specify the identifying mass spectrum quantitation ions for the internal standards and surrogates, toluene-d₈ and chlorobenzene-d₅. These criteria are based on EPA Method 8260 section 17.0 Table 1A.

Necessity. These sections are necessary to ensure the unequivocal identification of the analytes of interest. The quantitation ions specified in the method performance criteria are specific to identification of toluene-d₈ and chlorobenzene-d₅.

Add Section 69511.6(h)(3)(C)3.

Purpose. The section specifies the timeframe in which the calibration of the instrument and the sample analysis must occur and the recommendations for tune verification standards. These criteria are based on EPA Method 8000D sections 9.2.1 and 11.7 and EPA Method 8260D section 7.10, 9.3.1, 11.3.1, and 17.0 Table 3.

Necessity. This section is necessary to ensure that the instrument remains calibrated and tuned to ensure analytical accuracy and precision. The samples and standard solutions also have an injection time frame to ensure sample viability. Additionally,

analysis of a reference compound, such as BFB, must be used to demonstrate the performance of the mass spectrometer to produce mass spectra with sufficient mass accuracy, mass resolution, and signal.

Add Section 69511.6(h)(3)(C)4.

Purpose. This section specifies that the initial calibration for each analyte and surrogate must use a minimum number of concentration points for a fitted line of the calibration curve. These criteria are based on EPA Method 8260D section 7.11.1, 11.3.2, and EPA Method 8000D sections 11.4, 11.4.1, and 11.5.1.

Necessity. This section is necessary to ensure that the number of concentration points generated in the initial calibration ensure accuracy to precisely measure and determine the concentrations of toluene in each analyzed nail product.

Add Section 69511.6(h)(3)(C)4.a.i.

Purpose. This section specifies the acceptable criteria for relative standard deviation of the average response of the target analyte. This criterion is based on EPA Method 8260 sections 11.3.4. 11.3.4.1, 11.3.4.2, 11.3.5, 11.7.2, and 17.0 Table 7 and EPA Method 8000D sections 11.5, 11.5.1, and 11.5.1.3.

Necessity. This section is necessary to ensure that the relative standard deviation of the average response of toluene is low, thereby confirming precision of the concentration of toluene in a tested nail product.

Add Section 69511.6(h)(3)(C)4.a.ii.

Purpose. This section specifies the acceptance criteria for the correlation coefficient or coefficient of determination when using a linear regression calibration model to determine the concentration of toluene in a nail product. These criteria are based on EPA Method 8260D sections 11.3.5.2 and 17.0 Table 7 and EPA Method 8000D section 11.5.2, 11.5.2.1, 11.5.2.2, and 11.5.2.3.

Necessity. This section is necessary for quantitative purposes to fit a linear regression calibration model thereby allowing calculation of the concentration of toluene in a tested nail product.

Add Section 69511.6(h)(3)C.5.

Purpose. This section specifies that the measured concentrations of the of the initial calibration standards true values must be within specific percent recovery ranges.

These criteria are based on EPA Method 8260D sections 11.3.5.4 11.3.6, and 17.0 Table 7.

Necessity. This section is necessary to ensure that the measured concentrations of the calibration standards are accurate when used for calculation of toluene in nail products.

Add Section 69511.6(h)(3)(C)6.

Purpose. This section specifies that the retention time intervals of each internal standard must be within 30 second of the retention time of the midpoint internal standard of the initial calibration. These criteria are based on EPA Method 8260D sections 11.4.4 and 17.0 Table 7, and EPA Method 8000D section 11.6.

Necessity. This section is necessary to establish retention time windows for each internal standard. Retention time windows are established to account for minor shifts in absolute retention times as a result of sample loadings and normal chromatographic variability.

Add Section 69511.6(h)(3)(C)7.

Purpose. This section specifies a second source for the internal calibration verification standard other than that of the initial calibration standard solution. It also specifies that the concentration must be at or midpoint of the calibration range. The acceptance criteria for the percent recover must be within 70 to 130 percent of the expected concentration and that no samples shall be analyzed until the initial calibration verification standard solution is analyzed. These criteria are based on EPA Method 8260D sections 7.11, 7.11.3, 9.3.2, 11.3.6, 17.0 Table 7 and EPA Method 8000D section 11.7.

Necessity. This section is necessary to ensure a second source standard is analyzed and passes the acceptance criteria. This ensures the accuracy and precision of the initial calibration before analysis begins. Analysis of calibration verification standards helps ensure that instrumentation is performing well and that false positive detections of analytes, false negative detection of analytes, and poor quantitation results are minimized.

