DEPARTMENT OF ECOLOGY
State of Washington

Quality Assurance Project Plan

Toxic Chemicals in Cosmetics

August 2022

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Quality Assurance Project Plan

Toxic Chemicals in Cosmetics

by Prajwol Tuladhar

August 2022

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EAP: Environmental Assessment Program
HWTR: Hazardous Waste and Toxics Reduction Program

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2.0 Abstract

Most people in the United States use personal care products in their daily lives regardless of their race, age, gender, and economic status. Personal care products that are poured, sprinkled, sprayed on, or applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearances, are defined as "cosmetics" by the Federal Food, Drug, and Cosmetic Act (FDCA). Most commonly used personal care products are categorized as cosmetics. These include, but are not limited to, skin moisturizers, perfumes, lipsticks, nail polishes, eye and facial makeup preparations, shampoos, permanent waves, and hair colors. Because the word "cosmetics" is frequently equated with eye and facial makeup preparations, such as rouge or mascara, this document uses the phrase "personal care products" to help clarify that the scope of this project includes all applicable cosmetic products, not just makeup.

People of color, especially women of color, are disproportionately exposed to harmful ingredients in cosmetics because of the different beauty standards influenced by their unique cultural ideals, product preferences, and beauty practices. Cosmetics and beauty products are an understudied source of environmental exposure to these ingredients, as the disclosure of chemical ingredients can be limited and inconsistent.

The Washington State Legislature has appropriated one-time funding for the Washington State Department of Ecology (Ecology) to:

- Investigate and identify cosmetic products marketed to, or used by, people of color, including adults and children.
- Test those cosmetic products for potentially harmful chemicals or chemical classes.

Beginning July 2022, Ecology will conduct a study to test a variety of cosmetic products used by, or marketed to, people of color for the presence of formaldehyde, lead, cadmium, and arsenic.

3.0 Background

3.1 Introduction and problem statement

Almost everyone uses some kind of personal care product regardless of race, age, gender or economic status. These products have become an essential part of our everyday lives. While the Federal Food, Drug, and Cosmetic Act (FDCA) does not particularly define "personal care products", most of the items found in the health and beauty section of drug and department stores are considered personal care products. FDCA identifies products like skin moisturizers, perfumes, lipsticks, nail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes and deodorants as cosmetics (FDA, 2016). However, items such as lip balms, diaper rash creams, mouthwashes, antiperspirants, and treatments for dandruff and acne are considered drugs because they are labeled as skin protectants or marketed with therapeutic claims. Some personal care items such as anti-dandruff shampoos, deodorants, and toothpaste may be categorized as cosmetics and drugs (FDA, 2016).

Some chemicals used in cosmetic products have been linked to harmful impacts on health. Chemicals such as formaldehyde, methylene glycol, coal tar, cadmium and cadmium

compounds, arsenic and inorganic arsenic compounds are listed as known human carcinogens by the International Agency for Research on Cancer (IARC, 2018). Similarly, triclosan, phthalates, some parabens, alkylphenols, cyclosiloxanes, and synthetic musk fragrances are known hormone disruptors (Dodson et al., 2012). These chemicals have been commonly used as antimicrobial agents (triclosan), preservatives (parabens, formaldehyde), fillers (clay and talc contaminated with metals), and colorants (metal contaminants) in cosmetic products (FDA, 2022a; NIEHS, 2021).

Cosmetics use are an understudied source of environmental chemical exposure. Cosmetics have limited and inconsistent disclosure of chemical ingredients and most lack adequate data on health and safety (Zota and Shamasunder, 2017). In particular, women of color[1] are disproportionately exposed to harmful ingredients in cosmetics because of the different beauty standards influenced by their unique cultural ideas of beauty, product preferences, and beauty practices. Products such as skin lighteners, hair relaxers, "Brazilian Blowout"™ treatments, and acrylic nails that are mostly marketed to women of color contain some of the most worrisome ingredients (CSC, 2022d).

In addition to causing harm to human health, chemicals in cosmetics also make their way into the environment. The environmental fate of these chemicals is largely unknown. In some cases, they are removed during the wastewater treatment process but most of these chemicals escape conventional treatment processes and may persist in the environment at unexpected levels (Juliano and Magrini, 2017).

