Express Terms

6 NYCRR Part 352 Product Chemical Restrictions and Disclosure.

Subpart 352-1, 1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products

(Statutory Authority: ECL sections 1-0101, 3-0301, 35-0105, and 37-0117)

6 NYCRR Part 352 Product Chemical Restrictions and Disclosure is being added as follows:

Subpart 352-1, 1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products

352-1.1 Purpose and Applicability

(a) Purpose

The purpose of this Subpart is to implement the maximum allowable concentrations of 1,4-dioxane in household cleansing products as set forth in article 35 of the Environmental Conservation Law (ECL) and for personal care and cosmetic products as set forth in Title 1 of article 37 of the ECL. This regulation includes procedures to apply for waivers as provided in articles 35 and 37, requirements for compliance evaluations of regulated products and method performance criteria for laboratory testing.

(b) Applicability

This Subpart applies to any household cleansing product that is distributed, sold, offered or exposed for sale, and to any personal care or cosmetic product that is sold or offered for sale in the State of New York.

352-1.2 Definitions

(a) ‘Continuing Calibration Verification’ means an assessment of an analytical instrument’s calibration drift and memory effects over the course of an analytical sequence.

(b) ‘Correlation Coefficient’ means the statistical relationship between two variables.

(c) ‘Cosmetic product’ means any article (1) intended to be rubbed, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for beautifying, promoting attractiveness, or altering the appearance, and (2) intended for use as a component of any such article. The term ‘cosmetic product’ shall not include any personal care product as defined in this section for which a prescription is required for distribution or dispensation as provided in section 281 of the Public Health Law or section 6810 of the Education Law.

(d) ‘Household cleansing product’ means any product, including but not limited to, soaps, detergents, and other similar products that include an antimicrobial agent, which contain a surfactant as a wetting or dirt emulsifying agent and are used primarily for domestic or commercial cleaning purposes, including but not limited to, the cleansing of fabrics, dishes, food utensils, automobiles, and household and commercial premises. Household cleansing product shall not mean:

(1) foods, drugs and cosmetics, including personal care items such as toothpaste, shampoo and hand soap;

(2) products labeled, advertised, marketed, and distributed for use primarily as pesticides, as defined in article 33 of the Environmental Conservation Law; or

(3) cleansing products used primarily in industrial manufacturing, production and assembling processes.

(e) ‘Initial Calibration’ means a plot of instrument responses to an analyte versus known concentrations of analyte from certified reference materials. The initial calibration must cover a range containing the applicable limitation set forth in section 352-1.3 of this Part.

(f) ‘Initial Calibration Verification’ means an assessment of the reference materials used to calibrate an analytical instrument by analyzing certified reference materials obtained from a second source.

(g) ‘Internal Standard’ means a chemical substance that is similar, but not identical to, the analyte or analytes of interest that are added to a sample at a known concentration. An internal standard is used

for quantitation of 1,4-dioxane and to account for matrix effects or variability in instrument response by normalizing the response of 1,4-dioxane, or both, thereby decreasing measurement bias to the extent that their behavior mimics that of 1,4-dioxane.

(h) 'Laboratory Control Sample or Laboratory Control Sample Duplicate' means a clean matrix prepared and analyzed in the same analytical batch and in exactly the same manner as the other routine samples. The laboratory control sample or laboratory control sample duplicate is used to assess general method performance based on the ability of the laboratory to successfully recover 1,4-dioxane from the matrix.

(i) 'Limit of Detection' means the minimum concentration of an analyte that can be reliably detected with a signal to noise ratio of 3:1 or greater.

(j) 'Limit of Quantitation' means the minimum concentration of an analyte that can be reliably quantitated with defined accuracy and precision, and a signal to noise ratio of 10:1 or greater.

(k) 'Manufacturer' means any person who (1) manufactures, produces or substantially produces any covered household cleansing product, personal care product or cosmetic product for sale in the State under its own brand name or under any other brand name for sale in the State; (2) sells in the State, under its own brand name, any covered household cleansing product, personal care product or cosmetic product; (3) owns a brand name that it licenses to another person for use on any covered household cleansing product, personal care product or cosmetic product sold in the State; (4) imports any covered household cleansing product, personal care product or cosmetic product for sale in the State; or (5) manufactures any covered household cleansing product for sale in the State without affixing a brand name.

(l) 'Matrix Spike or Matrix Spike Duplicate' means samples to which known concentrations of 1,4-dioxane have been added before extraction and analysis.

(m) ‘Method Blank’ means a clean matrix containing only the internal standard. The method blank is used to assess background interference or contamination that exists in the analytical system that might lead to the reporting of elevated concentration levels or false positive data. Results from tests of the method blank should be below the limit of quantitation.

(n) ‘Multiple Reaction Monitoring’ means a mass spectrometry scanning mode whereby a particular ion mass-to-charge is selected in the first stage, fragmented in a second stage, and specific product ions resulting from the fragmentation are detected in the third stage. Multiple reaction monitoring typically results in increased sensitivity of the instrumentation.

(o) ‘Percent Recovery’ means the amount of 1,4-dioxane analyzed relative to the known amount spiked, converted to percentage.

(p) ‘Percent Relative Standard Deviation’ means a statistical analysis that determines how measurements in a data set are scattered around the average. Percent relative standard deviation is defined as the standard deviation of the measurements in the data set divided by their average, converted to percentage.

(q) ‘Person’ means any individual, partnership, firm or corporation, or unincorporated association

(r) ‘Personal care product’ means any product intended for cleaning or cleansing any part of the body, such as the skin and hair, and including but not limited to, hair shampoo, hair conditioner, soap, bath gels and other bath products. The term ‘personal care product’ shall not include any product for which a prescription is required for distribution or dispensation as provided in section 281 of the Public Health Law or section 6810 of the Education Law.

(s) ‘Relative Percent Difference’ means a statistical analysis between two measurements defined as the absolute difference between the two measurements, divided by their average, then converted to percentage.

(t) ‘Selected Ion Monitoring’ means a mass spectrometry scanning mode in which only a limited mass-to-charge ratio range is transmitted/detected by the instrument. Select ion monitoring typically results in increased sensitivity of the instrumentation.

(u) ‘Signal to Noise Ratio’ means a measure that compares the level of a desired signal to the level of background noise.

(v) ‘State’ means the State of New York.

352-1.3 Prohibitions.

(a) No person shall distribute, sell, offer for sale, or expose for sale in the State any household cleansing product or personal care product which contains 1,4-dioxane in excess of two parts per million on or after December 31, 2022.

(b) No person shall distribute, sell, offer for sale, or expose for sale in the State any household cleansing product or personal care product which contains 1,4-dioxane in excess of one part per million on or after December 31, 2023.

(c) No person shall distribute, sell, offer for sale, or expose for sale in the State any cosmetic product which contains 1,4-dioxane in excess of ten parts per million on or after December 31, 2022.

(d) If a manufacturer is uncertain whether a product is a household cleansing, personal care, or cosmetic product for purposes of determining which 1,4-dioxane limit applies, the manufacturer may request that the department determine the applicable product category. Such request must be submitted on a form approved by the department. The department will notify the manufacturer which product category is applicable.

352-1.4 Waiver Application.

(a) General Provisions

(1) A manufacturer of any household cleansing, personal care, or cosmetic product may apply to the department for a one-year waiver from the applicable requirements of section 352-1.3 of this Part for a specific household cleansing, personal care, or cosmetic product upon proof that the manufacturer has taken steps to reduce the presence of 1,4-dioxane in that product and is unable to comply with the applicable requirements of section 352-1.3 of this Part. Thereafter, a manufacturer may apply for one additional one-year waiver for that product, upon the submission of similar proof. Waivers will be granted in the department's sole discretion, based upon the department's evaluation of the application and the efforts undertaken by the manufacturer to comply with the 1,4-dioxane limits set forth in section 352-1.3 of this Part.

(2) A manufacturer must submit its waiver application in a format approved by the department. Each application must contain a certification signed by an authorized representative of the manufacturer. Such application with a certifying signature shall be considered a written instrument that could subject the signatory to liability under article 175 of the New York State Penal Law for filing a false statement or false information.

(3) Each household cleansing, personal care, or cosmetic product for which a waiver is sought must be individually named in the application and identified by product type, i.e., household cleansing, personal care or cosmetic product.

(4) Each household cleansing, personal care, or cosmetic product that contains the same formulation, but different fragrance blends, must be identified as a separate product, although the manufacturer can rely on the same proof for the purpose of requesting a waiver if the proof is the same. All information required in subdivision (b) of this section must be provided for each product but may be aggregated into one manufacturer-wide waiver application.

(5) At the time of submission of a waiver application, a manufacturer may request in writing that certain information in its application be deemed confidential business information by the department in accordance with the provisions of Part 616 of this Title. The department will evaluate such a request in accordance with and subject to the criteria set forth in Part 616. The name of the product, whether the product is a household cleansing, personal care or cosmetic product, and the current level of 1,4-dioxane in such product may not be claimed as confidential.

(b) Proof for Waiver

(1) A manufacturer must provide proof that it has taken steps to reduce the concentration of 1,4-dioxane for each household cleansing, personal care, or cosmetic product identified in its waiver application, but is not able to meet the 1,4-dioxane limits set forth in section 352-1.3 of this Part by the applicable statutory deadline. The waiver application must include:

(i) Certification of the concentration of 1,4-dioxane that is currently in each product for which a waiver is sought. The reported concentration must be the highest of any variation that exists on the market at the time the waiver is submitted.