Add Section 69511.6(h)(3)(C)8.

Purpose. This section specifies the time range for analysis of the continuing calibration verification standard to 12 hours. Criteria are also set for the recovery of the analyte at 20%. If these criteria are not met, then another aliquot of continuing calibration verification standard shall be analyzed, or a new initial calibration shall be conducted.

These criteria are based on EPA Method 8260 sections 7.11, 7.11.2, 9.3.3, 11.3.6, 11.4, 11.4.1, 11.4.3, 11.4.3.1, and 11.4.3.3 and EPA Method 8000 section 11.7.

Necessity. This section is necessary to ensure that the instrument retains accuracy in analyte recovery over the course of sample analysis and guidance if these criteria are not met. Analysis of continuing calibration verification standards during each 12-hour analytical period ensures the accuracy and precision of the initial calibration on a regular basis. Analysis of calibration verification standards helps ensure that instrumentation is performing well and that false positive detections of analytes, false negative detection of analytes, and poor quantitation results are minimized.

Add Section 69511.6(h)(3)(D)1.

Purpose. This section specifies the insertion of instrument blanks after the continuing calibration verification standard solution before the sample analysis and as needed between analysis of samples. These criteria are based on EPA Method 8260D sections 9.5.1, 9.5.2, 9.5.3, 9.5.4, 9.5.5, 11.4.2, 11.5.5, and 17.0 Table 7 and EPA Method 8000D section 4.2, 9.2.1, and 9.2.6.8.

Necessity. This section is necessary to ensure that there is no carryover of toluene from sample to sample due to high toluene concentrations. Analysis of one or more instrument blanks between samples ensure accurate determination of toluene concentrations in each tested nail product.

Add Section 69511.6(h)(3)(D)2.

Purpose. This section specifies that the response of the internal standard for all samples be within 50 to 200 percent of the midpoint of the initial calibration or continuing calibration verification. These limits are used as a diagnostic check on the addition of the internal standards to the samples or extracts and injection of the sample aliquot into the instrument. These criteria are based on EPA Method 8260 section 11.4.5, 11.5.6, and 17.0 Table 7 and EPA Method 8000D 11.4.3.

Necessity. This section is necessary for the precision of the analysis of the analyte of interest within the midpoint of the calibration range.

Add Section 69511.6(h)(3)(D)3.

Purpose. This section specifies the retention time acceptance criteria for of the analyte of interest at the beginning of the 12-hour analytical period. These criteria are used to monitor whether retention times for the analyte of interest of the internal calibration standards shift during analysis. These criteria are based on EPA Method 8260D section 11.6.1.2 and 17.0 Table 7.

Necessity. This section is necessary to ensure the specificity and identification of toluene in each nail product, as well as to ensure the precision of the instrument. A significant retention time shift may indicate a problem with the instrumentation.

Add Section 69511.6(h)(3)(E)1.

Purpose. This section specifies the quality control criteria that must be met for the analysis of toluene in nail products for each batch of 20 samples and each type of nail product analyzed. This includes sample preparation and analysis of a method blank, duplicate sample, matrix spike and matrix spike duplicate, and a laboratory control sample and laboratory sample duplicate. Analysis of quality control samples ensure the accuracy and precision of the analysis of measurements of toluene in test nail product samples. These criteria are based on EPA Method 8260 sections 9.6 and 17.0 Table 7, EPA Method 5000 section 8.1.

Necessity. This section is necessary to ensure consistent analysis of the analyte of interest in nail products. The duplicate analysis of the sample, matrix spike, and laboratory control sample are for confirmation of results and to ensure the accuracy and precision of measured concentrations of toluene in nail products.

Add Sections 69511.6(h)(3)(E)(1)(a) through 69511.6(h)(3)(E)1.d.

Purpose. This section specifies the quality control criteria that must be met for the analysis of toluene in nail products. This includes sample preparation and analysis of a method blank, duplicate sample, matrix spike and matrix spike duplicate, and a laboratory control sample and laboratory sample duplicate. These criteria are based on EPA Method 8260 sections 9.5.1, 9.5.2, 9.6, 9.6.1, 9.6.2, 9.6.3, 9.6.4 and EPA Method 8000D sections 9.2.6, 9.2.6.1 through 9.2.6.12, 9.4, 9.4.1 through 9.4.4, 9.6, 9.6.1 through 9.6.12, and Method 5000 sections 3.2, 5.4, 5.5, 5.6, 8.1, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 9.1.

