Quality Assurance Project Plan: Digestion Method Study for Pigmented Eye Shadow and Clay Masks

By

Michael Zahn and Karna Holquist

For the

Environmental Assessment Program

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COVER PHOTO: Colorful eye shadow palette. Photo by melanfolia and free to use from pexels.com

Contact Information

Publications Coordinator
Environmental Assessment Program
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600
Phone: 564-669-3028

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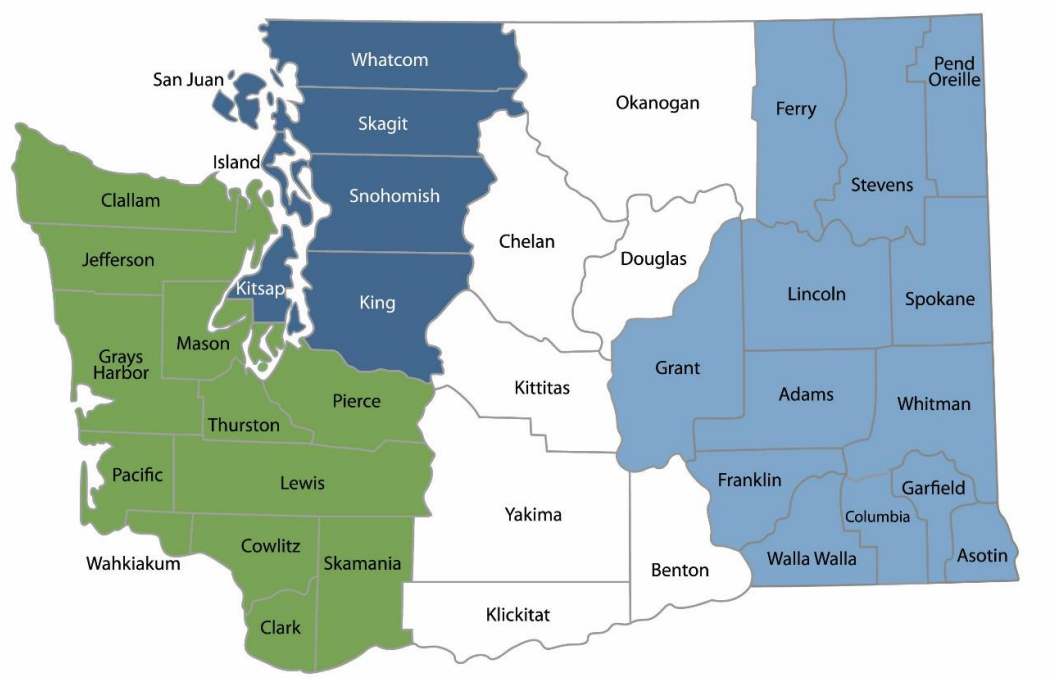

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Quality Assurance Project Plan
Digestion Method Study for Pigmented Eye Shadow and Clay Masks

By Michael Zahn and Karna Holquist
August 2026

QAPP Approval Signatures

Signature: Date:

Jessica Archer, Client, Author's Section Manager, EAP

Signature: Date:

Sara Sekerak, Client, Author's Unit Supervisor, EAP

Signature: Date:

Karna Holquist, Author / Project Manager, EAP

Signature: Date:

Michael Zahn, Author / Principal Investigator, EAP

Signature: Date:

Rob Waldrop, Director, Manchester Environmental Lab, EAP

Signature: Date:

Christina Frans, Ecology Quality Assurance Officer, EAP

EAP: Environmental Assessment Program

Signatures are not available on the Internet version.

1.0 Table of Contents

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2.0 Abstract

Under the Toxic-Free Cosmetics Act (TFCA), Washington State restricts lead present at or above one part per million (ppm) in a cosmetic product. Pigmented cosmetics and clay-based products have been identified as product categories that may contain toxic metals. The primary goal of this study is to evaluate the ability of available testing methods for detecting lead, cadmium, and arsenic in selected cosmetic products at low levels. For this work, a comparison of preparatory digestion methods will be assessed. Additional work will include evaluation of certified or standardized reference materials and certain commonly used cosmetic ingredients, such as talc, bentonite, and synthetic mica, for reference and quality assurance purposes.

3.0 Background

3.1 Introduction and problem statement

Lead is a well-documented as persistent, bioaccumulative, and toxic (PBT) heavy metal and is known to cause many adverse health effects in humans. Lead is linked to cancer, hormone disruption, and reproductive and developmental toxicity, to name a few. Chronic low-level exposure to toxic metals can occur through repeated use of contaminated consumer products like cosmetics (ATSDR 2007, IARC 2012). Repeated dermal application of cosmetics that contain toxic metals can contribute to increased exposure, especially for products often applied near the mouth, eyes, or on compromised skin (Sainio et al. 2000, Bocca et al. 2014).

Dermal absorption of lead is generally lower than inhalation or ingestion, but repeated use of cosmetics with these chemicals can increase absorption over time, especially when exposure occurs alongside additional sources (ATSDR 2020). Lead exposure in children can cause brain and nervous system damage resulting in slowed growth and development, learning and behavior problems, as well as hearing and speech problems (CDC 2024). There is no known safe amount of lead (CDC 2025, WHO 2022).

Cadmium is similarly concerning since it can accumulate in the kidneys and liver. Chronic exposure has been associated with kidney dysfunction, bone demineralization, and cancer (ATSDR 2012, IARC 2012). Arsenic exposure has been associated with skin lesions, cardiovascular disease, neurotoxicity, and increased risks of certain cancers. Balali-Mood et al. (2021) further describes that prolonged exposures to lead, cadmium, and arsenic can be toxic to humans through molecular and cell damage and disruption of enzyme and DNA pathways.

Washington's TFCA (chapter 70A.560 RCW) restricts certain toxic chemicals and chemical classes from use in cosmetic products manufactured, distributed, or sold in or into Washington State. Like the Food and Drug Administration's (FDA) definition, cosmetics are products designed for use on the human body for cleansing, beautifying, promoting attractiveness, or altering appearance. Washington's law aims to prevent toxic chemicals in cosmetics from causing widespread impacts to public health and the environment, as these products may end

up in the water, soil, and air when discarded down the drain or are thrown in the trash. Eventually, disposal of products can lead to environmental contamination (Jindal 2025).

Cosmetic industry feedback regarding compliance with low lead levels within certain cosmetics indicates a possible challenge to regulating lead and other toxic chemicals within cosmetic products (Ecology 2024a). Cosmetic manufacturers have indicated that compliance with 1 ppm limit is challenging for face masks and colored cosmetics like eye shadows (Ecology 2024a). Pigmented eye shadow and clay masks are widely used cosmetic products that could contain heavy metals, including lead, as impurities (Ecology 2009). These metals may come from raw materials such as mineral pigments, clays, and color additives. Other potential sources of metals in cosmetics are discussed in section 3.2.3.

A key question prompting this study is how digestion conditions influence the ability to fully dissolve sample material and release any bound heavy metals. Cosmetics often contain minerals and oxides, like mica and titanium dioxide, which require aggressive digestion conditions to dissolve for analysis. Use of hydrofluoric acid (HF) is particularly effective because it completely dissolves minerals and oxides to release strongly bound metals. However, HF is also highly toxic, hazardous, and can cause severe chemical burns and deep tissue damage. Because of these risks, alternatives to HF are preferred in many labs.

Digestion conditions without HF may be suitable for certain more easily digested samples when metals and other constituents are more weakly bound to sample materials. However, cosmetic samples may require digestion with HF to ensure the sample is completely dissolved for analysis. Choosing an appropriate digestion technique is needed to fully release all forms of heavy metals and to fully dissolve all constituents within the sample. Understanding the completeness of the digestion process helps in determining the accuracy of the final results.

3.2 Study area and surroundings

This study will assess toxic heavy metals, including lead, cadmium, and arsenic in cosmetics as marketed or available for purchase in Washington State. This study will focus on two specific cosmetic categories: pigmented eye shadows and clay face masks. Multiple price points, purchase locations, retail stores, and online purchases will be included. Cosmetic products may be collected if described as eye shadow, eye powder, clay mask, mineral mask, or face masks with kalinite, zeolite, or mineral ingredients on packaging or related product marketing. Additional ingredient identification may include talc, synthetic mica, and bentonite.