(ii) A written explanation of the efforts conducted, or those that are being conducted, to reduce the concentration of 1,4-dioxane in a product or formulation, and why additional time is necessary to comply with the limits set forth in section 352-1.3 of this Part.

(iii) If a manufacturer is seeking waivers for multiple products based on the same explanation for not meeting the limitations set forth in section 352-1.3 of this Part, the manufacturer may provide a detailed explanation once and create a shorthand for such explanation to identify the products to which that explanation is applicable.

(2) While a waiver is in effect, the manufacturer must be able to produce documentation of the stated concentration of 1,4-dioxane upon request by the department. Documentation must include the information specified below.

(i) If the stated 1,4-dioxane concentration is a result of testing that has been conducted on the product, such documentation must be dated, detail the test method(s) used, show that the criteria detailed in section 352-1.6 of this Part were met, and name the lab that conducted the test(s).

(ii) If the stated 1,4-dioxane concentration is a result of a dilution calculation, such documentation must include:

('a') the name of the ingredient(s) that cause(s) 1,4-dioxane to be present in the final product;

('b') a dated test result that shows the concentration of 1,4-dioxane in the ingredient(s);

('c') documentation of the test method(s) used and that the criteria detailed in section 352-1.6 of this Part were met, and the name of the lab that conducted the test(s);

('d') the percentage of the final product that consists of each ingredient identified as containing 1,4-dioxane;

('e') the dilution calculation that was used to obtain the reported 1,4-dioxane concentration in the product; and

('f') an attestation that no other ingredients in the product contain 1,4-dioxane.

(c) Filing Process and Timeline.

A manufacturer may submit its waiver application via e-mail or regular mail following directions published by the department. The department may set a date for the submission of applications.

(d) Additional One-Year Waiver

(1) A manufacturer of any household cleansing, personal care, or cosmetic product may apply to the department for one additional one-year waiver from the applicable requirements of section 352-1.3 of this Part, in accordance with subdivisions (a)-(c) of this section upon the submission of similar proof.

(2) An application for an additional one-year waiver must update all the information required in subdivision (b) of this section that was included in the original application, in addition to updating information on the efforts undertaken towards meeting the statutory limits.

(3) An application for waiver renewal must be submitted in the third quarter of the effective timeframe of the initial waiver.

(4) Applications for an additional one-year waiver must state that more time is needed to comply with the 1,4-dioxane limitations set forth in section 352-1.3(b) or (c) of this Part. Additional one-year waivers will not be granted to allow more time to comply with the 1,4-dioxane limitations set forth in section 352-1.3(a) of this Part.

(e) Applicability of Waiver

(1) A waiver of the limitations set forth in section 352-1.3(a) or (c) of this Part will be valid through December 30, 2023. A waiver of the limitations set forth in section 352-1.3(b) of this Part will be valid until December 30, 2024.

(2) If the department grants an additional one-year waiver of the limitation set forth in section 352-1.3(b) of this Part, the waiver will be valid until December 30, 2025.

(3) A household cleansing, personal care, or cosmetic product that has been granted a waiver may be sold in the State while the waiver is in effect notwithstanding that it contains 1,4-dioxane in excess of the limits set forth in section 352-1.3 of this Part. In no case shall a waiver issued by the department be effective after December 30, 2025.

352-1.5 Compliance Evaluation.

(a) A manufacturer must conduct a compliance evaluation to demonstrate compliance with the limitations set forth in section 352-1.3 of this Part for any household cleansing, personal care, or cosmetic product that is distributed, sold, offered or exposed for sale in the State. The compliance evaluation must include one or more of the following analyses:

(1) A reasonable inquiry and documentation by the manufacturer of its raw material suppliers regarding the chemical composition of the raw materials in the household cleansing, personal care, or cosmetic product(s);

(2) A reasonable assessment by the manufacturer of the sum of the concentrations of 1,4-dioxane contributed by each raw material in the finished product formulation; and

(3) Analytical testing conducted in accordance with the criteria in section 352-1.6 of this Part, for the household cleansing, personal care, or cosmetic product(s) or raw material(s) that contribute 1,4-dioxane to the final product formulation.

(i) If a manufacturer is aware or anticipates that variation may exist between formulations of a household cleansing, personal care, or cosmetic product which may affect the concentration of 1,4-dioxane in the product, such that it would alter compliance with the applicable threshold stated in section 352.1-3 of this Part, the manufacturer must conduct the product's compliance evaluation actions for the formulation that the manufacturer expects to result in the highest 1,4-dioxane concentration and which may be distributed, sold or offered for sale in the State.

(ii) A manufacturer must retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the State, including any records demonstrating that laboratory testing was performed in accordance with section 352-1.6 of this Part.

(iii) A manufacturer must submit the compliance evaluation to the department upon request within 15 days.

352-1.6 Guidelines for Laboratory Tests

(a) The following method performance criteria ensure that analytical testing conducted to determine the concentration of 1,4-dioxane in a product or raw material is reliable and accurate. Provided all

criteria set forth in this subdivision are met, a manufacturer may utilize any analytical method to assess compliance.

(1) Sample preparation criteria.

(i) Different sample preparation techniques may be used, including but not limited to those needed for headspace, solid phase microextraction, and direct inject, provided that all other performance criteria are met.

(ii) The product should be mixed or shaken prior to sampling, as needed, to ensure the sample is representative of the product contents.

(2) Method criteria.

(i) The method must use isotope dilution with 1,4-dioxane-d_8 as an internal standard. It is recommended that the concentration of the internal standard in the sample be within the calibration range of 1,4-dioxane.

(ii) A signal to noise ratio of 3:1 must be met for all 1,4-dioxane ions in all samples, including calibration solutions.

(iii) The Limit of Detection should be at or below one tenth of the applicable limitation set forth in section 352-1.3 of this Part. For example, for products with a limit of one part per million, the limit of detection must be less than or equal to 0.1 part per million.

(iv) The Limit of Quantitation should be at or below the applicable limitation set forth in section 352-1.3 of this Part.

(v) Methods may use full scan, selected ion monitoring, or multiple reaction monitoring scanning modes to meet the limit of quantitation, depending on available instrumentation.

(vi) Methods must incorporate, at a minimum, one quantitation and one qualifier ion for 1,4-dioxane and internal standard identification.

('a') 1,4-Dioxane

(‘1’) Quantitation Ion:

(‘i’) For scan and select ion monitoring: 88

(‘ii’) For multiple reaction monitoring: 88 in the first stage; 57 in the second stage

(‘2’) Qualifier Ion:

(‘i’) For scan and select ion monitoring: 57, 58

(‘ii’) For multiple reaction monitoring: 88 in the first stage; 58 in the second stage

(‘b’) 1,4-Dioxane-d_8

(‘1’) Quantitation Ion:

(‘i’) For scan and select ion monitoring: 96

(‘ii’) For multiple reaction monitoring: 96 in the first stage; 62 in the second stage

(‘2’) Qualifier Ion:

(‘i’) For scan and select ion monitoring: 62, 64

(‘ii’) For multiple reaction monitoring: 96 in the first stage; 64 in the second stage

(3) Instrument criteria.

(i) All study samples must be analyzed on a properly calibrated instrument and meet the instrument manufacturer’s specifications. If the instrument calibrations, or other instrument check requirements (i.e., mass spectrometer tune, mass calibration check, or qualitative identification criteria), are outside the acceptable criteria, standard measures to correct the problem must be performed prior to analyzing any sample.

(ii) The use of a gas chromatograph/mass spectrometer is recommended for the chromatographic separation and fragmentation of analytes for identification. The ratios of qualifier ions should be established during calibration and must be maintained throughout sample analysis to verify the identity of 1,4-dioxane and ensure that there are no interfering peaks.

(4) Calibration.

(i) The instrument tune check must be done prior to calibration. The use of 4-bromofluorobenzene tune for full scan, and check tune for select ion monitoring and multiple reaction monitoring, is recommended.

(ii) Retention time and relative retention time requirements:

('a') the internal standard retention time must be within 0.33 minutes to mid-point of initial calibration; and

('b') the analyte retention time must be less than 0.17 minutes to mid-point of initial calibration or first Continuing Calibration Verification.

(iii) The initial calibration must utilize at least five non-zero calibration concentrations. The fitted line of the calibration curve must have a relative standard deviation of less than or equal to 20 percent of the average response factor or must be linear with a correlation coefficient greater than 0.99. The lowest calibration level must be within 50 percent of its true value.

('a') An initial calibration verification standard solution, with a concentration at or near the mid-point of the calibration curve, must be analyzed immediately following the initial calibration and be within 30 percent of its true value.

('b') A continuing calibration verification standard solution must be analyzed before sample analysis, after every tenth analytical run, and at the end of analysis. The determined concentration must be within 20 percent of the true value. If the calibration verification does not meet the acceptance criteria, perform any necessary instrument maintenance, and inject another aliquot of the continuing calibration verification solution. If the response of the analyte is still not within 20 percent of the true value, then a new initial calibration curve is recommended as described in subparagraph 352-1.6(a)(4)(iii) of this Part.

(iv) Solvent blanks should be inserted between samples with high concentration analytes to verify no carryover or cross contamination of 1,4-dioxane from one sample to the next.