A bill relating to the use and disclosure of harmful chemicals in cosmetic products, the Toxic-Free Cosmetics Act (Senate Bill 5703), was introduced during the 2022 Washington State Legislative session. Based on laws adopted in California, Maryland, and parts of the European Union (EU), the proposed bill would have prohibited the following intentionally added chemicals or chemical classes beginning January 1, 2025:

- Ortho-phthalates
- Perfluoroalkyl and polyfluoroalkyl substances
- Phenolic compounds
- Formaldehyde (CAS 50-00-0) and FRAs
- Arsenic and arsenic compounds (CAS 7440-38-2)
- Ethylene glycol (CAS 107-21-1)
- Methylene glycol (CAS 463-57-0)
- Mercury and mercury compounds (CAS 7439-97-6)
- Styrene (CAS 100-42-5)
- 1,4-dioxane (CAS 123-91-1)
- Cadmium and cadmium compounds (CAS 7440-43-9)
- Octamethylcyclotetrasiloxane (CAS 556-67-2)
- Decamethylcyclopentasiloxane (CAS 541-02-6)
- Toluene (CAS 108-88-3)
- Parabens

[1] The term "women of color" is used with the recognition that this includes women from a wide variety of backgrounds including but not limited to African American (or Black), Latina, Native American, Asian, and Asian Pacific Islander.

- Lead and lead compounds (CAS 7439-92-1)
- Asbestos
- Hydroquinone (CAS 123-31-9)
- 2-Ethylhexyl acrylate (CAS 103-11-7)
- Ethyl acrylate (CAS 140-88-5)
- Aluminum salts
- Sodium laurel sulfate (CAS 151-21-3)
- Sodium laureth sulfate (CAS 3088-31-1)
- Benzalkonium chloride (CAS 8001-54-5)
- Coal tar compounds
- Triclosan (CAS 3380-34-5)
- Methylisothiazolinone (CAS 2682-20-4)
- Methylchloroisothiazolinone (CAS 26172-55-4)
- m-phenylenediamine and its salts (CAS 108-42-5)
- o-phenylenediamine and its salts (CAS 95-54-5)
- p-phenylenediamine and its salts (CAS 106-50-3)
- synthetic fragrances

The proposed bill would have also required Ecology, in consultation with the Washington State Department of Health (DOH), to create a community engagement plan to test cosmetic products marketed to women of color. This would include:

- Identifying potentially harmful chemicals or chemical classes, as well as providing education and outreach concerning harmful chemicals or chemical classes, by December 1, 2022.
- Establishing certain disclosure requirements for cosmetic products manufactured on or after January 1, 2023.

Although SSB 5703 did not pass, the Legislature instead provided one-time funding for Ecology to identify cosmetic products marketed to or used by people of color, including adults and children, and test those products for potentially harmful chemicals or chemical classes. Engrossed Substitute Senate Bill 5693 Sec. 302 (56) (2022) stipulates:

> "$266,000 of the model toxics control operating account—state appropriation is provided solely for the department, in consultation with the department of health and community and social justice organizations, to identify cosmetic products marketed to or used by people of color, including adults and children, and test those products for potentially harmful chemicals or chemical classes. The department must provide a technical report on the results of the tests to the appropriate committees of the legislature by December 31, 2022."

This study plan details Ecology's process to investigate chemicals in the cosmetic products used by or marketed to people of color in the state of Washington. Data from this study will be included in a technical report sent to the Legislature, and may be used to support future legislation.

3.2 Study area and surroundings

Ecology is committed to the principles of environmental justice and share the mission established by the Office of Equity and Environmental Justice to eliminate environmental and health disparities for communities most at risk from pollution and other environmental impacts

through fair and just practices that support the wellbeing and resilience of Ecology's workforce and the people of Washington (Ecology, 2022). Cosmetic products or cosmetic product types to be tested for this study will target products used by or marketed to people of color and will be identified primarily through community outreach led by Ecology. In addition, priority product types will also be selected based on prior research related to product usages by people of color (See Appendix A).

Products chosen for the study may be purchased in any physical location (e.g., discount stores, department stores, supermarkets, and warehouse clubs) within Washington State or online, if they can be purchased online by Washington residents or businesses. Products that are available in larger chain stores and online generally reflect merchandise available to residents across Washington State. Demographic data and community outreach may be used to identify retail stores within Washington State that mostly serve communities of color. For this study, Ecology will focus on purchasing products from stores within the Puget Sound area.