This study will also assess multiple reference materials as additional quality control (QC) samples to evaluate method quality objectives. Reference materials in specific cosmetic matrices (i.e., pigmented eye shadow or clay mask) are difficult to obtain. Therefore, reference material QC testing data is intended for method comparisons only.

3.2.1 History of study area

Historically, lead may have been added directly to cosmetics as a colorant (Beck 2018, Lewis 2022). Modernly, lead and other metals can be unintentional impurities in cosmetics that have mineral pigments like talc, mica, or bentonite since metals are present in natural geological sources. Toxic metal impurities can persist through the supply chain of source ingredients and eventually be present in finished products.

3.2.2 Summary of previous studies and existing data

Studies throughout the world have shown varying amounts of toxic metals in cosmetics. The presence of metals in these products is often linked to contaminated raw materials from natural sources. Cosmetic ingredients such as minerals, pigments, and fillers can be contaminated with metals, leading to contaminants found in finished cosmetic products (Batool et al. 2025; FDA 2022a; NIEHS 2021). In 2023, a platform that certifies cosmetic products to be free of harmful chemicals identified that mica and artificial pigments are claimed to be sources of lead contamination in some products, but they noted little specific research has been done and contamination sources have not been identified (Madesafe 2023).

Previous and ongoing studies have found heavy metals, including lead, in numerous mineral cosmetic ingredients including talc, synthetic mica (also known as fluorphlogopite), and bentonite. These minerals are common ingredients in pigmented eye shadows and clay masks. Talc and bentonite are naturally occurring minerals and may contain trace metals, including lead (IARC 2025), depending on source and processing methods (USGS 2025). Clay based minerals, such as bentonite, may also contain metals coming from initial sources (ECHA 2025). Synthetic mica can contain trace impurities from raw materials, colorants, or production processes. As noted, heavy metals, including lead, may not be intentionally added but can be present as an unavoidable impurities (FDA 2024, Ecology 2024a).

In 2012 and 2013, the FDA evaluated lead, cadmium, chromium, cobalt, nickel, and arsenic in other externally applied products such as eyeshadows, blushes, lotions, mascaras, foundations, body powders, compact powders, shaving creams, and face paints. They concluded that products such as eyeshadows, blushes, and compact powders contained more heavy metals than other types of cosmetics (FDA 2022b). Mineral-rich cosmetics can contain lead, as FDA data showed lead levels above 1 ppm in some cosmetics. The FDA advises a limit of 10 ppm lead in cosmetics (FDA 2016a).

The FDA has approved a limited number of pigments for use in make-up (FDA 2022a). A literature review of eye shadow products formulated with high pigment content have been found to have variable lead concentrations, with some results ranging above 50 ppm (Al-Saleh 2009). Pigments used in cosmetics have been found to contain heavy metals, including lead at levels above 1 ppm (Plume 2020). A study of lead in U.S. cosmetics, particularly lipsticks, found levels around 10 ppm in most samples (FDA 2009). Other studies have looked at cosmetics from global sources, but not all those products are available to Washington State residents. For

example, traditional homemade eyeliners like khol, kajal, and surma have been well documented to have concerning levels of heavy metals including lead (Pure Earth 2025).

Attard et al. (2022) published a comprehensive review of studies related to heavy metals in U.S. and global cosmetics. In their review, Attard et al. compiled a table with studies that tested for heavy metals, including lead, based on the product types studied. Based on the compiled results from the Attard studies, eyeshadows contained a maximum of 81.50 ppm lead, 55.59 ppm cadmium, and 3.70 ppm arsenic. In 2022 a study was conducted to assess cosmetics in the UK and found that within the 91 cosmetic products tested (10 of which were eye shadow)- the eye shadows had the highest detections of arsenic, cadmium and lead at approximately 1.62 ppm, 0.05 ppm, and 8.8 ppm, respectively (Axford et al. 2023).

Ecology has performed previous work that includes heavy metals testing on some cosmetics (Ecology 2009, 2023b). Ecology's 2022-2023 toxic chemicals in cosmetics study (Ecology 2023b) found lead > 1 ppm detected in two dark-tint powder foundations and one lipstick. A dark-tint powder foundation with a lead concentration of 5.5 ppm and an arsenic concentration of 2.1 ppm were reported from the work.

Data is limited, however mineral based clay used for clay masks, and clay evaluated for topical application have been found to contain lead at levels above 1 ppm (Whiteside 2020; Bastos 2022). One study of mud masks showed a range of lead from 0.29 ppm to 2.44 ppm, and an average of 1.93 ppm (Ahmed et al. 2024). Clay is known to occasionally contain lead as an impurity, and some clay masks have been recalled by the FDA for high lead content (FDA 2016b).

Studies evaluating elemental impurities in cosmetics commonly use microwave-assisted acid digestion methods. These approaches to sample preparation are widely regarded as industry-standard procedures for subsequent trace metal determination by Inductively Coupled Plasma spectroscopy (ICP) methods. EPA method 3052 explicitly includes HF in microwave digestion protocols for silicate and refractory materials, noting that HF is required when complete decomposition of aluminosilicate matrices is needed for total elemental analysis (EPA 1996). United States Pharmacopeia (USP) general chapters <232> and <233> allow flexibility of digestion under a 'fit-for-purpose' validation framework – meaning HF may be used when required to achieve complete recovery from mineral rich matrices (USP 2018; USP 2026).

Several validation and comparison studies have reported that non-HF digestion methods may provide acceptable recoveries for some sample types, whereas methods using HF can be preferential for determining total elemental concentrations from materials requiring near-complete dissolution of silicate rich and other geologic oxide materials (Pawlaczyk 2021).

3.2.3 Parameters of interest and potential sources

Table 1. Laboratory analytes to be assessed.

Metals	Abbreviation	Chemical Abstract Number (CAS#)
Lead	Pb	7439-92-1
Cadmium	Cd	7440-43-9
Arsenic	As	7440-38-2

The primary parameters of interest for this study are lead, cadmium and arsenic in pigmented eye shadow and clay masks. Products with labelled ingredients of talc, synthetic mica, or bentonite will be targeted.

Heavy metals can come from a variety of sources and historically have been used for a wide variety of purposes. Mineral-based cosmetic ingredients, such as talc, mica, and bentonite, are geologically sourced and may contain naturally occurring contaminants including heavy metals such as lead, cadmium, and arsenic. These contaminants are generally considered unavoidable impurities during processing of geologic materials (Becker et al. 2015; Bocca et al. 2014; CIR 2003; Fiume et al. 2015; Stoiber et al. 2020).

Eye shadows are commonly formulated using mineral pigments and fillers, including iron oxides, mica, titanium dioxide, talc, kaolin, and other minerals. Mineral-based ingredients can be sourced from natural deposits that inherently contain trace amounts of lead. The concentration of lead in raw mineral materials can vary depending on origin, collection processes, and other supply chain controls (FDA 2022b). Mineral pigments are one example of raw materials. Even though cosmetic pigments are subject to impurity standards (FDA 2022a), lead may remain at some amount due to incomplete removal during processing.

Clay masks are primarily formulated with natural clays, such as bentonite, kaolin, montmorillonite, and others, and are sourced from natural formations. These natural sources can contain trace metals, including lead and other heavy metals, as part of their composition (USGS 2014) and can retain impurities even after processing.

Lead has been used in pigments for plastics, ceramics, glass, and enamels. It has also been used as a stabilizer for polyvinyl chloride (PVC) and in alloys and coatings on steel and other metals (ASTDR 2012). Cadmium is used in pigments for plastics, ceramic, glass, and enamels. It is also used as a stabilizer for PVC and in alloys and coatings on steel and other metals. Most cadmium used in the United States is extracted during the production of other metals like zinc, lead, and copper (ASTDR 2012). Arsenic is a naturally occurring element widely distributed in the earth's crust (ASDR 2007), is known to exist in some ceramic glazes and colorants (Aderemi et al. 2017) and can cooccur with aluminum deposits. Historically, arsenic was used in green dyes for home goods. Arsenic can be used in alloys of lead for hardening (EPA 2025b) and can be used in pesticides.