(5) Quality control.

(i) All data must adhere to a quality control protocol and include a duplicate sample preparation and analysis for each product analyzed. Quality control protocols are acceptable if they incorporate steps to ensure that method blanks, analytical accuracy, and precision are maintained for each run and the protocol can demonstrate a relative percent difference less than or equal to 20 percent and an extraction recovery between 70 and 130 percent of the expected analyte concentrations. An acceptable quality control protocol must include the following:

('a') A method blank is run with every batch of up to 20 samples. The concentration of 1,4-dioxane in all method blanks must be less than the limit of quantitation.

('b') A laboratory control sample and laboratory control sample duplicate preparation are analyzed with every batch of 20 samples and must be within 30 percent of the true value and relative percent difference less than or equal to 20 percent.

('c') A matrix spike and matrix spike duplicate are analyzed with every batch of 20 samples with a recovery value within 70 and 130 percent and relative percent difference less than or equal to 20 percent. The laboratory may establish internal control limits but must not exceed the 70 to 130 percent recovery range.

('d') The retention time of the analyte of interest in the sample is less than ten seconds to the mid-point of the initial calibration or the first continuing calibration verification.

('e') The limit of quantitation must be within 50 percent recovery of the spiked reference concentration and relative standard deviation less than or equal to 20 percent of four to seven replicates.

352-1.7 Severability.

If any provision of this Part, or its application to any person or circumstance is held to be invalid, the remainder of this Part, and the application of that provision to other persons or circumstances, will not be affected.

Summary of Regulatory Impact Statement

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

6 NYCRR Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

The New York State Department of Environmental Conservation (Department) is proposing to adopt 6 NYCRR Subpart 352-1 to implement the amendments to Article 35 and Article 37 of the Environmental Conservation Law (ECL), adopted in 2019, which established limits on the amount of 1,4-dioxane that can be present in household cleansing, personal care, and cosmetic products sold or offered for sale in New York State (L.2019, c. 613, § 1, eff. Jan. 1, 2022; L.2020, c. 44, § 1, eff. Jan. 1, 2022) (hereinafter referred to as "the Law"). The Law establishes a maximum allowable concentration of 2 parts per million (ppm) of 1,4-dioxane effective December 31, 2022, and 1 ppm effective December 31, 2023, for household cleansing and personal care products, and 10 ppm of 1,4-dioxane effective December 31, 2022, for cosmetic products.

The Department's statutory authority for these regulations is found in ECL sections 1-0101, 3-0301, 35-0105, and 37-0117. The New York State Legislature enacted the Law to protect New York's public waters and drinking water, by reducing the amount of 1,4-dioxane entering the State's waters by way of the covered products. The Legislature also included waiver provisions in the Law to allow manufacturers who cannot meet the statutory limits additional time to develop methods for removing 1,4-dioxane from their products. This proposed regulation is in line with the Legislature's intent, as it implements the provisions of the Law.

This proposed regulation implements the statutory limits on the amount of 1,4-dioxane allowed in covered products, provides detail on how manufacturers can apply for a waiver of these limits for a

limited amount of time, and sets method performance criteria, which would allow regulated entities to use any analytical method of their choosing provided the method meets the criteria set forth in the regulation, ensuring manufacturers use a consistent approach to determine compliance with these limits.

According to United States Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) database, 1,4-dioxane is identified as "likely to be carcinogenic to humans." Despite the known health risks, 1,4-dioxane is still found in many consumer products, such as cosmetics, detergents, deodorants, and shampoos, where it is typically formed as a contaminant during the manufacturing process of such products. These products are used by consumers and then enter from sinks and drains into residential septic systems where they enter local wastewater treatment systems. Elevated levels of 1,4-dioxane have been found in municipalities across the State.

In response to the elevated levels, in 2020, New York State adopted a Maximum Contaminant Level (MCL) for drinking water for 1,4-dioxane of 1 part per billion (ppb).

The Law establishes maximum allowable, trace concentrations and authorizes the Department to periodically review such trace concentrations and determine whether such concentrations should be lowered. This proposed regulation will implement the statutory limitations of 1,4-dioxane in covered products, thereby reducing the amount of 1,4-dioxane in the State's waters.

The proposed regulation does not impose any additional costs to the regulated community (manufacturers) beyond that which is imposed by the Law. The cost of compliance with the Law greatly depends on how much 1,4-dioxane is currently in each product and the method by which compliance is achieved. If a manufacturer does not sell any covered products that have more 1,4-dioxane than the maximum concentration, their initial cost of compliance is essentially zero. However, each product a manufacturer sells with 1,4-dioxane in excess of the maximum concentration will add

to their cost of initial compliance. To bring each product into compliance, manufacturers may choose to reformulate with substitute surfactants, modify manufacturing facilities to remove 1,4-dioxane from raw materials, or work with raw material suppliers to do either of the above or find other options that satisfy compliance obligations. More details on the options and costs are discussed in the complete Regulatory Impact Statement.

The State will not incur additional costs due to the issuance of the proposed regulations beyond the costs associated with implementing the Law. However, to implement the Law and regulations, the Department will incur costs associated with purchasing and testing products for compliance. To evaluate compliance, staff overseeing the program will need to conduct sampling and analysis of products to determine the concentration of 1,4-dioxane and may utilize existing contracts with laboratories for support in evaluating compliance. There are no known costs to local government that are directly related to the implementation and continuing compliance of the proposed regulations.

Neither the proposed Subpart 352-1 nor the Law impose any requirements on local governments.

The proposed regulation does not impose any reporting requirements beyond that which is imposed by the Law. However, the proposed regulation does provide more detail than the Law on certain paperwork requirements. In most cases, paperwork may be submitted and maintained in electronic format.

Manufacturers who seek a waiver from the statutory limits must submit an application to the Department. If a manufacturer chooses to seek a waiver, it must maintain records for the duration of the waiver documenting the levels 1,4-dioxane in the product(s) for which a waiver is granted.

A manufacturer must also, upon request by the Department, submit records that demonstrate

the compliance evaluation that was conducted for the covered product(s).

This proposed regulation does not duplicate any existing regulations pertaining to the presence of 1,4-dioxane in these product categories at the federal or state level.

The Department considered other alternatives to the proposed regulation but determined that a regulation was necessary to implement the statutory requirements.

Since the Law and the proposed Subpart 352-1 set quantitative standards on the 1,4-dioxane content in household cleansing, personal care and cosmetic products, the Department sought to include an approved analytical method in the regulation to clarify how 1,4-dioxane content should be measured in covered products; however because certain methods have not yet been peer-reviewed or are not being used by authoritative entities for regulatory purposes, the Department felt it appropriate to instead develop method performance criteria, which would allow regulated entities to use any analytical method of their choosing so long as it meets the outlined criteria, which ensures the method will produce reliable results.

The Department also clarified certain definitions and statutory requirements based on inquiries received from the public during public meetings, and further, considered additional regulatory provisions based on comments received, but decided not to implement all suggestions for reasons detailed in the full Regulatory Impact Statement.

The federal government does not have a standard for how much 1,4-dioxane is acceptable in household cleansing, personal care, or cosmetic products.

Regulatory Impact Statement

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

The New York State Department of Environmental Conservation (Department) is proposing to adopt 6 NYCRR Part 352, Product Chemical Restrictions and Disclosure, which will include Subpart 352-1, 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products. This rulemaking will implement the amendments to Article 35 and Article 37 of the Environmental Conservation Law (ECL), adopted in 2019, which establish limits on the amount of 1,4-dioxane that can be present in household cleansing, personal care, and cosmetic products sold or offered for sale in New York State (L.2019, c. 613, § 1, eff. Jan. 1, 2022; L.2020, c. 44, § 1, eff. Jan. 1, 2022) (hereinafter referred to as “the Law”). The Law establishes a maximum allowable concentration of 2 parts per million (ppm) of 1,4-dioxane beginning December 31, 2022, and 1 ppm beginning December 31, 2023, for household cleansing and personal care products. The Law also establishes a maximum allowable concentration of 10 ppm of 1,4-dioxane beginning December 31, 2022, for cosmetic products. These proposed regulations seek to implement those statutory provisions.

1. STATUTORY AUTHORITY

The Department's statutory authority for these regulations is found in Environmental Conservation Law (ECL) sections 1-0101, 3-0301, 35-0105, and 37-0117. The relevant statutory provisions are summarized below.

ECL section 1-0101(1) declares it is a policy of New York State to conserve, improve and protect its natural resources and environment and to prevent, abate and control water, land and air pollution in order to enhance the health, safety and welfare of the people of the State and their overall economic and social well-being.

ECL section 3-0301(2)(m) authorizes the Department to adopt regulations as may be necessary to carry out the environmental policy of the State set forth in section 1-0101.

ECL section 35-0101 declares that the State fully exercises the exclusive right to regulate and control the labelling and ingredients of household cleansing products distributed, sold, offered, or exposed for sale in the State, within the scope and limitations of Article 35.