3.2.1 History of study area

Even though there are thousands of chemicals used in cosmetics and a vast amount of cosmetic product types in the market, there is relatively limited information in the U.S. scientific literature on toxic or other potentially harmful chemicals in cosmetics and personal care products. Cosmetic industry in the U.S. is self-regulatory and does not require testing of products. This could be one of the causes for limited testing studies in the U.S. Few studies that have been conducted in the U.S. and other parts of the world highlight the presence of some of the chemicals of concern in cosmetics and personal care products.

- In 2012, Dodson et al. published a study testing 213 consumer products for parabens, bisphenols (BPA), triclosan, ethanolamines, alkylphenols, fragrances, glycol ethers, cyclosiloxanes, and ultraviolet (UV) filters (Dodson et al., 2012).
- In 2014, Liao and Kannan published a study testing 213 products from China and U.S. for alkylphenols, bisphenols, and triclosan (Liao and Kannan, 2014).
- Per and polyfluoroalkyl substances in personal care products have been studied by Fujii et al. (2013), Yukioka et al. (2017), Schultes et al.)(2018), Brinch et al. (2018) and Whitehead et al. (2021).

We summarize other studies that tested for formaldehyde and metals in cosmetics and personal care products in Sec. 3.2.2 of this Quality Assurance Project Plan.

3.2.2 Summary of previous studies and existing data

U.S. Food and Drug Administration (FDA)

Following reports of lead in lipsticks published by Campaign for Safe Cosmetics (CSC)[2] in 2007 (CSC, 2007), the FDA conducted surveys in 2007 and 2010 to determine the amount of lead in lipsticks available for sale. In addition to the 20 products reported by CSC, they studied 400 additional lipsticks and determined that manufacturers should be able to limit lead content in cosmetics to be in accordance with their guided recommendation of 10 ppm or less.

[2] A national coalition of nonprofit women's, environmental, health, faith, consumer and worker organization.

Manufacturers can achieve this by being careful about selecting ingredients and following good manufacturing practices (FDA, 2022b and 2022c).

In 2012 and 2013, the FDA looked at 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).

Campaign for Safe Cosmetics (CSC)

In 2009, CSC published a report on heavy metals in Halloween makeup kits for kids. The results showed low, but detectable, levels of lead in 10 of 10 (100%) makeup kits tested (Sarantis et al., 2009b).

In 2009, CSC conducted a separate study that tested children's products such as lotions, shampoos, liquid shower soaps, hair relaxers, and other personal care products for formaldehyde and 1,4-dioxane. Findings from that study included 82% (23 of 28) products contained formaldehyde at levels up to 610 ppm, and 67% (32 of 48) products contained 1, 4-dioxane at levels up to 35 ppm (Sarantis et al., 2009a).

In 2016, the CSC tested 48 components from 14 makeup kits for heavy metals. They also tested 65 components from 51 products for volatile organic compounds (VOCs). They found arsenic in 8%, cadmium in 29%, and lead in 4.6% of samples at concentrations ranging from 0.58 – 14 ppm (Engel et al., 2016).

Washington State Department of Ecology (Ecology)

Ecology has limited studies that include testing on cosmetics and personal care products. A 2014-2015 Ecology study focused on parabens, phthalates, and metals in children's products as a part of a seasonal based study (Trumbull et al., 2017). This study tested 174 cosmetic and personal care products, out of 1033 products collected across seven studies. Parabens were mostly tested and detected in cosmetics and personal care products. Methyl paraben and propyl paraben were mostly detected in samples of lip gloss/lip balms, lotions, shower gels, eyeshadows, lipsticks, and costume makeup. The highest levels of methyl paraben was detected in a gel blood component of a Halloween makeup kit at 3800 ppm. The highest level of propyl parabens were detected in eyeshadows at 1700 ppm.

In 2017, an Ecology study assessed formaldehyde, D4, MEK, and Styrene in children's products purchased in Washington State (Sekerak, 2017). Out of 84 total products collected, 20 were personal care products applied to skin, nails, hair, or were intended for oral use such as dental cleansing products, and 11 were baby care products. A total of 60% of the personal care products tested contained formaldehyde with concentrations ranging from 12.1 - 436 ppm. Formaldehyde was also detected in four of the seven baby hygiene products, ranging from 13 - 897 ppm.