Necessity. This section is necessary to ensure consistent analysis of the analyte of interest in nail products. The duplicate of the sample, matrix spike, and laboratory control sample are for confirmation of results.

Add Section 69511.6(h)(3)(E)2.

Purpose. This section specifies that the product sample, method blank, sample duplicate, laboratory control sample, laboratory control sample duplicate, matrix spike, and matrix spike duplicate shall be spiked with a surrogate standard solution prior to extraction and analysis. These criteria are based on EPA Method 8260D sections 7.8 and 9.7 and Method 5000 sections 5.4, 5.4.1, 5.4.2, 8.3.6, and 9.1.

Necessity. This section is necessary to ensure the accuracy and precision of analytical data. Surrogate standards are recommended for the analysis of toluene.

Add Section 69511.6(h)(3)(E)3.

Purpose. This section specifies the acceptance criteria for each matrix spike, matrix spike duplicate, laboratory control sample, and laboratory control sample duplicate to demonstrate a relative percent difference less than or equal to 20 percent for duplicate samples and each spiked quality control sample shall have a spike recovery between 70 to 130 percent of the true value of the spiked concentrations. These criteria are based on EPA Method 8260D sections 9.7, 11.4.3.2, 17.0 Table 7 and EPA Method.

Necessity. This section is necessary to ensure accuracy and precision of analytical results. The percent difference measures how close, or accurate, a measured concentration is to the “true” value of analytes spiked into a matrix spike sample or lab control sample. The relative percent difference measures precision, which is necessary to ensure that the results between duplicates agree with one another.

Add Section 69511.6(h)(3)(E)4.

Purpose. This section specifies that a laboratory may establish more rigorous quality control limits than specified in Section 69511(h)(3)(E)(3) but must, at minimum meet those control limits.

Necessity: This section is necessary to clearly state than more rigorous control limits are allowable.

Add Section 69511.6(h)(3)(E)5.

Purpose. This section specifies the acceptance criteria for the spike recovery of the surrogate standard solution in the sample, method blank, sample duplicate, laboratory control sample, laboratory control sample duplicate, and the matrix spike. These criteria are based on EPA Method 8260D sections 9.7 and 17.0 Table 7 and EPA Method 8000D section 9.5.

Necessity. This section is necessary to ensure accurate measurement of the analyte of interest in the sample and standards. The surrogate is used to evaluate extraction efficiency and matrix interference on a sample specific basis as they are compounds which are chemically similar to the analytes of interest and assist in monitoring the closeness of a result to the true value and the extent to which the results agree with one another.

Add Section 69511.6(h)(3)(F)

Purpose. This section provides definitions for the terminology used for the method performance criteria.

Necessity. This section is necessary to clarify technical concepts and enable us to have a common understanding of each technical term.

MANDATES ON LOCAL GOVERNMENTS AND SCHOOL DISTRICTS

DTSC has determined that this regulatory action will not result in mandates to any local agencies or school districts.

ECONOMIC IMPACT ASSESSMENT

As required by Government Code section 11346.3, DTSC assessed the potential for this proposed regulation to cause adverse economic impacts to California businesses and individuals. There have been no changes to the assumptions or information presented in the Form 399 and Attachment since it was completed on September 29, 2022.

REASONABLE ALTERNATIVES CONSIDERED

Government Code section 11346.2, subdivision (b)(4) requires DTSC to consider and evaluate reasonable alternatives to the proposed regulatory action and provide reasons for rejecting those alternatives. This section discusses alternatives evaluated and provides reasons why these alternatives were not included in the proposal. As explained below, no alternative proposed was found to be less burdensome and equally effective in achieving the purposes of the regulation in a manner than ensures full compliance with the authorizing law. DTSC has not identified reasonable alternatives that would lessen any adverse impact on small business.

Alternative 1: Allow two ways for a manufacturer to demonstrate that their Priority Product meets the exemption from completing an AA by submitting:

- certificates of analysis from ingredient suppliers as well as calculations of toluene in the final product; or
- laboratory analytical data which meets the method performance criteria specified in the regulatory amendment.

This option was selected because it provides clear directions to manufacturers on what is allowed to demonstrate that the concentration of toluene in their product does not exceed the AAT of 100 ppm for toluene in nail products. Further, this option provides

clear criteria that must be met to ensure that analytical laboratory data is both accurate and precise regardless of the laboratory that conducts the analysis.