3.2.4 Regulatory criteria or standards

This study is not designed to assess compliance with Washington State laws, but rather to evaluate digestion preparation and analytical results for pigmented eye shadows and clay mask cosmetics.

Several laws in Washington do regulate heavy metals in consumer products at different levels for different reasons. In December of 2000, Ecology released its Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State to guide the continual reduction of risks to human health and Washington's environment from exposures to PBTs, including lead and cadmium (Ecology 2000). PBT's persist in the environment, have the potential to cause harm, and concentrate up the food chain.

More recently, the Toxic Free Cosmetic Act (TFCA) (Chapter 70A.560 RCW) established restrictions on lead in cosmetics. TFCA currently restricts lead and lead compounds in cosmetics where they are added intentionally or are present at or above 1 ppm. Intentionally added mercury and mercury compounds are also restricted. Following a study on lead, cadmium, and arsenic on cosmetics used by people of color in Washington State, Ecology has continued with ongoing rulemaking efforts since the law was enacted. The focus on lead in cosmetics was initiated in late 2024 to identify possible limits for lead that balance consumer and environmental protection with business interests (Ecology 2024a).

Different states have adopted different regulatory strategies and timelines. California enacted their own cosmetics safety laws taking effect on January 1, 2025, including only mercury as a restricted toxic metal.

Cosmetics marketed in the US are regulated under the Federal Food, Drug, and Cosmetic Act, which requires products to be safe for their intended use. However, the FDA does not perform pre-market testing for products available in the U.S. Lead is not an approved cosmetic ingredient, however it may occur as an unintended impurity in cosmetic ingredients. Impurities may make cosmetics unsafe when used, and subject to enforcement.

The Resource Conservation and Recovery Act (42 U.S.C. §6901 et seq) establishes standards for lead, cadmium, and or arsenic in solid waste. In recent years, the EPA has focused on strengthening hazardous and municipal solid waste programs while promoting recycling and pollution prevention (EPA 2025a). Washington has a companion policy (Chapter 173-303 WAC) for regulating lead, cadmium, and arsenic in dangerous waste from products and industries. Washington standards are not intended to regulate discarded products coming from households, rather these standards are applicable to dangerous and hazardous waste generators, and owner/operators responsible for holding discharge permits.

3.3 Water quality impairment studies

NA

3.4 Effectiveness monitoring studies

NA

4.0 Project Description

This study will evaluate methods for assessing levels of heavy metals in pigmented eye shadow and clay masks marketed or available for purchase in Washington State. Products are limited to those available to Washington State residents in retail stores and online. Homemade cosmetics, cosmetics distributed specifically from outside the U.S., or those distributed by third party sellers will not be studied. The method evaluation will help to determine whether the HF digestion method is comparable or more effective than non-HF digestion methods on cosmetic product samples to assess heavy metals. Secondarily, if qualified as useable, this data may be validated to help fill information gaps and inform rulemaking.

Split samples will be submitted to Ecology's Manchester Environmental Laboratory (MEL) for metals analysis by modified EPA Method 3052 and 6020B by inductively coupled plasma mass spectrometry (ICP-MS) and to a contract lab. The sample preparation at MEL is EPA Method 3052 without use of HF, due to safety concerns. Split samples will also be submitted to a contract lab for sample preparation by modified EPA Method 3052, using HF and a conventional oven, instead of a microwave.

The reference material QC samples in this study are reference material ingredients with certificates of analysis, and certified reference material (CRM) or standard reference material (SRM®) with known values.

Reference material ingredients such as talc, bentonite, and synthetic mica typically do not have standardized or certified values. Rather, a vendor certificate of analysis is provided. Vendors use multiple analysis methods to report information on their certificate of analysis, so some ingredient analyses may not include all analytes and should be used for reference purposes only. Analysis of three non-pigmented ingredients talc, synthetic mica, and bentonite will be evaluated for additional quality assurance (QA) purposes.

CRM are characterized by suitable homogeneity, stability, and traceability, with certified values, including uncertainties and a specific matrix (Gorewoda 2025). SRM® are specifically obtained from the National Institute of Standards and Technology (NIST), and are well characterized in composition, properties, or both. SRM are used as part of overall QA programs to perform instrument calibrations to verify the accuracy of specific measurements and to support the development of new measurement methods. This study will use NIST SRM® 8704 since it is the replacement for NIST SRM® 2704 which was used during the development of the EPA 3052 method. Use of NIST SRM® 8704 is for QA purposes of this study only and does not imply assessment of the EPA 3052 method itself.

Laboratory data will be reviewed for quality assurance and be made publicly available. A report documenting study findings, including a data comparison, and a data narrative will be published. Final usable data will be reported in Ecology's Consumer Products Database[1] (CPD).

4.1 Project goals

This study is designed to meet the following goals:

- Determine if any methodological challenges exist for measuring lead, cadmium, and arsenic in eye shadow, clay masks, and selected cosmetic ingredients at the method reporting level (MRL) of 1 ppm.
- Assessment of heavy metal levels, including lead, cadmium, and arsenic in two categories of cosmetics (pigmented eye shadow and clay masks).

4.2 Project objectives

Study goals will be met through the following objectives:

- Purchase up to 30 pigmented eye shadow and 30 clay mask products. These will include products marketed or offered for sale in Washington State at physical retail stores or online.
- Purchase up to three CRM or SRM® samples containing documented values of lead, cadmium, and arsenic.
- Purchase up to two each of non-pigmented ingredients commonly used in cosmetics such as talc, bentonite, or synthetic mica.
- Send up to 74 samples for laboratory analysis of lead, cadmium, and arsenic including two digestion preparation methods based on EPA method 3052 with and without HF at different laboratories.

4.3 Information needed and sources

A literature review of previous studies on heavy metals in pigmented eye shadow and clay masks will be conducted. Literature exclusively about other cosmetics may be reviewed for data on pigments, as other categories will not be included in this study. Literature will be reviewed for measurement and sample preparation techniques as well as result values. Information such as product Universal Product Codes, product brands, and ingredient labels will also be reviewed to identify similar products available in the current market.

[1] https://apps.ecology.wa.gov/consumerproducts/

4.4 Tasks required

The following tasks will be performed for this study:

- Review previous Ecology studies, research literature and available data of pigmented cosmetics, reference material samples, and ingredients to prioritize purchasing.
- Conduct in-store and online searches for availability of pigmented eye shadow, clay masks, and ingredients. Prioritize products for purchase.
- Purchase up to 60 cosmetics products.
- Purchase up to three total CRM or SRM® samples.
- Purchase up to two each (six total) of non-pigmented cosmetic ingredients such as talc, bentonite, or synthetic mica.
- Document purchasing information, product details, and product component descriptions in the database.
- Prepare, homogenize, and split samples for lab analyses.
- Submit up to 74 component split samples for analysis of lead, cadmium, and arsenic at MEL with digestion preparation without HF.
- Submit up to 74 component split samples for analysis of lead, cadmium, and arsenic at a contract lab with digestion preparation using HF.
- Perform data verification and review lab case narratives.
- Review data validation report, only if the data use requires validation.
- Report data to the database and perform a QA review of product and lab analysis data.
- Analyze study data and write a report for publication by Ecology.
- Publish final usable data with product information through Ecology's CPD.

4.5 Systematic planning process

This QAPP addresses comprehensive systematic planning for this study.

5.0 Organization and Schedule

5.1 Key individuals and their responsibilities

Table 2 shows the responsibilities of those who will be involved in this project.

Table 2. Organization of project staff and responsibilities.