Voller et al. 2019

In 2019, Voller et al. investigated nail polishes that claimed to be formaldehyde free. They purchased 29 nail polishes, with 28 claiming to be formaldehyde free. They found five polishes contained formaldehyde at detectable levels of 2 ppm, even though four of them claimed to be formaldehyde free. None of the five products had formaldehyde listed in their ingredients.

Attard et al. 2022

Attard et al. (2022) recently published a comprehensive review of studies, in the U.S. and worldwide, related to heavy metals in cosmetics. Lipstick product groups were found to be the most widely investigated cosmetic group for heavy metals. In their review, Attard et al. compiled a table with studies that tested for lead, cadmium, nickel, mercury, and arsenic based on the product types. Based on the compiled results from studies in their table, lipsticks contained at a maximum: 252.40 ppm lead, 60.20 ppm cadmium, and 6.93 ppm arsenic. Similarly, eyeshadows contained at a maximum: 81.50 ppm lead, 55.59 ppm cadmium, and 3.70 ppm arsenic (Attard et al., 2022).

Some of the other categories of cosmetics that had higher reported levels of lead were eyebrow pencils and eyeliners (61.22 ppm), makeup foundations (190 ppm), face paints (370 ppm), body lotions (47.5 ppm), beauty creams (50.39 ppm), skin lightening creams (143 ppm), and hair shampoo and conditioners (54.56 ppm). Higher levels of cadmium were also detected in makeup foundations (17 ppm) and face paints (19.2 ppm). Arsenic was detected in beauty creams (10.74 ppm), toothpaste (26.94 ppm), and skin lightening creams (12.30 ppm) (Attard et al., 2022).

3.2.3 Parameters of interest and potential sources

In this 2022 Ecology study, formaldehyde, lead, cadmium, and arsenic will be analyzed in cosmetic products marketed to people of color.

Formaldehyde is a colorless, strong-smelling gas used in a wide range of industries and products including building materials, walls, cabinets, furniture, and personal care products (ATSDR, 2016). Formaldehyde and formaldehyde releasing preservatives (FRPs) are intentionally added to many personal care products. Formaldehyde can be found in nail polishes, nail glues, eyelash glues, hair gels, hair-smoothing products, baby shampoo, body soap, body wash, and color cosmetics. In personal care products, formaldehyde can be added directly, or more often, it can be released from preservatives such as quaternium-15, DMDM hydantoin, imidazolidinyl urea, diazolidinyl urea, polyoxymethylene urea, sodium hydroxymethylglycinate, bromopol, and glyoxal (CSC, 2022a).

Lead can be found in the air, the soil, the water, and even inside our homes. Lead and lead compounds have been used in a wide variety of products found in and around our homes, including paint, ceramics, pipes and plumbing materials, solders, gasoline, batteries, ammunition, and cosmetics (EPA, 2022).

Cadmium is mainly emitted to soil, water, and air by non-ferrous metal mining and refining, manufacture and application of phosphate fertilizers, fossil fuel combustion, and waste incineration and disposal (ATSDR, 2012).

Arsenic is a naturally occurring element that is found throughout the environment. Inorganic arsenic can be released into the air by volcanoes, weathering of arsenic-containing minerals and ores, and commercial or industrial processes. Elevated levels of inorganic arsenic may be present in soil, either from natural mineral deposits or contamination from human activities, which may lead to dermal or ingestion exposure (ATSDR, 2007).

Heavy metals such as lead, cadmium, and arsenic have been found as contaminants in a range of cosmetic products including sunscreen, foundation, nail polish, lipstick, and whitening toothpaste. Several ingredients derived from plant sources, like cottonseed oils and rice derivatives, may also contain heavy metals such as lead and mercury (CSC, 2022c). While some metals are contaminants from the chemical combining process, others serve as colorants. Some color additives, such as D&C Red 6, may be contaminated by heavy metals such as arsenic, lead, and mercury. Products that contain contaminant metals are not listed on the ingredient labels (CSC, 2022c). FDA surveys concluded that eyeshadows, blushes, and compact powders contained more heavy metals than other types of cosmetics, and most of these heavy metals come from minerals used as pigments and fillers, such as clay and talc (FDA, 2022b).