Alternative 2: Only allow laboratory data and not certificates of analyses and calculations to demonstrate that the toluene concentration in a manufacturer's Priority Product does not exceed the AAT of 100 ppm.

This option was dismissed because toluene may be found more frequently at low concentrations as a contaminant in the nail product ingredients rather than as an added ingredient. Ingredient suppliers for the final nail product may already have contaminant toluene concentrations noted in their certificates of analyses. It is typically less financially costly for a manufacturer to provide certificates of analyses rather than conduct analytical lab testing.

Alternative 3: Do not provide method performance criteria for laboratory analysis to demonstrate that toluene does not exceed the AAT of 100 ppm in a Priority Product.

This was considered as an alternative but dismissed as an option due to providing no clear parameters to manufacturers what is required when conducting laboratory analysis to determine the concentration of toluene in a Priority Product. If no method performance criteria were provided, the potential for inaccurate and inconsistent data submissions would be greatly increased.

Small Business Alternatives Considered

DTSC has not identified reasonable alternatives that would lessen any adverse impact on small business.

SUMMARY OF COMMENTS AND AGENCY RESPONSE

Government Code section 11346.9(a)(3) requires DTSC to include in the FSOR a summary of each objection or recommendation made regarding the proposed regulation and an explanation of how the proposal or procedures for adopting the regulation was changed or not changed in response.

Written comments were received during the January 20 through February 6, 2023, comment period and the May 15 through May 30, 2023, comment period.

List of Commenters and their Affiliations

The tables below provide a complete list of commenters, their affiliations, and the number DTSC assigned to their correspondence or oral comment for both comment periods, beginning with the first comment period. Most of the comment letters cover

more than one theme. To organize the comments, DTSC numbered individual letters as shown and assigned a number to each individual comment. For example, the number “CL4-2” refers to the second comment in the comment letter numbered 4.

Table 1: List of Commenters during the 15-Day Comment Period (January 20, 2023 – February 6, 2023)

#	Commenter	Affiliation
CL1	Thomas F. Myers	Personal Care Products Council
CL2	Suzanne Hume	CleanEarth4Kids.org

Table 2: Index of Comment Letters and Individual Comments Made During the 15-Day Comment Period (January 20, 2023 – February 6, 2023)

Comment #	Location in Comment Letter	Page # in FSOR
CL1-1	Page 2, paragraph 1, reference 3.B.3	p. 18
CL1-2	Page 2, paragraph 2, reference 3.B.4	p. 18
CL1-3	Page 2, paragraph 3, reference 3.D.1	p. 18
CL1-4	Page 2, paragraph 4, reference 3.D.2.a.	p. 18
CL1-5	Page 2, paragraph 5, reference 3.D.2.b.	p. 19
CL1-6	Page 2, paragraph 6, reference 3.D.3	p. 19
CL1-7	Page 3, paragraph 2, reference 3.D.3.a.	p. 19
CL1-8	Page 3, paragraph 3, reference 3.D.4	p. 20
CL1-9	Page 3, paragraph 4, reference 3.D.5	p. 20
CL1-10	Page 3, paragraph 5, reference 3.E.1	p. 21
CL1-11	Page 3, paragraph 6, reference 3.E.1.b.	p. 21
CL1-12	Page 4, paragraph 1, reference 3.E.1.c.	p. 21
CL1-13	Page 4, paragraph 2, reference 3.E.2	p. 22
CL1-14	Page 4, paragraph 3, reference 3.E.3	p. 22

Comment #	Location in Comment Letter	Page # in FSOR
CL1-15	Page 4, paragraph 4, reference 3.E.4.e.	p. 22
CL1-16	Page 4, paragraph 5, reference 3.F.11	p. 23
CL1-17	Page 5, paragraph 2, reference 3.F.13	p. 23
CL2-1	Page 1, paragraph 1	p. 24
CL2-2	Page 2, paragraph 2, sentence 1	p. 23
CL2-3	Page 2, paragraph 2, sentence 1	p. 24
CL2-4	Page 2, paragraph 2, sentence 1	p. 24
CL2-5	Page 2, paragraph 2, sentence 1	p. 24
CL2-6	Page 2, paragraph 2, sentence 1	p. 24

Summary of Objections and Recommendations during the 15-Day Comment Period (January 20, 2023 – February 6, 2023)

DTSC received two comment letters during the comment period from January 20, 2023, through February 6, 2023). The comments fall into one of the following categories:

- I. Suggestions for changes to the method performance criteria
- II. Opposition to setting the AAT at 100 ppm
- III. Proposal to ban toluene in all products

DTSC grouped and summarized the comments according to the listed themes, presenting summaries and responses in each section. Table 1 lists the commenters and Table 2 contains an Index of Comment Letters and Individual Comments.