Staff[1]	Title	Responsibilities
Karna Holquist Product Studies Unit Statewide Coordination Section Phone: (564) 669-4189	Principal Investigator/Project Manager	Contributes to the QAPP. Oversees field sampling and transportation of samples to the laboratory. Conducts QA review of data, analyzes and interprets data, and enters data into CPD. Writes the draft report and final report.
Michael Zahn Product Studies Unit Statewide Coordination Section Phone: 564-669-4394	Principal Investigator/Project Manager	Writes the QAPP. Oversees field sampling and transportation of samples to the laboratory. Conducts QA review of data, analyzes and interprets data, and enters data into CPD. Writes the draft report and final report.
Jenna Rushing Product Studies Unit Statewide Coordination Section Phone: (360) 819-3670	Sample Prep Lead	Reviews draft QAPP and approves final QAPP. Enters purchasing and product data into CPD upon sample receipt. Assists with method development and sample processing. Assists in QA review of project data in the database. Enters data into the database.
Sara Sekerak Product Studies Unit Statewide Coordination Section Phone: 360-480-9501	Client, PSU Unit Supervisor	Provides internal review of the QAPP, approves the project scope and budget, and approves the final QAPP. Oversees project progress, reviews draft report and approves final report.
Jessica Archer Statewide Coordination Section Phone: 360-890-2721	Client; Statewide Coordination Section Manager	Reviews the project scope and budget, tracks progress, reviews the draft QAPP, and approves the final QAPP and report.
Rob Waldrop Manchester Environmental Laboratory Phone: 360-519-2083	Laboratory Director	Reviews and approves the final QAPP.
Christina Frans Phone: 360-407-6964	Ecology Quality Assurance Officer	Reviews and approves the draft QAPP and the final QAPP.

[1]All staff are from EAP.

CPD: Consumer Product Database; EAP: Environmental Assessment Program; EIM: Environmental Information Management database; PSU: Product Studies Unit; QAPP: Quality Assurance Project Plan; SCS: Statewide Coordination Section

5.2 Special training and certifications

Staff making purchases with an Ecology credit card must attend the online training programs and have a signed credit card authorization on file.

All staff will follow appropriate SOPs detailed in Chapters 8 and 9.

5.3 Organization chart

NA

5.4 Proposed project schedule

Tables 3 and 4 list key activities, due dates, and lead staff for this project.

Table 3. Schedule for completing field and laboratory work.

Task	Due Date	Lead Staff
Product purchasing	July 31, 2026	Karna Holquist Jenna Rushing Michael Zahn
Product data entry	August 14, 2026	Jenna Rushing
Product data entry QA	August 21, 2026	Karna Holquist Michael Zahn
Sample processing	September 4, 2026	Karna Holquist Jenna Rushing Michael Zahn
Samples sent to labs	September 8, 2026	Karna Holquist Michael Zahn
Laboratory analyses – Contract lab	October 30, 2026	Contract Lab
Laboratory analyses - MEL	November 11, 2026	MEL staff

Table 4. Schedule for final report.

Task	Due Date	Lead Staff
Draft to supervisor	March 2027	Michael Zahn Karna Holquist
Draft to client/ peer reviewer	May 2027	Michael Zahn Karna Holquist
Final draft to publications team	June 2027	Michael Zahn
Final report due on web	July 2027	Michael Zahn

5.5 Budget and funding

Tables 5 and 6 show the project budget and funding.

Table 5. Project budget and funding.

Item	Cost ($)
Products and reference material samples	2,200
Laboratory analyses (MEL)	10,064
Laboratory analyses (Contract Laboratory- ALS Kelso quote# 60515 - 04.03.2026)	9,300
Project Total	21,597

Table 6. Laboratory budget details.

Parameter	Number of Samples	Number of QC Samples	Total Number of Samples	Cost Per Sample ($)	Lab Subtotal ($)
Percent Solids – PCTSOL: SM2540 (MEL)	2	0	2	16.50	33.00
Metals (lead, cadmium, arsenic)- MEL	60	14*	74	136	10,064
Metals (lead, cadmium, arsenic)- Contract Laboratory	60	14*	74	125 per sample + one time 50 sustainability fee	9,300

* Does not include method or laboratory QC

Matrix Spike, Matrix Spike Duplicate, and Duplicate sample analyses are not listed in Table 6 but expected per Table 12 (1 per batch; 4 batches expected).

6.0 Quality Objectives

6.1 Data quality objectives

The overall data quality objective (DQO) is to provide analytical data that meets all documented precision and bias standards. Ecology's product studies follow established Guidelines for Data Verification and Validation of Chemical Data from Ecology's QA Coordinator (Ecology 2024b).

Analytical laboratory testing will follow standard methods that meet measurement quality objectives (MQO) outlined in section 6.2 below. Digestion image review may not have specific MQOs. Images will be reviewed by the project manager and principal investigator.

6.2 Measurement quality objectives

6.2.1 Targets for precision, bias, and sensitivity

The MQOs expressed as precision, bias, and sensitivity of metals data are presented in Table 7.

Table 7. Measurement quality objectives.

Parameter	Sample and Lab Duplicates (RPD)	Matrix Spike Duplicate and Laboratory Control Sample Duplicate (RPD)	Lab Control Sample (% Recovery)	Matrix Spike (% Recovery)	Method Blank	Lowest Concentrations of Interest
Lead	≤ 20%	≤ 20%	85–115	75–125	< LLOQ	1 ppm (MEL); <1ppm (CL)
Cadmium	≤ 20%	≤ 20%	85–115	75–125	< LLOQ	1 ppm (MEL); <1ppm (CL)
Arsenic	≤ 20%	≤ 20%	85–115	75–125	< LLOQ	1 ppm (MEL); <1ppm (CL)

CL: Contract Laboratory; LLOQ: Lower Limit of Quantitation; RPD: Relative Percent Difference; ppm: Parts per Million

Table 8 describes the MQO's for reference material, CRM, and SRM®. The certified value specified on the material certificate will be assessed and compared for each method. If a method is found to present a bias outside of the range listed, then the results will be qualified.

Table 8. Measurement quality objectives[1] for reference materials, CRM, and SRM®.

Parameter	Reference Material: Bentonite	Reference Material: Talc	Reference Material: Synthetic Mica	CRM BiPEA Eye Shadow TCC0007QC*	CRM Trace Metals Taiwan Clay 2*	NIST SRM® 8704*
Lead	70–130	70–130	70–130	70–130	70–130	70–130
Cadmium	70–130	70–130	70–130	70–130	70–130	70–130
Arsenic	70–130	70–130	70–130	70–130	70–130	70–130
Expected Result	Certificate value	Certificate value	Certificate value	Certified value	Certified value	Certified value

[1]Parameter ranges for analytes listed are as percentages (%) of the expected result value.
CRM: Certified Reference Material; SRM®: Standardized Reference Material.
*Subject to availability. Alternative may be used if required.

6.2.1.1 Precision

Precision is a measure of variability among replicate measurements due to random error. Laboratory precision will be assessed through analysis of one sample duplicate, matrix spike duplicate (MSD) and laboratory control spike duplicate (LCSD) per analytical batch. Precision for duplicate samples will be measured as the relative percent difference between the two results.

6.2.1.2 Bias

Bias is the difference between the sample mean and the true value. Laboratory analysis bias will be assessed through laboratory control samples (LCS) and matrix spike (MS) samples. MQOs for LCS and MS are shown in Table 7.

Reference material QC samples will also be submitted for laboratory analysis. The CRM and SRM® samples have known concentrations and are submitted for the method comparison purposes of the study. MQOs for CRM and SRM® samples are shown in Table 8.

6.2.1.3 Sensitivity

Sensitivity is a measure of the capability of a method to detect a substance. It is commonly described as a detection limit. The method detection limit (MDL) describes laboratory sensitivity since it is the lowest quantity of a chemical analyte that is detectable above background noise by each instrument or laboratory method. Targets for acceptable sensitivity of all laboratory measurements are shown in Table 7.

6.2.2 Targets for comparability, representativeness, and completeness

6.2.2.1 Comparability

As discussed in section 6.1, comparability will be ensured by implementing standardized procedures for sampling and analyses. Data from this study can be compared to publicly available data of similar product types and analyzed using substantially similar analytical methods, if available.

Both laboratories will test the same sample sets (i.e., same duplicates, MS, MSD's, etc.). The project manager and principal investigator will communicate the request to the labs (MEL and contract lab) accordingly.

Differences in the analyte reporting limits (RL) between the labs may occur and could affect method assessment and comparison. If observed, then data normalization and qualification at the higher RL may be considered for both lab's data and a discussion will be included in the report.

6.2.2.2 Representativeness

Products purchased through retail stores or online for this study are intended to represent a range of the product categories marketed or available for purchase in Washington State but are not designed to be statistically representative of any particular population.

Sample splits are intended to be representative of the homogeneous composite parent sample. Effectiveness of sample homogenization will be assessed through analysis of six split sample duplicates.