3.2.4 Regulatory criteria or standards

This section provides information on the regulatory environment, under U.S. Federal and Washington State laws, for formaldehyde and heavy metals (lead, cadmium, and arsenic) in cosmetics and personal care products. This section also provides information on the regulatory criteria for chemicals in cosmetics that have been implemented in other U.S. states, the European Union (EU), and Canada.

Federal law

The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) defines cosmetics as articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance. Cosmetic product includes cosmetics marketed to professionals but does not include soap, dietary supplements, or food and drugs approved by the FDA (FDA, 2022d).

The FDCA prohibits cosmetics which are adulterated or misbranded. Cosmetics must also comply with labeling regulations published by the FDA under the authority of FDCA and the Fair Packaging and Labeling Act (FPLA). It is against the law for a cosmetic to contain any ingredient that makes the product harmful when consumers use it according to directions on the label, or in the customary or expected way. However, FDA does not explicitly prohibit or regulate the use of formaldehyde in cosmetics (FDA, 2022a). Under U.S. laws, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market. Color additive regulations of the FDA limit heavy metal impurities such as lead at 20 ppm, arsenic at 3 ppm, and mercury at 1 ppm. FDA has published a draft guidance for the industry that recommends a maximum level of 10 ppm for lead as an impurity in cosmetics (FDA, 2022b).

In 2021, leading U.S. Non-Government Organizations (NGOs) and cosmetic companies collaborated to introduce four pieces of federal legislation that focus on critical areas of cosmetic safety reform. This legislation is known as the "Safer Beauty Bill Package". One of the bills from the package, Toxic Free Beauty Act of 2021 (H.R. 5537), was introduced in the House of Representatives in October 2021. The bill proposed to add more chemicals to the FDA's list of prohibited chemicals in cosmetics. Chemicals proposed to be added include formaldehyde, per- or polyfluoroalkyl substances (PFAS), some phthalates, parabens, phenylenediamine and its salts, and mercury. As of June 2022, the bill is awaiting recommendations from the Subcommittee on Health (H.R. 5537).

Although cosmetics are generally considered to be outside the scope of Consumer Product Safety Commission (CPSC), children's products including cosmetics and personal care products are protected under the Consumer Product Safety Improvement Act (CPSIA). Under CPSIA, children's products must not contain more than 100 ppm total lead content in accessible parts. Also, no children's products may contain a concentration of lead greater than 90 ppm in paint or any similar surface coatings.

Washington State law

In 2019, Washington passed the Safer Products for Washington Act (SPWA; RCW 70A.350) that established a process for Ecology and DOH to designate priority chemicals, identify products that contain these chemicals, decide whether or not to regulate or restrict chemical product combinations, and adopt rules to implement those regulatory action. Phthalates, per- and polyfluoroalkyl substances (PFAS), organohalogenated flame retardants, phenolic compounds, and polychlorinated biphenyls (PCBs) were the first set of priority chemical classes identified by the law. Even though fragrances used in personal care products were identified as one of the priority products that contained phthalates, there are other products that use phthalates for functions not covered by SPWA. Also, there are many other chemicals in cosmetics and personal care products, which can cause harm to humans and the environment, that are not covered under SPWA.

Formaldehyde and the heavy metals lead, cadmium, and arsenic are identified as chemicals of high concern to children (CHCC), and manufacturers must report their use in children's products. Children's Safe Product Act (CSPA) of Washington (RCW 70A.430.020) further restricts lead and cadmium in children's products at 90 ppm and 40 ppm, respectively. "Children's products" include cosmetics and personal care products sold to children under the age of 12.

Other U.S. states

In 2020, California enacted the Toxics Free Cosmetics Act (AB 2762) prohibiting 24 harmful chemicals from cosmetics sold in California. In 2021, Maryland passed a similar law, House Bill 643. Both laws go into effect in 2025. Prohibited chemicals include formaldehyde, parabens, and 13 per- and polyfluoroalkyl substances (PFAS), some phthalates, phenylenediamine and its salts, and mercury.