ECL section 35-0105(4) prohibits the distribution, sale, offer or exposure for sale of household cleansing products in this State which contain 1,4-dioxane unless in trace concentrations of 2 ppm, or less, by December 31, 2022, and 1 ppm, or less, by December 31, 2023. ECL section 35-0105(7) authorizes the Department to promulgate such rules and regulations as it deems necessary to implement the provisions of section 35-0105, including rules and regulations with respect to any allowable trace concentrations of 1,4-dioxane established pursuant to section 35-0105(5). ECL sections 37-0117(3) and (4) prohibit the sale or offer for sale of cosmetic products in the State which contain 1,4-dioxane unless in trace concentrations of 10 ppm or less by December 31, 2022, and the sale or offer for sale of personal care products in the state which contain 1,4-dioxane unless in trace concentrations of 2 ppm or less by December 31, 2022, and 1 ppm or less by December 31, 2023.

ECL section 37-0117(6) authorizes the Department to promulgate such rules and regulations as it deems necessary to implement the provisions of section 37-0117, including rules and regulations with respect to any allowable trace concentrations of 1,4-dioxane.

2. LEGISLATIVE OBJECTIVES

The New York State Legislature enacted Chapter 613 of the Laws of 2019 limiting the amount of 1,4-dioxane that can be present in household cleansing, personal care and cosmetic products to protect public waters and drinking water. The legislation is intended to reduce the amount of 1,4-dioxane entering New York's drinking waters by prohibiting its presence, except in trace amounts, in household cleansing, personal care and cosmetic products where it appears most often.

3. NEEDS AND BENEFITS

The proposed regulation implements the statutory limits for 1,4-dioxane in household cleansing, personal care, and cosmetic products. Consistent with the Law, the proposed regulation also includes waiver provisions to allow manufacturers who cannot meet the statutory limits additional time to reformulate their products so that they can comply with the 1,4-dioxane limits. The proposed regulation establishes a process for how manufacturers may apply for a waiver and a time limit for the applicability of waivers. In no case shall a waiver issued by the Department be effective after December 30, 2025.

As the Law establishes concentration limits for 1,4-dioxane in products, there is a need for a standardized method of quantifying the 1,4-dioxane in subject products. Currently, there are methods being used in industry, but none of them are widely accepted or standardized for the quantification of 1,4-dioxane for products covered by this Law. Considering the lack of an accepted, standardized

analytical method to analyze 1,4-dioxane in products covered by this proposed regulation, the Department determined it appropriate to develop method performance criteria, which would allow regulated entities to use any analytical method of their choosing provided the method meets the criteria set forth in the regulation, ensuring the method will produce reliable results by providing a consistent mode of measurement that can eliminate, as much as possible, the variability from test to test, internal noise that can be inherent to testing systems and across different testers.

Therefore, the proposed regulation meets the intent of the Law by adopting the statutory limits for 1,4-dioxane and ensuring manufacturers use a consistent approach to determine compliance with these limits.

According to United States Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) database, 1,4-dioxane is identified as "likely to be carcinogenic to humans." Despite the known health risks, 1,4-dioxane is still found in many consumer products, such as cosmetics, detergents, deodorants, and shampoos, where it is typically formed as a contaminant during the manufacturing process of products. These products are used by consumers and then enter from sinks and drains into residential septic systems where they enter local wastewater treatment systems.

Elevated levels of 1,4-dioxane have been found in municipalities across the State. The Legislature noted in the Introducer's Memorandum in Support that EPA data shows that Long Island has the highest levels detected in the country, with 33 of 36 public water systems on Long Island reporting 1,4-dioxane contamination and one source in Hicksville reporting levels as high as 0.033 ppm.

In response to the elevated levels, New York State's Water Quality Rapid Response Team, a joint effort between the Department and New York State Department of Health, investigated and initiated corrective actions on water contamination in the State. In 2020, New York adopted a Maximum Contaminant Level (MCL) for 1,4-dioxane of 1 part per billion (ppb) which requires monitoring of 1,4-

dioxane in New York's drinking waters. In addition, the Legislature enacted amendments to ECL Articles 35 and 37 to restrict the concentrations of 1,4-dioxane in household cleansing, personal care, and cosmetic products with the goal of reducing the amount of 1,4-dioxane in the State's waters and protecting New York's citizens.

4. COSTS

a. Costs to Regulated Parties

The rule does not impose any additional cost to the regulated community (manufacturers) beyond that which is imposed by the Law. Below is a discussion of the costs to the regulated community imposed by the Law.

The Department cannot establish with certainty the cost of compliance with the Law and regulation. The cost of compliance greatly depends on how much 1,4-dioxane is currently in each product and whether and to what extent a product must be reformulated and how reformulation will occur. If a manufacturer does not sell any covered products that have more 1,4-dioxane than the maximum allowable concentration, their initial cost of compliance is essentially zero. If a manufacturer has multiple products that must be reformulated, the cost could increase. Regardless, the primary source of 1,4-dioxane in products is the use of one or more surfactants, and there are several options for reducing the 1,4-dioxane concentration in the finished product which have varying costs, as further discussed below.

Working with Suppliers

In some cases, a manufacturer may rely on various suppliers for raw materials that they use in making a finished product. If the suppliers are experiencing difficulties with reducing 1,4-dioxane concentrations, including needing to develop new raw material formulations or needing to install new

equipment to remove 1,4-dioxane from formulations, they may pass these costs on to manufacturers, and the costs will vary depending on the approach taken and how the costs are or may be spread among manufacturers who utilize the surfactant(s).

Obtaining Substitute Surfactants

Manufacturers may choose to work with suppliers to substitute existing surfactants for surfactants with lower 1,4-dioxane concentrations, or they may develop new surfactants with lower 1,4-dioxane concentrations which would introduce an initial cost to the production line. For this option, there may also be costs associated with research and development, efficacy and stability testing, relabeling, and scaling up production. If, in aggregate, this process required one full-time employee (FTE) per product, the cost of reformulating each product could be as high as $300,000 (assuming an FTE costs the manufacturer $100,000 per year).

Modifications to Manufacturing Facilities

Manufacturers may also choose to install new equipment at their facilities in order to remove 1,4-dioxane from their ingredient streams, which could require the reconfiguration of existing equipment, demolition of existing facilities and/or construction of new facilities to accommodate such equipment. These needs will vary depending on the existing layout of the facility, however each of these changes could result in significant costs to the manufacturer. Based on information provided by equipment manufacturers and companies subject to this Law, the cost of stripping equipment could range from several hundred thousand dollars to several million dollars.

Higher production costs borne by manufacturers or suppliers could lead to higher product costs, but such information is not readily available to, and has not been shared with, the Department. Because there are multiple pathways to achieving compliance, the Department cannot provide a comprehensive estimate of the costs of compliance with the Law.

Costs of Product Testing

In the long term, if a manufacturer assesses compliance using a lab for hire, the cost for each test may vary among labs. Research done for the Department shows a wide range in the price of testing products for 1,4-dioxane. The lowest rate found was $250 per sample and the highest was $1030 per sample. However, it is common for commercial labs to decrease the per sample price based on the total number of samples being tested. Likewise, if a manufacturer assesses compliance by testing each finished product, the cost is likely to be much higher than if they test each surfactant used among their products and calculate how much 1,4-dioxane is present in each final product based on dilution. The cost to the manufacturer is even lower, if not zero, if they rely on reports from their supplier of the amount of 1,4-dioxane in the surfactants to calculate the amount of 1,4-dioxane in the final product.

b. Costs to the Department, the State and Local Governments

The State will not incur additional costs due to the implementation of the proposed regulations. To evaluate compliance, Department staff overseeing the program will need to purchase products and conduct sampling and analysis of products to determine the concentration of 1,4-dioxane. Staff may utilize existing contracts with laboratories for support in evaluating compliance, however the cost to evaluate compliance would have been incurred regardless of the rulemaking. There are no known costs to local government that are directly related to the implementation and continuing compliance of the proposed regulations.

5. LOCAL GOVERNMENT MANDATES

Neither the proposed Subpart 352-1 nor the Law imposes any requirements on local governments.

6. PAPERWORK

The proposed regulation does not impose any reporting requirements.

Manufacturers who seek a waiver from the statutory limits must submit an application to the Department, including details on which products the manufacturer is seeking a waiver for, how much 1,4-dioxane is currently in each of the products for which a waiver is being sought, the efforts the manufacturer has undertaken to reduce the amount of 1,4-dioxane in those products, and the reason those products are not able to meet the applicable 1,4-dioxane limit by the statutory deadline. If a manufacturer chooses to seek a waiver, it must maintain records for the duration of the waiver concerning how much 1,4-dioxane is in the product(s) granted a waiver.

Proposed Section 352-1.5 includes a provision that, upon request by the Department, a manufacturer must submit records that demonstrate the compliance evaluation that was conducted for the household cleansing, personal care, or cosmetic product(s) identified by the Department within fifteen days or respond that no such records exist.

7. DUPLICATION

New York State's regulation on the amount of 1,4-dioxane that can be present in household cleansing, personal care, or cosmetic products does not conflict with any law or regulation of the federal government. This regulation does not duplicate any existing regulations pertaining to the presence of 1,4-dioxane in these product categories at the federal or state level.

8. ALTERNATIVES

The Department considered the "no action alternative" approach to implementing the 1,4-dioxane thresholds but rejected it because the proposed regulations would provide additional clarity on criteria

for laboratory testing in the form of method performance criteria as well as the process for applying for a waiver that would facilitate implementation of the Law.

The Department also considered implementing the 1,4-dioxane limits through the issuance of a program policy but determined that a regulation would provide more clarity and allow for greater public input.