Comments suggesting changes to the method performance criteria

Comment: CL1-1

Comment Summary: This comment suggests specifying a signal-to-noise ratio of 10:1 for the limit of quantitation and a signal-to-noise ratio of 3:1 for the limit of detection in proposed section 69511.6(h)(3)(B)3.

DTSC Response: DTSC has clarified this provision by removing the section with the signal-to-noise ratio criteria. DTSC is instead relying on the quantitation criteria for accuracy and precision.

Comment: CL1-2

Comment Summary: This comment suggests clarifying the limit of quantitation by including mention of the analytical method in proposed section 69511.6(h)(3)(B)4.

DTSC Response: DTSC has adjusted the criteria for the limit of quantitation to be at or below 1/3 of the AAT in proposed section 69511.6(h)(3)(B)3. This reflects the practice of DTSC's Environmental Chemistry Laboratory.

Comment: CL1-3

Comment Summary: This comment suggests changing the GC/MS runtime to 24 hours in proposed section 69511.6(h)(3)(D)1.

DTSC Response: EPA Method 8260D sections 11.4, 11.4.1, 17.0 Table 7 and EPA Method 8000D section 9.2.1, 11.7, and 11.7. specify a 12-hour analytical period.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL1-4

Comment Summary: This comment requests clarification regarding the retention time for internal standards in proposed section 69511.6(h)(3)(D)2.a.

DTSC Response: DTSC revised the language within proposed section 69511.6(h)(3)(C)6 to specify that after the initial calibration, the retention time of each internal standard shall be within 30 seconds of the retention time of the internal standard at the midpoint of the initial calibration.

Comment: CL1-5

Comment Summary: This comment suggests the relative retention time should be no more than 2% in proposed section 69511.6(h)(3)(D)2.b.

DTSC Response: DTSC has revised language in proposed section 69511.3(h)(3)(C)6. to clarify that after the initial calibration, the retention time of each internal standard shall be within 30 seconds of the retention time of the internal standard at the midpoint of the initial calibration.

Comment: CL1-6

Comment Summary: This comment suggests the acceptance criteria at the limit of quantitation should be 75 to 125 percent or 50 to 115 percent, resulting in an accuracy of 85 to 115 percent in proposed section 69511.6(h)(3)(D)3.

DTSC Response: DTSC has clarified language in proposed section 69511.6(h)(3)(C)5. to specify that the concentration of toluene in the lowest calibration standard solution shall be accurate within 50 percent of its true concentration value. This means the percent recovery shall be within 50 to 150 percent of the expected concentration, and all other toluene calibration levels shall be within 30 percent of their true value, meaning the percent recovery shall be within 70 to 130 percent of the expected concentration.

These criteria are based on EPA Method 8260D sections 9.7 and 17.0 Table 7 and EPA Method 8000D section 9.5.

Comment: CL1-7

Comment Summary: This comment requests clarification for the relative standard deviation expression in proposed section 69511.6(h)(3)(D)3.a.

DTSC Response: DTSC has clarified that the relative standard deviation of the calibration standards and samples (expressed as relative percent difference) shall not exceed 20 percent in proposed sections 69511.6(h)(3)(E)3 and 69511.6(h)(3)(E)4.

Comment: CL1-8

Comment Summary: This comment suggests an initial verification standard at the midpoint of the curve is unnecessary in proposed section 69511.6(h)(3)(D)4.

DTSC Response: DTSC requires analyzing an initial calibration verification standard after the initial calibration curve, as indicated in proposed section 69511.6(h)(3)(C)7. The calibration verification standard is prepared from a second source and is therefore used to assess the reliability of results. Analysis of calibration verification standards at the midpoint of the calibration curve helps ensure that instrumentation is performing well and that false positive detections of analytes, false negative detection of analytes, and poor quantitation results are minimized. Further, DTSC clarified that the acceptance criteria is 70 to 130 percent recovery of the known concentration of the calibration verification standard. These criteria are based on EPA Method 8260D sections 7.11, 7.11.3, 9.3.2, 11.3.6, 17.0 Table 7 and EPA Method 8000D section 11.7.