In 2013, Minnesota banned formaldehyde in children's personal care products such as lotions, shampoos, and bubble baths. Formaldehyde-releasing preservatives in products intended for children under eight are also restricted at 0.05%.

The European Union and Canada

Cosmetic regulations in the United States generally have not kept pace with other developing countries. In comparison to the EU's prohibition on close to 1328 chemicals known or suspected to cause harm to human health, the U.S. currently prohibits or restricts only 11 (CSC, 2022b). In Canada, the heavy metals lead, cadmium, and arsenic are prohibited for use in cosmetic products while formaldehyde is prohibited in aerosol products and restricted depending on its use. The EU also prohibits the use of heavy metals and carry certain restrictions on formaldehyde and formaldehyde-releasing preservatives in their cosmetic products.

4.0 Project Description

Beginning July 2022, Ecology will purchase cosmetic products prioritized as marketed to, or used by, people of color. Priority products or product types were identified primarily through community outreach led by Ecology. Priority product types were also selected based on prior research on product type usage found in literature reviews. The outreach and the research used for determining each of the priority product types are explained in Appendix A. The products will be purchased online and/or in retail stores in Washington state. The product samples will then be sent to Ecology's Manchester Environmental Laboratory (MEL) for analysis.

4.1 Project goals

The primary goals of this study is to (1) assess the presence of some specific chemicals in cosmetics marketed to, and used by, people of color in Washington and (2) summarize and report findings to the state Legislature.

4.2 Project objectives

The following objectives will be carried out to meet the study goals:

- Purchase cosmetic products from similar stores identified during research and community outreach. These include, but are not limited to, large retail chain stores such as Walmart, Target, Fred Meyer, and Costco that do not specialize in one type of merchandise.
- Investigate the harmful metal contaminants, lead, cadmium, and arsenic, in lipstick and foundation products sold in large retail chain stores.
- Investigate powdered foundation makeup sold in large retail chain stores that are low cost, or targeted to people with darker skin tones, for the presence of formaldehyde, which may not be listed as an ingredient.
- Investigate cosmetic products sold in large retail chain stores that are low cost, or marketed to people of color, that have a formaldehyde releaser (DMDM Hydantoin) listed in their ingredients for formaldehyde.

4.3 Information needed and sources

Ecology's Hazardous Waste and Toxics Reduction Program (HWTR), in partnership with DOH, coordinated outreach efforts with community and social justice groups to identify products or product types marketed to, or used by, people of color, including adults and children.

The resulting priority list of products obtained from outreach and available literature review data is presented in Appendix A. Ecology will make a reasonable effort to purchase exact products or product types from the list provided in Appendix A. If an exact product cannot be found in retail stores or online during the purchase timeframe, Ecology may substitute it with a similar product type from a different brand following the guidelines in Appendix A. Ecology will not substitute it with a different product type. For example, a hair gel will not be substituted with a leave-in conditioner.

4.4 Tasks required

This study will include the following tasks:

- On or before July 1, 2022, acquire the list of priority products obtained from community outreach.
- Scope the availability of priority products online and in retail stores to strategize purchasing events.
- Purchase 50 unique cosmetic products either online or in retail stores.
- Record purchase and product information, including product photos, in Ecology's Product Testing Database (PTDB).
- Process product components from cosmetics products into samples for lab analysis.
- Submit up to 50 product samples to Ecology's Manchester Environmental laboratory (MEL) for analysis.
- Submit lab data packages to MEL's data validation team for data validation.
- Enter final validated lab data into the PTDB.
- Conduct quality assurance (QA) review on analytical data and database entries.
- Analyze findings and document methods, data quality assessment, and results.
- On or before October 27, 2022, update HWTR on the draft content for study methods, data quality assessment, and results to be included in a report to the Legislature.
- When the report is published, make lab data and product information from the study available to the public on Ecology's PTDB website when the report is published.

4.5 Systematic planning process

This QAPP and subsequent addenda to this QAPP address suitable systematic planning for the specific study.

5.0 Organization and Schedule

5.1 Key individuals and their responsibilities

Table 1 shows the responsibilities of those who will be involved in this study.

Table 1. Organization of project staff and responsibilities.