6.2.2.3 Completeness

The project manager will consider purchasing for this study to be complete if 90% of the identified products are collected within the study collection timeframe. The project manager will consider the study to be complete if 95% of the laboratory samples meet the MQOs in Table 7.

6.3 Acceptance criteria for quality of existing data

NA

6.4 Model quality objectives

NA

7.0 Study Design

7.1 Study boundaries

The study will include pigmented eye shadows and clay masks cosmetics available for purchase in Washington State. Specifically, products will be purchased if they are marketed or available for purchase in Washington State, including online retailers. Items are detailed in Table 9.

Table 9. Anticipated purchasing categories of cosmetics and reference materials.

Material	Target number of products
Pigmented Eye Shadow	30
Clay Mask	30
Talc	2
Bentonite	2
Mica, synthetic	2
Certified Reference Material	2
Standardized Reference Material®	1

An effort will be made to purchase the number of items within each material category listed. Lack of availability or other factors may change the number of products purchased from each category. Multiple products of the same type may be purchased if additional weight is needed for analysis.

Effectiveness of sample digestion methods will be determined by assessment of the following from the data provided by both laboratories:

- Comparison of data from reference samples with known values.
- Comparison of data from the split cosmetic samples.
- Comparison of whether or not samples fully digested during preparation.

Determination of the effectiveness of both preparatory digestion methods for the specific analytes and cosmetic categories being tested will be assessed. Evaluation of the sample digestions will be by visual evaluation of images of digested samples provided by the laboratories. Digestion images will be reviewed for any remaining insoluble material after the digestion process. The electronic data deliverables (EDD) from both laboratories are expected to record if the samples were digested or not by reporting with a “Yes” or “No” in the column marked as “WasSampleMatrixDigestionComplete”. Any sample found to be partially or incompletely digested should be deemed as a “No”. Final digestion disposition will be confirmed by the principal investigator after image review. Comparison of the number of samples that were fully digested or not will be assessed between the labs.

If one preparatory digestion method is found to yield significantly different results compared to the other method, the report may include a recommendation to use that method for the specific analytes (lead, cadmium, and arsenic) and cosmetic categories being assessed (pigmented eye shadow and clay masks).

If the preparatory digestion method using HF is found to yield significantly lower recoveries compared to digestion without HF, then the report may include discussion that incomplete digestions or affected results could be due to use of the modified EPA 3052 method with use of conventional oven instead of microwave.

If neither method is found to be significantly different, or if both methods are found as equally comparable, then the report may include a recommendation to use either method or the method with the most accurate recoverability for the specific analyte and cosmetic category only. This could be if one or both methods satisfy criteria similarly or only partially, including for only certain analytes or samples. In such case, the method with the most reference material, CRM, and SRM® analytes with closest correlation(s) to the certificate values and strongest overall QC correlations (Tables 7 and 8) will be discussed in the report and may be considered for acceptance via the analyte and cosmetic category only.

7.2 Field data collection

Products will be purchased from retail stores in the Puget Sound area of Washington and online. Field data collected for this study will be the store name and date of purchase.

7.2.1 Sampling locations and frequency

Retail stores will be prioritized for purchasing if they have multiple locations across Washington State, to include a minimum of at least one “specialty type” store and two large retail “big box” physical stores. Specialty type stores may include those that are focused on selling a specific, narrow category of products (i.e., one particular brand or type of cosmetics), whereas big box stores are considered as those which sell a wide variety of goods (i.e., multiple brands or types of cosmetics and other unrelated products).

Online purchasing will include stores that make available or market for purchase in Washington State. Products from third party sellers will be excluded from the online portion of the study.

7.2.2 Field parameters and laboratory analytes to be measured

There are no field parameters to be measured in this study. Table 1 lists laboratory analytes to be studied.

7.3 Modeling and analysis design

NA

7.4 Assumptions underlying design

Products purchased for this study are assumed to reflect those currently available and on the market for sale to residents of Washington. It is assumed that large retail stores (“big box”) or cosmetic store chains sell similar products at locations throughout Washington State.

Eyeshadows can typically use a standard or common base mixture of fillers, binders, and preservatives. The base can then be varied by changing the colorant pigments to create a range of colors from one base formula. Because many eyeshadows in a collection, or palette, share a base but differ in color, the FDA allows manufacturers to list the primary ingredients and use a "May contain:" label to list the various pigments used to make different shades (FDA 2022a). Our assumption is that manufacturers use similar base materials within a product containing multiple colors (ex: palettes and multi-packs/variety packs) but will vary pigment/colorant as the major difference. Colors (including white, opaque, etc.) may be combined within a multi-pack/palette to make one sample for this project. We are assuming that all shades within the same palette will be made with the same base mixture.

Assessment of results from the reference material samples are expected to give a clearer understanding in terms of samples without complex matrices, with the understanding and assumption that the results may not reflect all cosmetics in general.

We expect both laboratories to test samples in the same sets meaning they will test the same sample duplicates, MS, and MSDs. The principal investigator will communicate the request to the labs accordingly. We assume the sample splits are representative of the whole homogeneous sample.

7.5 Possible challenges and contingencies

The possible logistical challenges, constraints, and schedule limitations for this study are described in the subsections below.

7.5.1 Logistical problems

Possible logistical problems in this study include difficulties procuring appropriate grades of materials, possible challenges with dissolution during sample digestion, and possible supply and sample delays.

Cosmetic grade, or as close to cosmetic grade as available, ingredient reference materials will be purchased. It may not be possible to get the exact same materials used in cosmetics.

7.5.2 Practical constraints

Researching purchase options and establishing a purchasing plan will help guide sampling. However, since product availability and shortages are unpredictable, the plan must remain flexible and include alternatives. For purchasing products online, if the product marketing or labeling is incorrect then that may lead to purchasing products outside of the anticipated category.

7.5.3 Schedule limitations

The samples to be included in this study, including consumer product samples, can contain complex matrices which may require an extended period of time for laboratory analysis. Additional cleaning or purging tasks can be common when analyzing consumer product

samples. Complex data sets may require extended data QA procedures or data validation. Immediate communication about laboratory staff or resource shortages, including instrument or other issues, will help inform management of schedule and deadline changes.

8.0 Field Procedures

8.1 Invasive species evaluation

NA

8.2 Measurement and sampling procedures

Product purchasing and processing will follow SOP PTP001 v.2.2 (Ecology 2023a). Data entry and data quality assurance will follow SOP PTP002 v.3.0 (Ecology 2025).

Products collected for this study will be brought to Ecology's Product Studies Preparation Room, where they will be stored and processed under secure holding conditions.

Products intended to be diluted by label instruction (e.g., add water at 1:1 ratio and mix) will not be diluted prior to sample submission. Additionally, products with high water content will not be dried prior to analysis. We assume that the product form could be applied "as-is" by consumers and that any portion of the product could contain heavy metals. Results will reflect a non-diluted and non-dried product. We will also test reference materials, CRM and SRM® without drying first. Correction factors for percent solids may be applied to CRM or SRM® materials via method SM2540 at MEL. The same correction factor obtained from MEL analyses could be applied for both laboratory data sets.

Analysis of ingredients and reference material samples will be analyzed as QC samples following the same steps as all other samples.

Samples will be composited then split and sent for analysis at both labs. Eye shadow products that are sold as a palette or individually bulked will be combined and composited by first transferring the entire amount of product to a single sample jar. The sample will then be physically mixed in the jar (approximately 30 seconds using a stainless steel spatula or similar) and visually assessed. Repeated mixing may be required. Then, an appropriate quantity of the sample will be physically transferred to an additional sample jar or jars as required. Some palettes may be made of multiple shades of eyeshadow in containers too small for analysis alone. Multiple shades will be combined into one composite sample to collect enough weight for analysis. Composite sampling allows for testing of small component sizes that would otherwise not meet the minimum size required for laboratory testing.

Clay mask products and reference materials will be visually assessed to determine if any product separation is observed in the original product container. If so, the same process above will be followed.

Product samples will be submitted "as is" and will not be diluted regardless of any label instruction.

8.3 Containers, preservation methods, holding times

Table 10 presents sample containers, minimum quantity, storage and preservation, and holding times for sample matrices.

Table 10. Sample containers, preservation, and holding times.