The Department received numerous inquiries whether a household cleansing product includes products that serve a dual-purpose of cleansing and disinfecting or cleansing and sanitizing.

"Household cleansing product" is defined in the Law to mean “any product, including but not limited to soaps and detergents, containing a surfactant as a wetting or dirt emulsifying agent and used primarily for domestic or commercial cleaning purposes, including but not limited to, the cleansing of fabrics, dishes, food utensils and household and commercial premises" (ECL 35-0103(1)).

The definition excludes “foods, drugs, cosmetics, insecticides, fungicides and rodenticides or cleansing products used primarily in industrial manufacturing, production and assembling processes as provided by the commissioner by rule and regulation.” Proposed Subpart 352-1 clarifies that household cleansing products that are primarily used for cleaning purposes and which contain a surfactant are included in the definition even if they also perform a sanitizing or disinfectant function.

The Department determined that such products, which are primarily used by consumers for household cleansing purposes, and which contain a surfactant, likely contain 1,4-dioxane and should be subject to the Law and these regulations.

Thus, the proposed definition of household cleansing product in Subpart 352-1 includes cleaning products that also contain antimicrobial agents. Products labeled, advertised, marketed, and distributed for use primarily as pesticides, which would include, for example, products serving solely as disinfectants and sanitizers or products targeting insects that are not used for cleaning purposes,

would not be included in this definition. Further, as there are numerous automotive cleansing products that are used for domestic and commercial cleansing purposes that may contain 1,4-dioxane, the Department's proposed regulation clarifies that products used for the cleansing of automobiles are within the scope of this definition.

As the Law sets quantitative standards for 1,4-dioxane concentrations in subject products, but does not specify how manufacturers will demonstrate compliance, the Department is proposing to include compliance evaluation requirements in the proposed Subpart 352-1. However, to allow flexibility in the method by which manufacturers demonstrate compliance, the Department is allowing three options for compliance determinations. They include: (1) making a reasonable inquiry of raw materials suppliers regarding chemical composition of the raw materials; (2) conducting a reasonable assessment of sum of 1,4-dioxane contributions of each raw material in the finished product; and (3) conducting analytical testing on the finished product or the raw materials that contribute 1,4-dioxane to the finished product.

Additionally, since the Law and proposed Subpart 352-1 set quantitative standards on the 1,4-dioxane content in household cleansing, personal care and cosmetic products, the Department sought to include an approved analytical method in the regulation to clarify how 1,4-dioxane content should be measured in covered products. However, the Department could not identify an analytical method that is currently widely accepted and used in these industries or approved by the federal government for measuring 1,4-dioxane in household cleansing, personal care and cosmetic products. EPA has published analytical methods to measure 1,4-dioxane in water, soil, air, sludge, solid waste, oily waste, and tissue, but those analytical methods were not designed to be used on complex mixtures and substances with higher viscosity, such as a laundry detergent and other products covered by this regulation. However, there are methods being used in industry, but none of them are

widely accepted, nor standardized for 1,4-dioxane quantification of products covered by this Law. Considering the lack of an accepted, standardized analytical method to analyze 1,4-dioxane in products covered by this proposed regulation, the Department felt it appropriate to instead develop method performance criteria, which would allow regulated entities to use any analytical method of their choosing so long as it met the outlined criteria, ensuring the method will produce reliable results. In conjunction with California Department of Toxic Substances Control (DTSC), the Department developed and released for public comment method performance criteria for 1,4-dioxane testing. This set of criteria outlines accuracy and precision levels that must be met by a test method to be considered credible and reliable by the Department. The Department believes this is the best approach to ensuring all manufacturers are using a reliable method to quantify 1,4-dioxane in their products, ensure compliance, and allow for flexibility as the science evolves. Following the development of the method performance criteria, the Department held a public meeting for stakeholders and other interested parties to consider and offer comments and proposed regulatory language related to the method performance criteria. The Department received 11 written comments and made minor changes to the method performance criteria based on the comments received. Additional comments received related to sample introduction methods, and test methods, but the Department did not make changes to the method performance criteria in response as the suggested changes were seen as overly prescriptive and would limit the flexibility of the test methods and the availability of laboratories capable of meeting the criteria.

The Department received comments in favor of limiting the scope of the term “manufacturer” in conjunction with including a sell-through provision to allow the continued sale of products that were compliant prior to December 31, 2022, but are non-compliant as of December 31, 2022, or 2023. A comment was also received opposing a sell-through provision. The Department edited the definition

of manufacturer for clarity, which has been incorporated in the proposed regulation. Regarding a sell-through provision, the Department notes that the Law does not grant it authority to allow sell-through of non-compliant products, especially given the provision for manufacturers to seek a waiver. Additionally, the Department considered different approaches for determining whether a product falls into the definition of household cleansing, personal care, or cosmetic product. The Department created an optional form that a manufacturer may complete if it would like clarity on if a product is a household cleansing, personal care or cosmetic product, and therefore which threshold is applicable. Lastly, the Department considered different approaches to allowing manufacturers to claim certain information contained in their waiver applications as confidential commercial information in accordance with the provisions of 6 NYCRR Part 616. The Department determined that the name of the product, whether the product is a household cleansing, personal care or cosmetic product, and the current level of 1,4-dioxane in the product may not be claimed as confidential. If this information was kept as confidential, consumers of products covered by the rule would not be able to ascertain whether they are purchasing products that contain concentrations of 1,4-dioxane that comply with the statutory limits. Further, any person could conceivably purchase a product on the shelf and subject it to testing to determine the amount of 1,4-dioxane it contains as the Department did when it arranged for product testing. Because the concentration of 1,4-dioxane can be determined through testing, the Department did not consider it to be confidential.

9. FEDERAL STANDARDS

The federal government does not have a standard for how much 1,4-dioxane is acceptable in household cleansing, personal care, or cosmetic products.

10. COMPLIANCE SCHEDULE

The Law sets forth the deadlines for compliance with the applicable 1,4-dioxane limitations for covered products. Additionally, the Law provides manufacturers the ability to apply for a waiver if their products cannot meet these limits, and if they can make the requisite demonstration why they need additional time to comply. Thus, manufacturers may have up to two additional years to meet 1,4-dioxane limitations. Since these timeframes are established by Law, the Department cannot extend them further.

Summary of Regulatory Flexibility Analysis for Small Businesses and Local Governments

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

The New York State Department of Environmental Conservation (Department) is proposing to adopt 6 NYCRR Part 352, Product Chemical Restrictions and Disclosure, which will include Subpart 352-1, 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products. This rulemaking will implement the amendments to Article 35 and Article 37 of the Environmental Conservation Law (ECL), adopted in 2019, which established limits on the amount of 1,4-dioxane that can be present in household cleansing, personal care, and cosmetic products sold or offered for sale in New York State (L.2019, c. 613, § 1, eff. Jan. 1, 2022; L.2020, c. 44, § 1, eff. Jan. 1, 2022) ("the Law"). The Law establishes a maximum allowable concentration of 2 ppm of 1,4-dioxane effective December 31, 2022, and 1 ppm effective December 31, 2023, for household cleansing and personal care products; and 10 ppm of 1,4-dioxane effective December 31, 2022, for cosmetic products. The proposed regulations seek to implement these statutory provisions.

The Law also includes a waiver provision to allow manufacturers to apply for additional time to meet these limits. Proposed Subpart 352-1 will implement these statutory limits by providing details on how manufacturers can apply for a waiver and establishes method performance criteria for test methods a manufacturer uses to determine compliance with 1,4-dioxane limits.

The Department conservatively estimates that there are approximately 120 potential small businesses in the manufacturing sector that could be affected by the proposed regulation, and 36,000 retail small businesses in the retail trade, statewide that may be impacted by the proposed regulation.

The implementation of these regulations will not adversely affect local governments since it does not impose any mandates, including compliance obligations or reporting and record keeping requirements, on local governments.

To minimize the impact of the proposed regulation on manufacturers, the proposed regulation does not prescribe specific steps manufacturers must take to reduce 1,4-dioxane concentrations in their products. There are several methods available to manufacturers for complying with the 1,4-dioxane limits in the Law, which have varying levels of economic and technological feasibility. A manufacturer may apply for a waiver pursuant to proposed section 352-1.4, if it is unable to comply with the applicable 1,4-dioxane limits but has taken steps to do so.

Under proposed section 352-1.5, a manufacturer must conduct a compliance evaluation to determine whether their covered product(s) complies with the limitations set forth in proposed section 352-1.3. The proposed regulation allows manufacturers to choose from various options to evaluate compliance. This approach offers flexibility to businesses, including small businesses, that is not otherwise available under the Law and thereby minimizes adverse economic impacts.

Manufacturers conducting compliance evaluations pursuant to section 352-1.5 may need to engage with an analytical laboratory to determine the concentrations of 1,4-dioxane in their products. However, as the Law requires manufacturers to comply with 1,4-dioxane limits beginning December 31, 2022, they likely have engaged with a laboratory to determine concentrations of 1,4-dioxane in their products. Additionally, manufacturers have the option to base their determination on reasonable inquiry of their ingredient suppliers, which would not require professional services. The Department has provided guidance on compliance evaluation to allow manufacturers maximum flexibility in meeting this requirement.