Staff[1]	Title	Responsibilities
Iris Deng ChemAction Unit P2RA, HWTR Phone: 360-480-6555	Client	Clarifies scope of the project. Provides internal review of the QAPP and approves the final QAPP.
Prajwol Tuladhar Product Testing Unit SCS, EAP Phone: 360-407-6745	Project Manager	Writes the QAPP. Coordinates with client and laboratory. Purchases products, enters purchases and products into PTDB, and conducts QA review of these entries. Oversees field sampling and transportation of samples to lab. Conducts QA review of data, analyzes and interprets data, and enters data into PTDB. Writes the report sections on study methods, data quality assessment, and results.
Sara Sekerak Product Testing Unit SCS, EAP Phone: 360-480-9501	Unit Supervisor for the Project Manager	Reviews the project scope and budget. Provides internal review of the QAPP, tracks progress, approves the budget, and approves the final QAPP
Jessica Archer SCS, EAP Phone: 360-890-2721	Section Manager for the Project Manager	Reviews the project scope and budget, approves peer reviewer of draft QAPP, and approves the final QAPP
Nathan Lubliner ChemAction Unit P2RA, HWTR Phone: 360-688-6703	Unit Supervisor for the Client	Coordinates client project scope. Reviews and approves the final QAPP
Richelle Perez P2RA, HWTR Phone: 360-742-6794	Section Manager for the Client	Reviews the project scope and budget and approves the final QAPP.
Christina Frans MEL Phone: 360-995-2473	QA Coordinator	Reviews QAPP, conducts data validation for metals analysis, and coordinates data validation for formaldehyde analysis.
John Weakland MEL Phone: 360-480-7515	Data Validation Chemist	Reviews QAPP and conducts data validation for formaldehyde analysis.
Alan Rue MEL Phone: 360-871-8801	Director	Reviews and approves the final QAPP.
Arati Kaza Phone: 360-407-6964	QA Officer, Ecology	Reviews and approves the draft QAPP and the final QAPP.

[1]All staff except the clients are from EAP.
EAP: Environmental Assessment Program
HWTR: Hazardous Waste and Toxics Reduction Program
MEL: Manchester Environmental Laboratory
P2RA: Pollution Prevention and Regulatory Assistance
PTDB: Product Testing Database
QAPP: Quality Assurance Project Plan
SCS: Statewide Coordination section

5.2 Special training and certifications

Ecology staff conducting, and assisting with, product testing studies will have undergone training documented by completing the Product Testing Preparation Staff Training Checklist. Training includes reviewing the study-specific QAPP, current approved product testing standard operating procedures (SOPs), and the location of personal protective equipment and safety equipment (e.g., first aid kit, eye wash station). Product testing training is outlined in Ecology's Product Testing SOP (PTP001) for Sample Collection and Processing.

Staff will follow and participate in all required Ecology health and safety trainings. Staff will also follow and participate in all required purchasing and contracts trainings as their role in this project requires.

5.3 Organization chart

Table 1 lists the key individuals and responsibilities.

5.4 Proposed project schedule

Tables 2 – 4 list key activities, due dates, and lead staff for this study.

Table 2. Schedule for completing product collection and data entry

Task	Due date	Lead staff
Product Purchase complete	Jul 31 2022	Prajwol Tuladhar
Product Data Entry complete	Aug 07 2022	Prajwol Tuladhar
Product Data Entry QA	Aug 30 2022	Prajwol Tuladhar

Table 3. Schedule for sending samples to the lab and lab analysis

Task	Due date	Lead staff
Samples sent to the lab complete	Aug 15 2022	Prajwol Tuladhar
All lab analyses complete (Metals)	Sep 15 2022	Heidi Chuhran
All lab analyses complete (Formaldehyde)	Sep 15 2022	Joan Protasio

Table 4. Schedule for data and study reviews and data transfer to client

Task	Due date	Lead staff
Lab data validation (Metals)	Sep 30 2022	Christina Frans
Lab data validation (Formaldehyde)	Sep 30 2022	John Weakland
Lab data QA reviewed	Nov 03 2022	Prajwol Tuladhar
Lab data loaded into internal PTDB	Nov 03 2022	Prajwol Tuladhar
PTDB study QA review complete	Nov 03 2022	Prajwol Tuladhar
Preliminary data transfer to client	Nov 03 2022	Prajwol Tuladhar
Study data published in the external PTDB	With published report	Prajwol Tuladhar