Parameter	Matrix	Minimum Quantity Required	Container	Preservative	Holding Time
Lead	Consumer Product – Cosmetic	2.5 g	4 to 8 oz. glass jars	Ambient temperature	1 year
Cadmium	Consumer Product – Cosmetic	2.5 g	4 to 8 oz. glass jars	Ambient temperature	1 year
Arsenic	Consumer Product – Cosmetic	2.5 g	4 to 8 oz. glass jars	Ambient temperature	1 year

8.4 Equipment decontamination

Decontamination procedures will follow protocols in SOP PTP001.

8.5 Sample ID

Upon entry into the database, individual product component identification codes are automatically assigned as outlined in SOP PTP002. Product IDs convey information about the store of purchase, the purchase event, product number, and component number. For example, "WM-1-3-1" means Walmart store, purchase event 1, product number 3, component number 1 of the product tested.

The same sample IDs will be used by Ecology for both laboratory sample submissions. Sample differentiation in the database will be noted by the different preparation methods and laboratories.

8.6 Chain of custody

Appropriate chain of custody procedures will be followed according to SOP PTP001. Products gathered for this study will be kept in locked cabinets in Ecology's Product Studies Unit Preparation Room for the duration of the study. Product component samples will be stored in glass sample jars in locked cabinets prior to shipment for laboratory analysis (Sekerak 2016). A detailed chain of custody form will accompany all samples during shipment to the lab.

8.7 Field log requirements

Product advertisements, photos of in-store or online marketing, and receipts for purchases will be collected during purchasing events and scanned and saved in the database. Purchasing event information will be entered into the database following SOP PTP002.

At a minimum, the store name, street address, website address, purchase date, purchase price, brand name, manufacturer name, manufacture date, and distributor name will be recorded in the database for all products in this study.

8.8 Field log requirements

NA

9.0 Laboratory Procedures

9.1 Lab procedures table

Table 11 presents the methods for the assessments that will be performed at the lab. Samples should be analyzed with any dilutions at the lowest possible factor.

Table 11. Measurement methods (laboratory).

Analyte	Sample Matrix	Sample (Number/ Arrival Date)	Expected Range of Results	Detection or Reporting Limit (RL)	Sample Preparation Method	Analytical (Instrumental) Method
Lead	Consumer Product – Cosmetic	74/ 9/8/2026	<1–100 ppm	1 ppm[1] < 1 ppm[2]	EPA 3052[1] Modified EPA 3052[2]	EPA 6020B
Cadmium	Consumer Product – Cosmetic	74/ 9/8/2026	<1–100 ppm	1 ppm[1] < 1 ppm[2]	EPA 3052[1] Modified EPA 3052[2]	EPA 6020B
Arsenic	Consumer Product – Cosmetic	74/ 9/8/2026	<1–100 ppm	1 ppm[1] < 1 ppm[2]	EPA 3052[1] Modified EPA 3052[2]	EPA 6020B
Digestion Images	Consumer Product – Cosmetic	74 / 9/8/2026	Visual Yes / No	NA	EPA 3052 [1 &2]	NA

[1] Preparation method modified to omit use of hydrofluoric acid (MEL)

[2] Preparation method modified to omit use of microwave oven but using HF (contract lab)

ppm: parts per million

9.2 Sample preparation method(s)

MEL sample preparation and digestion will follow EPA Method 3052, without the use of HF and with the use of a microwave oven. The omission of HF is to comply with MEL safety policies.

Contract laboratory sample preparation and digestion will follow modified EPA method 3052 (ALS SOP# MET-3052M r7) with HF and use of a traditional oven instead of microwave oven.

9.3 Special method requirements

Images of sample digestion results will be sent with each laboratory report to allow tracking of the digestion process.

9.4 Laboratories accredited for methods

Samples will be analyzed at MEL and a contract laboratory (ALS Environmental in Kelso, WA). MEL and ALS Environmental are both accredited by Washington State Department of Ecology for analysis of all target analytes by EPA Method 6020B.

10.0 Quality Control Procedures

10.1 Table of field and laboratory quality control

Table 12 presents the laboratory QC samples for this study. Laboratory QC tests will consist of laboratory control samples, laboratory control sample duplicates, sample duplicates, reference material samples (as additional QC), matrix spikes, and matrix spike duplicates.

Samples from this study should only be analyzed alongside other samples of the same matrix within the same batch of 20 or fewer samples.

Table 12. Quality control samples, types, and frequency.

Parameter	Laboratory Control Sample (LCS) / LCSD	Laboratory Method Blanks	Analytical Duplicates	Laboratory Matrix Spikes MS / MSD
Lead	1/batch	1/batch	1/batch	1/batch
Cadmium	1/batch	1/batch	1/batch	1/batch
Arsenic	1/batch	1/batch	1/batch	1/batch

LCS: laboratory control sample; LCSD: laboratory control sample duplicate; MS: matrix spike; MSD: matrix spike duplicate; Batch: 20 samples or fewer

10.2 Corrective action processes

Work for this study will follow the appropriate SOPs and study-specific processing and preparation protocols in this QAPP. MEL staff and contract laboratory will document whether project data meet method QC criteria. The laboratory will notify the project manager if

substantial departures of method techniques will be required. Any departures from stated analytical methods will be documented by the laboratory and described in the case narrative. When MQO or QC criteria are not met, or if the integrity of the processing and preparation processes are in question, the project manager will determine if samples should be re-collected, re-analyzed, rejected, or used with appropriate qualification.

11.0 Data Management Procedures

11.1 Data recording and reporting requirements

Product data logging will follow SOP PTP002 (Ecology 2025). Study data will be stored in Ecology's CPD. Study data records will include purchase receipts, product descriptions, product component descriptions, product photos, and laboratory testing data. Purchase and product metadata of store name, street address, website address, purchase date, purchase price, brand name, manufacturer name, and distributor name will be recorded in the database.

Laboratory data will be received as an analytical report in PDF format and an electronic data deliverable (EDD) or comparable package. The project manager will perform a final QA review of all data before they are uploaded into the CPD. All raw data, laboratory case narratives, and validation reports are managed under appropriate retention criteria.

11.2 Laboratory data package requirements

MEL and the contract laboratory will each provide a data package sufficient for a stage 4 validation. The laboratory data will contain all required specific content, along with sample and QC data. The data package must include all sample raw data, QC sample raw data, and chain of custody forms needed to perform independent verification of the results and sample handling procedures.

The laboratory report will discuss any problems encountered with the analyses, corrective action taken, changes to the requested analytical method, and a glossary for data flags.

Digestion completeness will be assessed visually by the laboratory and recorded in the EDD as 'Yes' or 'No' for digestion completeness.

11.3 Electronic transfer requirements

Laboratory analytical reports with case narratives will be in PDF format and EDDs will be in a .CSV spreadsheet format that meets Ecology's product testing formatting requirements unless an alternative format is approved in advance by the project manager.

11.4 CPD upload procedures

The data for this project will be stored and publicly made available through Ecology's CPD following SOP PTP002 Data Entry and Data Entry Quality Assurance (Ecology 2025).

11.5 Model information management

NA

12.0 Audits and Reports

12.1 Field, laboratory, and other audits

Analytical labs must participate in performance and system audits of their routine procedures. The product testing process conducted at Ecology will be audited at a minimum of one audit a year.

12.2 Responsible personnel

Ecology's QA Officer or their designee will conduct the product studies process audit, as necessary. The processes can include product acquisition, product documentation and data entry in the database, sample screening, sample processing, chain of custody, and adherence to product testing QAPPs and SOPs.

12.3 Frequency and distribution of reports

A final published report summarizing the data and findings will be written when the study is completed. The final report will include at a minimum:

- An overview of the study.
- Goals and objectives of the study.
- Discussion of the results.
- Discussion of methods, any corrective actions, and the significance of any problems encountered.
- Summary statistics of laboratory results.
- Summary tables and graphs of laboratory data.
- Discussion and presentations of method comparisons.
- Notes regarding any specialized preparation procedure for specific categories of cosmetics.
- The final report will be available online[2].

12.4 Responsibility for reports

The principal investigator and project manager will be responsible for the report.