Comment: CL1-9

Comment Summary: This comment suggests the end of the analysis should be within 24 hours of the instrument tune check, and that the acceptance criteria for the continuing calibration verification should be the same as the initial calibration verification in proposed section 69511.6(h)(3)(D)5.

DTSC Response: EPA Methods 8260D, EPA Method 8000D, and the DTSC Environmental Chemistry Laboratory's analytical methodology specify an analytical period of 12 hours. Further, DTSC clarified the acceptance criteria of the initial and continuing calibration verification are specified in proposed sections 69511.6(h)(3)(C)7 and 69511.6(h)(3)(C)8. These criteria are based on EPA Method 8260D sections 11.3.6, 11.4, 11.4.1, 11.4.3.1, and 11.4.3.3 and EPA Method 8000 section 11.7. Specifically, EPA Method 8260D sections 11.3.6 and 11.4.3.1 specify the acceptance criteria for the initial calibration verification and continuing calibration verification standards, and they are not the same.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL1-10

Comment Summary: This comment requests clarification on quality control preparation in proposed section 69511.6(h)(3)(E)1.

DTSC Response: DTSC has provided method performance criteria specifically for the analysis of toluene in nail products. The regulations are not intended to provide a standard operating procedure. This provides flexibility in each analytical testing approach as long as the performance criteria are met.

In order to provide clarification on the required quality control protocol, DTSC reorganized the order of the regulation text and added some additional language in sections 69511.6(h)(3)(E)1 through section 69511.6(h)(3)(E)5.

Comment: CL1-11

Comment Summary: This comment requests further clarification on the concentration level of toluene to be added to prepared matrix spike and matrix spike duplicate samples in proposed section 69511.6(h)(3)(E)1.b.

DTSC Response: DTSC has clarified the spiked concentration level of toluene in the matrix spike and matrix spike duplicate samples to be the middle range of the initial calibration in proposed section 69511.6(h)(3)(E)1.c.

Comment: CL1-12

Comment Summary: This comment requests acceptance criteria for analysis of a laboratory control sample and laboratory control sample duplicate in proposed section 69511.6(h)(3)(E)1.c.

DTSC Response: DTSC clarified the acceptance criteria for analysis of a laboratory control sample and laboratory control sample duplicate in proposed sections 69511.6(h)(3)(E)3 through 69511.6(h)(3)(E)5.

Comment: CL1-13

Comment Summary: This comment requests clarification of what surrogate standard solution to use if toluene-d₈ is the internal standard in proposed section 69511.6(h)(3)(E)2.

DTSC Response: DTSC has clarified in proposed section 69511.6(h)(3)(B)2 that either toluene-d₈ should be used as the internal standard with chlorobenzene-d₅ as a surrogate, or chlorobenzene-d₅ should be used as the internal standard and toluene-d₈ used as a surrogate.

Comment: CL1-14

Comment Summary: This comment suggests the concentration of toluene in each method blank should be less than the limit of detection not the limit of quantitation in proposed section 69511.6(h)(3)(E)3.

DTSC Response: DTSC has moved this performance criteria to section 69511.6(h)(3)(E)1.a., which indicates that the concentration of toluene in each method blank is not exceed one half of the lower limit of quantitation. This criterion is based on EPA Method 8260D section 9.5.2 and EPA Method 8000D section 9.2.6.5 and 9.2.6.9.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL1-15

Comment Summary: This comment suggests that the retention time of the target analyte should be within two percent or less, and that the analytical period should be 24 hours in proposed section 69511.6(h)(3)(E)4.e.

DTSC Response: DTSC revised section 69511.6(h)(3)(D)3 to clarify that the retention time of the analyte of interest shall be within 10 seconds of retention time of the midpoint of the initial calibration or within 10 seconds of the continuing calibration verification standard solution analyzed at the beginning of the 12-hour analytical period.

EPA Methods 8260D, EPA Method 8000D, and the DTSC Environmental Chemistry Laboratory's analytical methodology specify an analytical period of 12 hours. This criterion is based on EPA Method 8260D sections 11.4, 11.4.1, 17.0 Table 7 and EPA

Method 8000D section 9.2.1, 11.7, and 11.7.4. Thus, no change was made to the rulemaking or supporting documents with regard to the 12-hour analytical period.