The Department cannot determine with certainty the cost of compliance with the Law and proposed regulation. The cost of compliance greatly depends on how much 1,4-dioxane is currently in each product and the method by which compliance is ensured. If a manufacturer does not sell any covered products that have more 1,4-dioxane than the maximum concentration, their initial cost of compliance is essentially zero. However, each product a manufacturer sells with 1,4-dioxane in excess of the maximum concentration will add to their cost of initial compliance. Further, the cost of initial compliance depends greatly on how the manufacturer is able to bring each product into compliance. Since product reformulation will be driven by the 1,4-dioxane limits contained in the Law, and the proposed regulation implements statutory standards, manufacturers would incur the costs associated with product reformulation notwithstanding the proposed regulation. A more detailed estimate of compliance costs is included in the complete Regulatory Flexibility Analysis for Small Businesses and Local Governments document.

All manufacturers, regardless of size, may be required to maintain records and submit information to the Department. The proposed regulation requires manufacturers to retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the State. Upon request by the Department, a manufacturer must submit records that demonstrate the compliance evaluation that was conducted for the product(s) identified by the Department within fifteen days or respond that no such records exist. A manufacturer who has been granted a waiver must be able to produce documentation of the concentration of 1,4-dioxane in its products upon request by the Department for the duration of the waiver. Professional services are not expected to be needed to submit and maintain records.

A cure period or other opportunity for ameliorative action was not included in the proposed regulation as the Law already included a waiver provision which effectively delays the need for

manufacturers to comply with the 1,4-dioxane restrictions by up to two years while they conduct actions to reduce the presence of 1,4-dioxane in their products. As this provision offers an opportunity to achieve compliance over an extended schedule, additional ameliorative actions were not deemed necessary.

Rural Area Flexibility Analysis

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

INTRODUCTION

Proposed Subpart 352-1 codifies in regulation the statutory limits on 1,4-dioxane and will not place any additional burdens on rural areas or increase regulatory requirements applicable to such areas. The requirements that exceed those set forth in the Law apply to manufacturers of household cleansing, personal care, and cosmetic products. The Law will impact retailers across the State, including in rural areas, who must now ensure that the products they sell comply with the 1,4-dioxane limits established in the Law.

The Department has provided significant outreach to manufacturers; and has provided additional outreach via direct email to rural retailers regarding the Law and the sale of covered products. The Department will continue to provide a statewide outreach program to all entities affected by the regulations and other interested parties, including public and private interests in rural areas.

1. TYPES AND ESTIMATED NUMBER OF RURAL AREAS

For purposes of this analysis, “rural area” means those portions of the state so defined by Executive Law section 481(7) and SAPA section 102(10). Under Executive Law section 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, programs and such other entities or resources as are found therein. In counties of two hundred thousand or greater population, ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages,

individuals, institutions, communities, programs and such other entities or resources as are found therein." There are 44 counties in the State that have populations of less than 200,000 people and 71 towns in non-rural counties where the population densities are less than 150 people per square mile. The proposed Subpart 352-1 will apply statewide, including rural areas of the State.

2. REPORTING, RECORDKEEPING, OTHER COMPLIANCE REQUIREMENTS, AND NEED FOR PROFESSIONAL SERVICES

The proposed regulation does not include routine reporting requirements related to the 1,4-dioxane limits. However, there are regulatory provisions which may require manufacturers to submit information to the Department. Specifically, under the waiver application provisions of section 352-1.4, a manufacturer may apply for a waiver if they are unable to comply with the applicable 1,4-dioxane limits. While the waiver is in effect, the manufacturer must be able to produce documentation of the stated concentration of 1,4-dioxane upon request by the Department. The application process to obtain a waiver is applicable to manufacturers and will not affect rural areas. In any event, waivers will expire after December 30, 2025, and the waiver provisions will have no effect after that.

Additionally, under section 352-1.5, a manufacturer must conduct a compliance evaluation to determine whether their household cleansing, personal care, or cosmetic product(s) complies with the limitations set forth in section 352-1.3. Upon request by the Department, a manufacturer must submit records that demonstrate the compliance evaluation that was conducted for the product(s) identified by the Department within fifteen days or respond that no such records exist. Manufacturers conducting a compliance evaluation may need to engage an analytical laboratory to determine the concentrations of 1,4-dioxane in their products. However, the proposed regulation also provides for other options for determining compliance. Manufacturers may base their determination on reasonable

inquiry of their ingredient suppliers or on a reasonable assessment of the sum of the concentrations of 1,4-dioxane contributed by each raw material in the finished product formulation.

There is also a recordkeeping requirement associated with the compliance evaluation provisions of section 352-1.5 requiring that manufacturers retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the State. Professional services are not expected to be needed to maintain records associated with the compliance evaluation.

3. COSTS

The proposed regulation does not impose any additional costs on the regulated community, including manufacturers of covered products and retailers who must ensure that the products they sell are compliant, other than any increased costs that may result from the Law. The Department cannot determine with certainty the cost of compliance with the Law and regulation. Manufacturers will bear the brunt of the costs of the Law, which are associated with various methods of product reformulation. The Department does not expect that there will be variation in costs based on a manufacturer being located in a rural area. Below is a discussion of those costs.

The cost of compliance greatly depends on how much 1,4-dioxane is currently in each product and the method by which compliance is ensured. If a manufacturer does not sell any covered products that have more 1,4-dioxane than the maximum concentration, their initial cost of compliance is essentially zero. However, each product a manufacturer sells with 1,4-dioxane in excess of the maximum concentration will add to their cost of initial compliance. Further, the cost of initial compliance depends greatly on how the manufacturer is able to bring each product into compliance.

For the purposes of this analysis, we will assume the only way that 1,4-dioxane enters final products is through the surfactant. In reality, 1,4-dioxane may be a byproduct formed in another ingredient or it may be in the final product from multiple sources. However, the concepts discussed are applicable to these scenarios as well.

If a manufacturer can purchase a version of the same surfactant from their supplier with lower 1,4-dioxane, which can be achieved through chemical stripping, the cost of compliance would be the difference in cost between the surfactant with a higher level of 1,4-dioxane and the cost of the surfactant with lower 1,4-dioxane. While initially manufacturers would bear this cost, discussions with manufacturer industry associations lead the Department to believe that this difference would ultimately be passed to consumers through price increases.

If a manufacturer's surfactant supplier does not have the necessary technology to strip 1,4-dioxane out of its products, the manufacturer could either find a new supplier for their surfactant or request their current supplier to purchase stripping equipment. Based on conversations with equipment manufacturers, the cost of this equipment depends on the flowrate of the plant and could range from several hundred thousand dollars to several million dollars. And while the surfactant supplier is not a regulated entity under this Law, the cost would likely ultimately be borne by the manufacturer and then the end consumer.

The last initial compliance option for manufacturers is to reformulate their products so a surfactant that produces 1,4-dioxane as a byproduct is no longer used. This option is likely to be the most expensive as it requires research and development to find a new viable formulation, test it for performance and stability, secure suppliers for new ingredients, produce the new formulation and distribute it to retailers. If, in aggregate, this process required one full-time employee (FTE) per

product, the cost of reformulating each product could be as high as $300,000 (assuming an FTE costs the manufacturer $100,000 per year).

In the long term, if a manufacturer assesses compliance using a lab for hire, the cost for each test may vary among labs. Research done for the Department shows a wide range in the price of testing products for 1,4-dioxane. The lowest rate found was $250 per sample and the highest was $1030 per sample. However, it is common for commercial labs to decrease the per sample price based on the total number of samples being tested. Likewise, if a manufacturer assesses compliance by testing each finished product, the cost is likely to be much higher than if they test each surfactant used among their products and calculate how much 1,4-dioxane is present in each final product based on dilution. The cost to the manufacturer is even lower, if not zero, if they rely on reports from their supplier of the amount of 1,4-dioxane in the surfactants to calculate the amount of 1,4-dioxane in the final product.

As a result of the statutory limits that took effect on December 31, 2022, retailers, including those located in rural areas, may need to obtain assurances from manufacturers that the products on their shelves as well as any new products they purchase, comply with the Law. Proposed 352-1 does not create any additional burdens for retailers.

4. MINIMIZING ADVERSE IMPACTS

The Law establishes the 1,4-dioxane limits for covered products. The proposed regulation will not impose additional regulatory burdens on rural areas beyond what the statute requires. The Department estimates that there are fewer than ten manufacturers located in rural areas of the State that make products covered by the Law. Nonetheless, the proposed regulation minimizes adverse impacts on all affected manufacturers in several ways. First, the regulations allow manufacturers

flexibility in the way they achieve compliance with the 1,4-dioxane thresholds in that it does not prescribe specific actions that manufacturers need to take to reduce 1,4-dioxane concentrations in their products. The proposed regulation also offers regulatory flexibility by allowing manufacturers to use several options to evaluate compliance with the Law. However, other than the measures discussed here and the statutory provision for a waiver, the Department cannot provide additional flexibility regarding the sale and distribution of noncompliant products after December 31, 2022.

5. RURAL AREA PARTICIPATION

Based on the definition of ‘Rural area’ by Executive Law section 481(7) and SAPA section 102(10), the U.S. Census 2020 data was used to determine the rural counties and towns of the State. The Department of Labor’s website was utilized to filter for companies employing up to 99 employees in manufacturing in rural counties. According to this information, there are less than ten companies located in rural areas that manufacture covered products and that will be affected by this Law. Proposed Subpart 352-1 will apply statewide, including all rural areas of the State. The Department has provided outreach to the identified manufacturers and retailers in rural areas and will continue to provide a statewide outreach program to all affected entities and other interested parties, including public and private interests in rural areas. The Department does not believe that public sector entities will have any obligations under these regulations.