[2] https://apps.ecology.wa.gov/publications/UIPages/PublicationList.aspx?IndexTypeName=Topic&NameValue=Product+Testing&DocumentTypeName=Publication

13.0 Data Verification

13.1 Field data verification, requirements, and responsibilities

The principal investigator, project manager, or assigned designee, will conduct a final review of product purchases, product components, component screening, and additional product metadata entered into the database. All data will be reviewed by the project manager at several stages during the study according to SOP PTP002.

13.2 Laboratory data verification

Lab data verification is examination of a data set for errors or omissions, and assessment of the data quality indicators related to that data set for compliance with MQOs. Verification is a detailed quality review of a data set (Ecology 2004). Laboratory data will undergo verification by the project manager according to SOP PTP002. The project manager will review data packages and conduct a QA review of the data to assess suitability.

Images of the sample digestions will be reviewed by the project manager to confirm the EDD inputs. Sample results may be qualified if the digestion was not fully complete. The report will include discussion regarding if any digestion biases are found from either method.

The principal investigator is responsible for the final acceptance of laboratory data and will document all decisions in a case narrative. Based on these verification assessments, the data will be either accepted, accepted with qualifications, rejected with re-analysis considered, or rejected without re-analysis considered.

The project manager may convert any contract laboratory data flags using a systematic approach similar to that used by MEL (MEL 2016) into analytical data qualifiers like those shown in Table 13.

Table 13. Analytical data qualifiers.

Qualifier Symbol in Consumer Product Database	Qualifier Description
U	Analyte was not detected above the reporting limit.
UJ	Analyte was not detected above the reporting limit. However, the reporting limit is an estimated value.
J	Analyte was positively identified. The reported result is an estimate.
NJ	The analyte was tentatively identified in the sample, but the result value reported is an estimate.
REJ	The sample result was rejected due to serious deficiencies in the ability to analyze the sample, meet quality control criteria or other technical reason. The presence or absence of the analyte cannot be verified.

13.3 Validation requirements, if necessary

Data validation will not be performed for this project, but the full Level 4 data package will be available from each laboratory in case these data are needed for use beyond the primary goal of method evaluation. High risk data decisions and use of data for informing rulemaking, development of human health criteria, legislation, or litigation require third-party validation (Ecology 2024b).

13.4 Model quality assessment

NA

14.0 Data Quality (Usability) Assessment

14.1 Process for determining project objectives were met

The project manager will examine data from all field and laboratory procedures to ensure that the data were collected using proper procedures, fall into the expected range of results, and meet quality objectives as described in Sections 6, 8, and 9. The project manager will assess the quality of the data based on case narratives, data packages, and the laboratory report. Laboratory QC tests will be examined to determine if the laboratory met MQOs for method blanks, LCS, duplicates, MS samples, and surrogates when applicable. Reporting limits will be examined to ensure that the contract-defined reporting limit was met (Sekerak 2016).

If all MQOs and QC criteria are met, the quality of the data will be considered suitable for meeting study objectives. If a sample does not meet MQOs or QC criteria, the project manager may apply a "REJ" qualification to the data. The final report for this study will discuss the data quality findings, whether the project objectives were met, and if data use limitations exist.

14.2 Treatment of non-detects

Laboratory data will be reported down to the laboratory's reporting limit, with an associated "U" or "UJ" qualifier for samples below the reporting limit. All samples will be evaluated against the associated method blank for each analytical batch. Sample results less than or equal to 5x the method blank concentration will be qualified as non-detect due to laboratory background.

14.3 Data analysis and presentation methods

The final report will include a summary of the results of this study. Simple summary statistics and data will be presented in tables and graphs. Example summary statistics may include minimum, maximum, median, and frequencies of detection.

For comparing the data, statistical techniques for paired data sets will be applied. If the differences between pairs of data are normally distributed, a paired t-test will be used to evaluate if the mean difference between pairs is significantly different between digestion

methods. If the differences between pairs of data are not normally distributed, and cannot be normalized, the Wilcoxon signed-rank test will be used to evaluate differences between pairs subjected to different digestion methods. A Bland-Altman analysis will be used to evaluate the agreement interval between the two different laboratory methods. Significance for this study is set at $P < 0.001$ and confidence intervals are set at 95%.

Analyte values for the reference material QC samples will be compared to unqualified and accepted data results found from both laboratories. Qualified data (J or NJ) will be considered whether to be used or not on a case-by-case basis by the principal investigator. Non-detect (U and/or UJ) or rejected (REJ) data will not be considered for this purpose. If the majority of any sample group tested are found to be non-detect or rejected, then the resultant data cannot be statistically compared but will be in the report for discussion purposes only.

Data from samples digested with HF may be rejected if MQO and/or DQO are not achieved for those samples, and the MEL data (preparation without HF) would be used instead.

Laboratory preparation notes and case narratives will be reviewed along with visual inspections of images documenting digestion of each sample. Completeness of digestion documented by the laboratory will be confirmed or established if not documented by the laboratory.

14.4 Sampling design evaluation

The samples collected and tested are designed to determine method needs for digestion and metals analysis of specific cosmetic products, eye shadows and clay masks. This study design does not support estimating prevalence of cosmetic types in a population, identifying wider areas of contamination, making wider comparisons, or estimating a market parameter. The results of this study may be used to plan future study events, or to establish a follow-up on products tested within this study. The results of this study are not designed to determine regulatory compliance with any law or regulation.

Further use of this data to draw conclusions beyond those reported requires consultation with the principal investigator for this study and QA personnel to assess the need for data validation or a QAPP for using existing data for a separate goal.

14.5 Documentation of assessment

Final documentation of the data usability assessment will be in the final report. The report will include a link to the study data available in the CPD.

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16.0 Appendices

Appendix A. Glossaries, Acronyms, and Abbreviations

Acronyms and Abbreviations

CL	Contract laboratory
CPD	Consumer product database
CRM	Certified Reference Material
DQO	Data quality objective
Ecology	Washington State Department of Ecology
EDD	Electronic data deliverable
e.g.	For example
EIM	Environmental Information Management database
EPA	U.S. Environmental Protection Agency
et al.	And others
FDA	U.S. Food and Drug Administration
HF	Hydrofluoric Acid
ICP-MS	inductively coupled plasma mass spectrometry
i.e.	In other words
LLOQ	Lower limit of quantitation
MEL	Manchester Environmental Laboratory
MQO	Measurement quality objective

MRL	Method reporting level
NIST	National Institute of Standards and Technology
PBT	Persistent, bioaccumulative, and toxic substance
QA	Quality assurance
QAPP	Quality assurance project plan
QC	Quality control
RPD	Relative percent difference
RSD	Relative standard deviation
SOP	Standard operating procedures
SRM®	Standardized Reference Material
USP	United Stated Pharmacopeia
WAC	Washington Administrative Code

Units of Measurement

G	gram, a unit of mass
ppm	parts per million

Quality Assurance Glossary

Accreditation: A certification process for laboratories, designed to evaluate and document a lab's ability to perform analytical methods and produce acceptable data. For Ecology, it is "Formal recognition by (Ecology)…that an environmental laboratory is capable of producing accurate analytical data." [WAC 173-50-040] (Kammin, 2010).

Accuracy: The degree to which a measured value agrees with the true value of the measured property. USEPA recommends that this term not be used, and that the terms *precision* and *bias* be used to convey the information associated with the term *accuracy* (USGS, 1998).

Analyte: An element, ion, compound, or chemical moiety (pH, alkalinity) which is to be determined. The definition can be expanded to include organisms, e.g., fecal coliform, Klebsiella (Kammin, 2010).

Bias: The difference between the sample mean and the true value. Bias usually describes a systematic difference reproducible over time and is characteristic of both the measurement system and the analyte(s) being measured. Bias is a commonly used data quality indicator (DQI) (Kammin, 2010; Ecology, 2004).

Blank: A synthetic sample, free of the analyte(s) of interest. For example, in water analysis, pure water is used for the blank. In chemical analysis, a blank is used to estimate the analytical response to all factors other than the analyte in the sample. In general, blanks are used to assess possible contamination or inadvertent introduction of analyte during various stages of the sampling and analytical process (USGS, 1998).

Calibration: The process of establishing the relationship between the response of a measurement system and the concentration of the parameter being measured (Ecology, 2004).