Comment: CL1-16

Comment Summary: This comment requests clarification of the description of multiple reaction monitoring in proposed section 69511.6(h)(3)(F)11.

DTSC Response: DTSC has clarified the definition of multiple reaction monitoring in proposed section 69511.6(h)(3)(F)15 to specify that “Multiple Reaction Monitoring (MRM)” is a highly sensitive analytical method using a triple quadrupole mass spectrometer. The target analyte is ionized in the ion source which creates specific ions that are characteristic of the target analyte. Selected ions are allowed through the first quadrupole and are then subsequently fragmented into product (quantitation and qualifier) ions in the collision cell. These product ions are selectively passed through the final quadrupole, where they are detected. Multiple product ions can be detected at once.

This definition was updated to conform to the standard definitions used by DTSC’s Environmental Chemistry Laboratory.

Comment: CL1-17

Comment Summary: This comment requests clarification of the definition of the limit of quantification in proposed section 69511.6(h)(3)(F)13.

DTSC Response: DTSC has clarified the definition of the limit of quantitation in proposed section 69511.6(h)(3)(F)12 as the lowest measured concentration of the analyte that has gone through extraction or dilution and analysis and meets defined accuracy and precision criteria.

Comments in opposition to setting the Alternatives Analysis Threshold at 100 ppm

Comment: CL2-2

Comment Summary: This comment proposes that DTSC set the Alternatives Analysis Threshold at 0 ppm for all products in California.

DTSC Response: The Alternatives Analysis Threshold was established at 100 ppm and approved as part of the partially approved portion of this regulation proposal. This comment is outside the scope of the proposed regulation under consideration for this comment period.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comments proposing to ban toluene in all products in California

Comments: CL2-1, CL2-3, CL2-4, CL2-5, CL2-6

Comment Summary: These comments propose banning toluene in all products in California. This comment is outside the scope of the proposed regulation under consideration for this comment period.

No changes were made to the proposed regulation or supporting documents based on these comments.

Table 3: List of Commenters during the second 15-Day Comment Period (May 15, 2023 – May 30 2023)

#	Commenter	Affiliation
CL1	Alexandra Scranton	Women’s Voices for the Earth
CL2	Christina Walsh	Land Relief
CL-3	Thomas F. Myers	Personal Care Products Council
CL-4	Kevin Sheran	Keystone Industries

Table 4: Index of Comment Letters and Individual Comments Made During the second 15-Day Comment Period (May 15, 2023 – May 30, 2023)

Comment #	Location in Comment Letter	Page # in FSOR
CL1-1	Page 1, paragraph 1	p. 29
CL2-1	Page 1, paragraph 3	p. 29
CL2-2	Page 2, paragraph 1	p. 29
CL2-3	Page 2, paragraph 2	p. 30
CL3-1	Page 1, paragraph 3	p. 29
CL3-2	Page 1, paragraph 4	p. 28
CL3-3	Page 3, paragraph 1, reference 3.B.3	p. 26
CL3-4	Page 3, paragraph 2, reference 3.C	p. 26
CL3-5	Page 3, paragraph 3, reference 3.C.3	p. 27
CL3-6	Page 3, paragraph 4, reference 3.C.6	p. 27
CL3-7	Page 3, paragraph 5, reference 3.D.2	p. 27
CL3-8	Page 4, paragraph 1, reference 3.D.3	p. 28
CL3-9	Page 4, paragraph 2, reference 3.F.11	p. 28
CL4-1	Page 1, paragraph 4	p. 28
CL4-2	Page 1, paragraph 5	p. 28

Summary of Objections and Recommendations during the second 15-Day Comment Period (May 15, 2023 – May 30, 2023)

DTSC received four comment letters during the comment period from May 15, 2023, through May 30, 2023). The comments fall into one of the following categories:

- I. Suggestions for changes to the method performance criteria
- II. Support or Opposition to setting the AAT at 100 ppm
- III. Suggestions for effective implementation

DTSC grouped and summarized the comments according to the listed themes, presenting summaries and responses in each section. Table 3 lists the commenters and Table 4 contains an Index of Comment Letters and Individual Comments.

Comments suggesting changes to the method performance criteria

Comment: CL3-3

Comment Summary: This comment suggests defining the limit of quantitation through measurement of the signal-to-noise ratio in proposed section 69511.6(h)(3)(B)3.