For potentially affected manufacturers in rural areas, the Department has held two public meetings providing an overview of the regulations, sought public comment, and posted response to those comments, along with a recording of one of the meetings, on the webpage.

In addition, the Department has held stakeholder meetings with various stakeholder groups, including several major manufacturers and numerous industry associations that can share information on the

Law and rulemaking with members, including manufacturers and retailers in rural areas that were identified using DOL's website via targeted email correspondence. Further, association categories applicable to these stakeholders were researched, compiled and included in outreach efforts to disseminate information on the Law.

6. INITIAL REVIEW OF PROPOSED REGULATION

The Department will conduct an initial review of the proposed regulation within 3 years, as required by SAPA § 207.

Regulatory Flexibility Analysis for Small Businesses and Local Governments

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

INTRODUCTION

The proposed regulation is not expected to place any additional regulatory burdens on small businesses or local governments. The requirements of the proposed regulation that extend beyond those set forth in the Law apply to manufacturers of household cleansing, personal care, and cosmetic products. The Department has provided significant outreach and will continue to provide a statewide outreach program to all entities affected by the regulations and other interested parties, including public and private interests. Details on the Department's analysis of flexibility offered to, and impacts experienced by small businesses and local governments are discussed below.

1. EFFECT OF PROPOSED REGULATION

As ECL sections 35-0105 and 37-0117 already set forth 1,4-dioxane limits and a waiver provision, the primary effect of proposed Subpart 352-1 will be to implement the statutory limits on the amount of 1,4-dioxane allowed in covered products in a consistent manner, provide details on how manufacturers can apply for a waiver of these limits for a limited amount of time, and set method performance criteria for any test method a manufacturer uses to determine compliance with 1,4-dioxane limits. These requirements that implement the Law apply to manufacturers of household cleansing, personal care, and cosmetic products.

For the purposes of a regulatory flexibility analysis, "small business" means any business which is resident in this state, independently owned and operated, and employs one hundred or fewer

individuals. Therefore, the Department investigated the potential for impacts to businesses employing between one and 100 individuals.

The New York State Business Directory maintained by the Department of Labor is a publicly available data set of more than 850,000 companies searchable by industry sector and county (https://dol.ny.gov/potential-employers). These records were filtered to identify potentially impacted businesses. First, the records were limited to the manufacturing sector, then by company size. In this database, company size is given as ranges (1 to 4, 5 to 9, 10 to 19, 20 to 49, 50 to 99, and so on). These ranges do not match perfectly with the sizes needed for this analysis, so it was necessary to identify the businesses with between one and 99 employees (instead of one to 100). Statewide, there were approximately 19,800 manufacturing businesses with between one and 99 employees. Each business was evaluated for the likelihood that it manufactures the product categories covered by the Law (i.e., household cleansing, personal care, and cosmetic products). Many businesses were immediately excluded because they manufacture product categories that have no relevance to the proposed regulation. Businesses that were considered likely to be manufacturing potentially covered products included manufacturers of cosmetics, soaps and detergents, health and beauty products, janitorial supplies, and specialty cleaning products.

After narrowing the list based on product type, the Department estimated the number of small businesses that are likely to manufacture products subject to the proposed regulation. This estimate was derived by counting the number of businesses likely to be manufacturing covered products in several company size categories, determining the average number of “likely covered product manufacturers” based on these counts, and then extrapolating this average across the 19,800 small businesses in New York. The Department then applied a ten percent factor of safety in the calculation. Based on this calculation, the Department conservatively estimates that there are

approximately 120 small businesses in the manufacturing sector in the State that are potentially subject to the Law and, therefore, may be impacted by the proposed regulation.

Similarly, records were filtered to identify potentially impacted retail small businesses. The directory was filtered for retail trade in addition to the above criteria. Statewide, there were approximately 86,000 retail businesses with between one and 99 employees. Each business was evaluated for the likelihood that it sells the product categories covered by the Law (i.e., household cleansing, personal care, and cosmetic products). Many businesses were excluded because they sell product categories that have no relevance to the Law. Businesses that were considered likely to be selling covered products included, but not limited to retailers of cosmetics, soaps and detergents, health and beauty products, department stores, convenience stores, grocers, pharmacies, service stations, and stationary stores.

After narrowing the list based on product type, the Department estimated the number of retail small businesses that are likely to sell products subject to the proposed regulation. After counting, the Department determined the proportion of the businesses in these size categories and applied that proportion factor to all of the retail businesses in the “small business” size category. Based on this calculation, the Department estimates that there are approximately 36,000 retail small businesses in the retail trade in the State that are potentially subject to the Law and, therefore, may be impacted by the proposed regulation in terms of having to ensure they are selling compliant products.

There is some reason to believe that the figures provided here may overestimate the number of potentially affected small businesses. The New York State Business Directory is organized by county, and company size is the number of employees at the location in that county, not company-wide. Some manufacturers that initially appeared to be small businesses were later found to be just one location of a national or multinational company. In these instances, the business was removed from

the estimate of impacted businesses. This correction was only possible when there was sufficient additional information available on company websites and other resources such as Bloomberg or Dun & Bradstreet. While the estimates provided here exclude those sites definitively proven to be part of organizations with more than 100 employees, some may remain in which the number of employees was indeterminable.

The proposed regulation does not contain a mandate on local governments. Local governments have no additional compliance obligations.

2. COMPLIANCE REQUIREMENTS

All manufacturers, regardless of size, may be required to submit information to the Department to comply with proposed Subpart 352-1. Specifically, under the waiver application provisions of proposed section 352-1.4, a manufacturer may apply for a waiver if it is unable to comply with the applicable 1,4-dioxane limits. If the waiver application is approved, the manufacturer must be able to produce documentation of the stated concentration of 1,4-dioxane upon request by the Department for the duration of the waiver. In any event, the waiver provisions are short term as no waiver will be effective after December 30, 2025.

Additionally, under proposed section 352-1.5, a manufacturer must conduct a compliance evaluation to determine whether their household cleansing, personal care, or cosmetic product(s) complies with the limitations set forth in proposed section 352-1.3. Upon request by the Department, a manufacturer must submit records that demonstrate the compliance evaluation that was conducted for the product(s) identified by the Department within fifteen days or respond that no such records exist. To minimize adverse impacts on all affected manufacturers, the proposed regulation allows manufacturers flexibility in the manner in which they achieve compliance with the 1,4-dioxane

thresholds in that it does not prescribe specific actions that manufacturers need to take to reduce 1,4-dioxane concentrations in their products. Additionally, the proposed regulation also offers regulatory flexibility by allowing manufacturers to use several options to evaluate compliance with the Law. However, other than the measures discussed here and the statutory provision for a waiver, the Department cannot provide additional flexibility regarding the sale and distribution of noncompliant products due to the statutory limits.

There is also a proposed recordkeeping requirement requiring manufacturers to retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the State.

The implementation of these regulations will not adversely affect local governments since there are no standards or reporting and record keeping requirements for local governments.

3. PROFESSIONAL SERVICES

While the submission of records and record keeping may be required under the proposed regulation, professional services are not expected to be needed in order to submit and maintain records. Manufacturers conducting compliance evaluation actions in accordance with section 352-1.5 may need to engage with an analytical laboratory to determine the concentrations of 1,4-dioxane in their products. However, as the statute requires manufacturers to comply with 1,4-dioxane limits, they would likely have engaged with a laboratory to determine concentrations of 1,4-dioxane in their products prior to the regulation being finalized. Additionally, manufacturers also have the option to base their determination on reasonable inquiry of their ingredient suppliers, which would not require professional services. The Department has provided guidance on compliance evaluation to allow manufacturers maximum flexibility in meeting this requirement. They include: (1) making a reasonable

inquiry of raw materials suppliers regarding chemical composition of the raw materials; (2) conducting a reasonable assessment of sum of 1,4-dioxane contributions of each raw material in the finished product; and (3) conducting analytical testing on the finished product or the raw materials that contribute 1,4-dioxane to the finished product.

4. COMPLIANCE COSTS

The proposed regulation does not impose any additional compliance costs on regulated business or industry beyond that which is imposed by the Law. The Department cannot determine with certainty the cost of compliance with the Law and proposed regulation. The proposed regulation does not impose any obligations on local government, therefore there are no compliance costs for local government. Below is a discussion of the costs incurred by the regulated community to comply with the proposed regulation.

The cost of compliance greatly depends on how much 1,4-dioxane is currently in each product and the method by which compliance is ensured. If a manufacturer does not sell any covered products that have more 1,4-dioxane than the maximum concentration, their initial cost of compliance is essentially zero. However, each product a manufacturer sells with 1,4-dioxane in excess of the maximum concentration will add to that manufacturer’s initial capital costs to comply with the proposed regulation. Further, the cost of initial compliance depends greatly on how the manufacturer is able to bring each product into compliance.

For the purposes of this discussion, we will assume the only method 1,4-dioxane enters final products is through the surfactant. In reality, 1,4-dioxane may be a byproduct formed in another ingredient or it may be in the final product from multiple sources. However, the concepts discussed are applicable to these scenarios as well.