Check standard: A substance or reference material obtained from a source independent from the source of the calibration standard; used to assess bias for an analytical method. This is an obsolete term, and its use is highly discouraged. See Calibration Verification Standards, Lab Control Samples (LCS), Certified Reference Materials (CRM), and/or spiked blanks. These are all check standards but should be referred to by their actual designator, e.g., CRM, LCS (Kammin, 2010; Ecology, 2004).

Comparability: The degree to which different methods, data sets and/or decisions agree or can be represented as similar; a data quality indicator (USEPA, 1997).

Completeness: The amount of valid data obtained from a project compared to the planned amount. Usually expressed as a percentage. A data quality indicator (USEPA, 1997).

Continuing Calibration Verification Standard (CCV): A quality control (QC) sample analyzed with samples to check for acceptable bias in the measurement system. The CCV is usually a midpoint calibration standard that is re-run at an established frequency during the course of an analytical run (Kammin, 2010).

Control chart: A graphical representation of quality control results demonstrating the performance of an aspect of a measurement system (Kammin, 2010; Ecology 2004).

Control limits: Statistical warning and action limits calculated based on control charts. Warning limits are generally set at +/- 2 standard deviations from the mean, action limits at +/- 3 standard deviations from the mean (Kammin, 2010).

Data integrity: A qualitative DQI that evaluates the extent to which a data set contains data that is misrepresented, falsified, or deliberately misleading (Kammin, 2010).

Data quality indicators (DQI): Commonly used measures of acceptability for environmental data. The principal DQIs are precision, bias, representativeness, comparability, completeness, sensitivity, and integrity (USEPA, 2006).

Data quality objectives (DQO): Qualitative and quantitative statements derived from systematic planning processes that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions (USEPA, 2006).

Data set: A grouping of samples organized by date, time, analyte, etc. (Kammin, 2010).

Data validation: An analyte-specific and sample-specific process that extends the evaluation of data beyond data verification to determine the usability of a specific data set. It involves a detailed examination of the data package, using both professional judgment and objective criteria, to determine whether the MQOs for precision, bias, and sensitivity have been met. It may also include an assessment of completeness, representativeness, comparability, and integrity, as these criteria relate to the usability of the data set. Ecology considers four key criteria to determine if data validation has actually occurred. These are:

- Use of raw or instrument data for evaluation.

- Use of third-party assessors.
- Data set is complex.
- Use of EPA Functional Guidelines or equivalent for review.

Examples of data types commonly validated would be:

- Gas Chromatography (GC).
- Gas Chromatography-Mass Spectrometry (GC-MS).
- Inductively Coupled Plasma (ICP).

The end result of a formal validation process is a determination of usability that assigns qualifiers to indicate usability status for every measurement result. These qualifiers include:

- No qualifier – data are usable for intended purposes.
- J (or a J variant) – data are estimated, may be usable, may be biased high or low.
- REJ – data are rejected, cannot be used for intended purposes.
  (Kammin, 2010; Ecology, 2004).

Data verification: Examination of a data set for errors or omissions, and assessment of the Data Quality Indicators related to that data set for compliance with acceptance criteria (MQOs). Verification is a detailed quality review of a data set (Ecology, 2004).

Detection limit (limit of detection)**:** The concentration or amount of an analyte which can be determined to a specified level of certainty to be greater than zero (Ecology, 2004).

Duplicate samples: Two samples taken from and representative of the same population, and carried through and steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variability of all method activities including sampling and analysis (USEPA, 1997).

Field blank: A blank used to obtain information on contamination introduced during sample collection, storage, and transport (Ecology, 2004).

Initial Calibration Verification Standard (ICV): A QC sample prepared independently of calibration standards and analyzed along with the samples to check for acceptable bias in the measurement system. The ICV is analyzed prior to the analysis of any samples (Kammin, 2010).

Laboratory Control Sample (LCS): A sample of known composition prepared using contaminant-free water or an inert solid that is spiked with analytes of interest at the midpoint of the calibration curve or at the level of concern. It is prepared and analyzed in the same batch of regular samples using the same sample preparation method, reagents, and analytical methods employed for regular samples (USEPA, 1997).

Matrix spike: A QC sample prepared by adding a known amount of the target analyte(s) to an aliquot of a sample to check for bias due to interference or matrix effects (Ecology, 2004).

Measurement Quality Objectives (MQOs)**:** Performance or acceptance criteria for individual data quality indicators, usually including precision, bias, sensitivity, completeness, comparability, and representativeness (USEPA, 2006).

Measurement result: A value obtained by performing the procedure described in a method (Ecology, 2004).

Method: A formalized group of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, data analysis), systematically presented in the order in which they are to be executed (EPA, 1997).

Method blank: A blank prepared to represent the sample matrix, prepared and analyzed with a batch of samples. A method blank will contain all reagents used in the preparation of a sample, and the same preparation process is used for the method blank and samples (Ecology, 2004; Kammin, 2010).

Method Detection Limit (MDL): This definition for detection was first formally advanced in 40CFR 136, October 26, 1984 edition. MDL is defined there as the minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, and reported to be greater than zero (Federal Register 2025).

Percent Relative Standard Deviation (%RSD): A statistic used to evaluate precision in environmental analysis. It is determined in the following manner:

$$\%RSD = (100 * s)/x$$

where s is the sample standard deviation and x is the mean of results from more than two replicate samples (Kammin, 2010).

Parameter: A specified characteristic of a population or sample. Also, an analyte or grouping of analytes. Benzene and nitrate + nitrite are all parameters (Kammin, 2010; Ecology, 2004).

Population: The hypothetical set of all possible observations of the type being investigated (Ecology, 2004).

Precision: The extent of random variability among replicate measurements of the same property; a data quality indicator (USGS, 1998).

Quality assurance (QA): A set of activities designed to establish and document the reliability and usability of measurement data (Kammin, 2010).

Quality Assurance Project Plan (QAPP): A document that describes the objectives of a project, and the processes and activities necessary to develop data that will support those objectives (Kammin, 2010; Ecology, 2004).

Quality control (QC): The routine application of measurement and statistical procedures to assess the accuracy of measurement data (Ecology, 2004).

Relative Percent Difference (RPD): RPD is commonly used to evaluate precision. The following formula is used:

[Abs(a-b)/((a + b)/2)] * 100

where "Abs()" is absolute value and a and b are results for the two replicate samples. RPD can be used only with 2 values. Percent Relative Standard Deviation is (%RSD) is used if there are results for more than 2 replicate samples (Ecology, 2004).

Replicate samples: Two or more samples taken from the environment at the same time and place, using the same protocols. Replicates are used to estimate the random variability of the material sampled (USGS, 1998).

Representativeness: The degree to which a sample reflects the population from which it is taken; a data quality indicator (USGS, 1998).

Sample (field): A portion of a population (environmental entity) that is measured and assumed to represent the entire population (USGS, 1998).

Sample (statistical): A finite part or subset of a statistical population (USEPA, 1997).

Sensitivity: In general, denotes the rate at which the analytical response (e.g., absorbance, volume, meter reading) varies with the concentration of the parameter being determined. In a specialized sense, it has the same meaning as the detection limit (Ecology, 2004).

Spiked blank: A specified amount of reagent blank fortified with a known mass of the target analyte(s); usually used to assess the recovery efficiency of the method (USEPA, 1997).

Spiked sample: A sample prepared by adding a known mass of target analyte(s) to a specified amount of matrix sample for which an independent estimate of target analyte(s) concentration is available. Spiked samples can be used to determine the effect of the matrix on a method's recovery efficiency (USEPA, 1997).

Split sample: A discrete sample subdivided into portions, usually duplicates (Kammin, 2010).

Standard Operating Procedure (SOP): A document which describes in detail a reproducible and repeatable organized activity (Kammin, 2010).

Surrogate: For environmental chemistry, a surrogate is a substance with properties similar to those of the target analyte(s). Surrogates are unlikely to be native to environmental samples. They are added to environmental samples for quality control purposes, to track extraction efficiency and/or measure analyte recovery. Deuterated organic compounds are examples of surrogates commonly used in organic compound analysis (Kammin, 2010).

Systematic planning: A step-wise process which develops a clear description of the goals and objectives of a project, and produces decisions on the type, quantity, and quality of data that will be needed to meet those goals and objectives. The DQO process is a specialized type of systematic planning (USEPA, 2006).

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