DTSC Response: DTSC has determined that the limit of quantitation for toluene should be at or below one-third of the AAT of 100 ppm. This value can be verified by using the method performance criteria.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-4

Comment Summary: This comment suggests adding to the regulation that the linear range of the calibration curve must span from the limit of quantitation to at least the Alternatives Analysis Threshold in proposed section 69511.6(h)(3)(C).

DTSC Response: It is a standard analytical chemistry practice to ensure that a calibration range includes the concentration of any target analyte when measuring the concentration of an analyte.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-5

Comment Summary: This comment suggests tuning a mass spectrometer is not needed every 12 hours; this section should be removed or specify that tuning should be conducted according to the instrument manufacturer in proposed section 69511.6(h)(3)(C)3.

DTSC Response: EPA Methods 8260D and 8000D specify a 12-hour analytical period, which includes tuning the mass spectrometer.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-6

Comment Summary: This comment suggests the typical window for retention time of internal standards is closer to less than 0.1 minutes in proposed section 69511.6(h)(3)(C)6.

DTSC Response:

After the initial calibration, the retention time of each internal standard must be within 30 seconds of the retention time of the internal standard at the midpoint of the initial calibration. These criteria are based on EPA Method 8260D sections 11.4.4 and 17.0 Table 7, and EPA Method 8000D section 11.6.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-7

Comment Summary: This comment suggests a cutoff only for the internal standard is not necessary. Commenter suggests removing this section entirely or it should specify the ratio of toluene to the internal standard shall be within X% of the calibration standards in proposed section 69511.6(h)(3)(D)2.

DTSC Response:

EPA Method 8260 section 11.4.5, 11.5.6, and 17.0 Table 7 and EPA Method 8000D 11.4.3 specify that the response of the internal standard for all samples must be within

50 to 200 percent of the midpoint of the initial calibration or continuing calibration verification. These limits are used as a diagnostic check on the addition of the internal standards to the samples or extracts and injection of the sample aliquot into the instrument.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-8

Comment Summary: This comment suggests a calibration verification standard every 12 hours is not necessary in proposed section 69511.6(h)(3)(D)3.

DTSC Response: EPA Method 8260D and EPA Method 8000 specify a 12-hour analytical period.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: CL3-9

Comment Summary: This comment suggests a clean matrix may not be achievable depending on the product type in proposed section 69511.6(h)(3)(F)11.

DTSC Response: DTSC suggests method validation studies to verify matrix prior to the analysis of toluene in nail products.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comments in support or opposition to setting the Alternatives Analysis Threshold at 100 ppm

Comments: CL3-2, CL 4-1, CL4-2

Comment Summary: These comments either support or oppose setting the AAT at 100 ppm.

DTSC Response: The Alternatives Analysis Threshold was established at 100 ppm and approved as part of the partially approved portion of this regulation proposal. These comments are outside the scope of the proposed regulation under consideration for this comment period.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comments with implementation suggestions

Comment: CL1-1

Comment Summary: This comment requests DTSC verify that the commenter's current email address is included in DTSC's mailing list.

DTSC Response: DTSC has verified that the commenter's email address is included in the DTSC mailing list.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: CL2-1, CL3-1

Comment Summary: These comments request DTSC to provide an overview of the proposed requirements in layman's terms.

DTSC Response: The method performance criteria are necessarily specific to provide product manufacturers and their analytical partners the criteria needed to comply with the requirement to demonstrate compliance with the Alternatives Analysis Threshold if they conduct analytical testing and provide analytical data to DTSC. The purpose and applicability of the method performance criteria in the proposed regulations are described in layman's terms in the statement of reasons for this regulation.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: CL2-2

Comment Summary: This comment requests DTSC to actively seek out feedback from stakeholders to allow responsible entities to design feasible products that are safer for consumers.

DTSC Response: DTSC acknowledges the commenter's concerns. DTSC will have ongoing communications with stakeholders during the Alternative Analysis (AA) process to help product manufacturers design safer alternatives.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment CL2-3

Comment Summary: The comment requests DTSC to provide details on the enforcement of the proposed regulation.

DTSC Response: When the proposed regulation becomes effective, DTSC will require product manufacturers to use the method performance criteria if they are demonstrating compliance with the Alternatives Analysis Threshold using analytical data. Sections 69511.6(h) and 69511.6(h)(1) specify that a manufacturer shall demonstrate that the conditions for the Alternatives Analysis Threshold have been met and DTSC will enforce the regulations by verifying compliance with that requirement.

No changes were made to the proposed regulation or supporting documents based on this comment.