If a manufacturer is able to purchase a version of the same surfactant with less 1,4-dioxane from their supplier, which can be achieved through chemical stripping, the cost of compliance would be the difference in cost between the surfactant with a higher level of 1,4-dioxane and the cost of the surfactant with a lower level of 1,4-dioxane. While initially manufacturers would bear this cost, discussions with manufacturer industry associations lead the Department to believe that this difference would ultimately be passed to consumers through price increases.

If a manufacturer's surfactant supplier does not have the necessary technology to strip 1,4-dioxane out of its products, the manufacturer could either find a new supplier for their surfactant or request their current supplier to purchase stripping equipment. Based on conversations with equipment manufacturers, the cost of this equipment is dependent on the flowrate of the plant and could range from several hundred thousand dollars to several million dollars. And while the surfactant supplier is not a regulated entity under this Law, the cost would likely ultimately be borne by the manufacturer and may be passed on to the end consumer.

The last initial compliance option for manufacturers is to reformulate their products so a surfactant that produces 1,4-dioxane as a byproduct is no longer used. This option is likely to be the most expensive as it requires research and development to find a new viable formulation, test it for performance and stability, secure suppliers for new ingredients, produce the new formulation and distribute it to retailers. If, in aggregate, this process required one full-time employee (FTE) per product, the cost of reformulating each product could be as high as $300,000 (assuming an FTE costs the manufacturer $100,000 per year).

In the long term, if a manufacturer assesses compliance using a lab for hire, the cost for each test may vary among labs. Research done for the Department shows a wide range in the price of testing products for 1,4-dioxane. The lowest rate found was $250 per sample and the highest was $1030 per

sample. However, it is common for commercial labs to decrease the per sample price based on the total number of samples being tested. Likewise, if a manufacturer assesses compliance by testing each finished product, the cost is likely to be much higher than if they test each surfactant used among their products and calculate how much 1,4-dioxane is present in each final product based on dilution. The cost to the manufacturer is even lower, if not zero, if they rely on reports from their supplier of the amount of 1,4-dioxane in the surfactants to calculate the amount of 1,4-dioxane in the final product.

Finally, there is a recordkeeping requirement associated with the compliance evaluation provisions of proposed section 352-1.5 requiring manufacturers to retain records demonstrating that a compliance evaluation was conducted for as long as a product is distributed, sold, offered, or exposed for sale in the state. However, the recordkeeping requirement is not expected to result in costs to manufacturers.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY

There are no impacts anticipated for local government related to this proposed regulation.

As discussed in the Compliance Costs section above, there are several methods available to manufacturers for complying with the statutory 1,4-dioxane limits, which have varying levels of economic and technological feasibility. Small businesses that manufacture products exceeding the 1,4-dioxane limits could choose to comply with the limits using any of the above-described methods and may ultimately pass the increased cost on to consumers. However, they would need to comply with these thresholds regardless of the adoption of regulations under Subpart 352-1.

Manufacturers, including those that are small businesses, must also conduct compliance evaluation activities as set forth in section 352-1.5, to determine whether their products comply with the 1,4-

dioxane limits. The economic and technological feasibility of conducting these activities would be dependent upon whether they choose to conduct their evaluation based on reasonable inquiry of the raw material supplier or on analytical testing. The latter option would likely have higher costs (as outlined in Section 4 above) but would not require the adoption of new technologies as it would only require the manufacturer to collect product samples using basic sampling techniques and send the samples to a lab for analysis.

Based on the Department's analysis, the proposed regulation does not impose requirements on small businesses that would be technologically or economically infeasible to comply with.

6. MINIMIZING ADVERSE IMPACTS

The proposed regulation will not have any adverse economic impacts on the regulated community (including small businesses) beyond any adverse economic impacts of the enacted statute. While there are statutory provisions that apply regardless of the proposed regulation, the proposed Subpart 352-1 offers flexibility that would not be provided otherwise, as further described below. It is expected that there would be minimal adverse economic impact resulting from the implementation of the proposed regulation itself.

As described in previous sections, manufacturers requesting waivers in accordance with section 352-1.4 are offered flexibility by having two options for providing proof of 1,4-dioxane concentrations. They can either provide testing data or provide documentation for a dilution calculation upon request by the Department. This approach offers flexibility to small businesses that is not otherwise available under the statute, and thereby minimizes adverse economic impacts.

Manufacturers need to conduct a compliance evaluation in accordance with section 352-1.5. The proposed regulation offers flexibility by giving manufacturers two options for conducting compliance

evaluation activities – they may either conduct analytical testing or rely on information from their ingredient supplier. This approach offers flexibility to businesses, including small businesses, that is not otherwise available under the statute, and thereby minimizes adverse economic impacts.

As outlined in this analysis, it is the Department's belief that the proposed regulations will not cause a significant economic burden, place any additional burdens on small businesses or local governments, or increase the universe of regulatory requirements applicable to such entities. As such, additional approaches that minimize any adverse impact of the proposed regulation on these entities were not deemed necessary.

There are no impacts anticipated for local government related to this proposed regulation.

7. SMALL BUSINESS AND LOCAL GOVERNMENT PARTICIPATION

The Department has provided significant outreach and will continue to provide a statewide outreach program to all entities affected by the regulations and other interested parties, including small businesses and local governments.

For small businesses that may be affected by the regulations, the Department has already held two public meetings providing an overview of the regulations. Recordings of the meetings are posted on a webpage on the Department's website that was developed to provide information on the 1,4-dioxane law and rulemaking. The Department received public comments that were integrated into the 1,4-dioxane webpage, and compiled a comment response summary document, which answered concerns on sell-through of non-compliant products, proof required to obtain a waiver, and the automatic granting of a waiver; this is also posted on the Department's website.

In addition, the Department has held stakeholder meetings with various stakeholder groups, including several major manufacturers and numerous industry associations that can share information on the Law and rulemaking with their members, including small businesses.

After this proposed regulation is published in the Environmental Notice Bulletin, the Department will hold public hearings for a period of time, accept written comments, summarize those comments, incorporate them into the rulemaking, if so warranted, and make the comment summaries available to the public on the Department's website. The proposed regulations are intended to implement the requirements of the Law.

8. CURE PERIOD OR OTHER OPPORTUNITY FOR AMELIORATIVE ACTION

A cure period or other opportunity for ameliorative action was not included in the proposed regulation as the statute already included a waiver provision which effectively delays the need for manufacturers to comply with the 1,4-dioxane restrictions by up to two years while they conduct actions to reduce the presence of 1,4-dioxane in their products. As this provision offers an opportunity to achieve compliance over an extended schedule, additional ameliorative actions were not deemed necessary.

Job Impact Statement

6 NYCRR Part 352, Product Chemical Restrictions and Disclosure

Subpart 352-1: 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products

The New York State Department of Environmental Conservation (Department) is proposing to adopt 6 NYCRR Part 352, Product Chemical Restrictions and Disclosure, which will include Subpart 352-1, 1,4-Dioxane Limits in Household Cleansing, Personal Care, and Cosmetic Products. This rulemaking will implement the amendments to Article 35 and Article 37 of the Environmental Conservation Law (ECL), adopted in 2019, which establish limits on the amount of 1,4-dioxane that can be present in household cleansing, personal care, and cosmetic products sold or offered for sale in New York State (L.2019, c. 613, § 1, eff. Jan. 1, 2022; L.2020, c. 44, § 1, eff. Jan. 1, 2022) (hereinafter referred to as “the Law”). The Law establishes a maximum allowable concentration of 2 parts per million (ppm) of 1,4-dioxane on December 31, 2022, and 1 ppm on December 31, 2023, for household cleansing and personal care products. The Law also establishes a maximum allowable concentration of 10 ppm of 1,4-dioxane on December 31, 2022, for cosmetic products.

1. NATURE OF IMPACT

There should be no impact on jobs associated with this proposed regulation. In most cases there are surfactants with lower 1,4-dioxane concentration, or alternative ingredients that do not contain the chemical as a contaminant that can be used to manufacture the covered products of the Law. In the few cases where there may be few alternatives available, research and new product development and practices will find replacements for these products. Consequently, the proposed amendment

should not inhibit the growth of or employment in the personal care, household cleansing, and cosmetic industry.

2. CATEGORIES AND NUMBERS OF JOBS OR EMPLOYMENT OPPORTUNITIES AFFECTED

The proposed regulation will not have an impact to jobs and employment opportunities in the State beyond that which would result from the implementation of the Law itself. The 1,4-dioxane limits on household cleansing, personal care, and cosmetic products will take effect by operation of Law regardless of whether this proposed rule is adopted. Further, manufacturers of household cleansing, personal care, and cosmetic products have several options for complying with the Law, which may include reformulating their products, including a stripping process to remove 1,4-dioxane, or finding alternative raw material suppliers to comply with the limits. While adoption of these options may result in increased costs to manufacturers, these costs will likely be passed along to consumers, and are not expected to create substantial adverse impacts on jobs or employment opportunities in New York State.

3. REGIONS OF ADVERSE IMPACT

The regulation applies statewide, and as such, there will be no disproportionate adverse impact on existing jobs, nor will it disproportionately promote the development of new employment opportunities. Therefore, the Department does not anticipate any region-specific adverse impacts

4. MINIMIZING ADVERSE IMPACT

The Department concludes that this regulatory proposal would not have a substantial adverse impact on jobs within the State