QA: Quality Assurance
PTDB: Product Testing Database

Table 5. Schedule for final report

Task	Due date	Lead staff
Draft sections due to supervisor/peer reviewer	Oct 25 2022	Prajwol Tuladhar
Draft sections due to HWTR	Nov 03 2022	Prajwol Tuladhar
Final report published	Nov 10 2022	HWTR

5.5 Budget and funding

Total estimated cost for the study is projected to be $16,154, which includes the cost of product collection, lab analysis, and data validation. Table 6 presents the estimated study budget. Table 7 presents lab costs, estimated to be $10,354. Funding for this study is provided by a cosmetics proviso in the state appropriations budget.

Table 6. Study budget

Item	Cost ($)
Product Collection* (up to 50 products)	3,000
Laboratory (see Table 7 for details)	10,354
MEL Data Validation Fee	2,800
Total	16,154

*Some products may be purchased in replicate of up to four to provide a sufficient amount of sample for lab analysis and/or field sample duplicates.

Table 7. Study budget for laboratory analysis

Lab analysis	Number of Lab Samples for Analysis	Lab QC Samples*	Total Number of Samples	Cost Per Sample ($)	Lab Subtotal ($)
Metals: Lead, Cadmium, Arsenic	20	6	26	124	3224
Formaldehyde	40	6	46	155	7,130
Total	60^	12	72	-	10,354

*Quality control (QC) samples in this table are those not provided free of charge (matrix spike, matrix spike duplicate, and sample duplicate).

^ The total number of samples sent to the lab will be 50. Since there are 10 samples that will be analyzed for both formaldehyde and metals separately, the total number of lab analysis conducted will be 60.

6.0 Quality Objectives

6.1 Data quality objectives

The overall quality objective is to obtain results of documented accuracy (e.g., bias and precision) in product samples from a specific product at the time of purchase or collection. Common indicators of data quality include the measurement quality objectives (MQOs) for precision, bias, and sensitivity. These are described in Section 6.2 and Table 8.

6.2 Measurement quality objectives

6.2.1 Targets for precision, bias, and sensitivity

Table 8 shows MQOs for analysis of formaldehyde, lead, cadmium, and arsenic expressed in terms of acceptable precision, bias, and sensitivity. MEL's modified procedure for formaldehyde analysis uses a surrogate, and the MQO for surrogate standards is updated to reflect this modification.

Table 8. Measurement quality objectives

Analyte	LCS (recovery)	Matrix Spike (recovery)	Sample and LCS Duplicates (RPD)	Matrix Spike Duplicates (RPD)	Surrogate Standards (recovery)	Target Reporting Limit Ω
Formaldehyde	50-150%	50-150%	≤ 40%	≤ 40%	50-150%	10 ppm
Lead, Cadmium, Arsenic	85-115%	75-125%	≤ 20%	≤ 20%	N/A	1 ppm

LCS = laboratory control sample
RPD = relative percent difference
ppm = parts per million
Ω Individual lab reporting limits may vary based upon specific matrix type

6.2.1.1 Precision

Precision is a measure of variability among replicate measurements due to random error. Lab analysis precision will be assessed using lab duplicate samples for all matrices and analyses. Table 8 shows the MQO for lab control standard duplicates and sample duplicates.

6.2.1.2 Bias

Bias is the difference between the sample mean and the true value. Lab analysis bias will be assessed through lab control samples. MQOs for LCS 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 or reporting limit. Target reporting limits for all the analytes are shown in Table 8.

6.2.2 Targets for comparability, representativeness, and completeness

6.2.2.1 Comparability

Comparability will be ensured by implementing standardized procedures for sampling and analysis. Data from this study can be compared to publicly available data of similar product types and analyzed using substantially the same analytical methods, if available.

6.2.2.2 Representativeness

Products purchased and collected for this study will be representative of products marketed to, or used by, people of color available to Washington state residents and agencies.

6.2.2.3 Completeness

The project manager will consider the study to have achieved completeness if 95% of the lab samples are analyzed acceptably.

6.3 Acceptance criteria for quality of existing data

Not applicable to this study.

6.4 Model quality objectives

Not applicable to this study.

7.0 Study Design

7.1 Study boundaries

Ecology will purchase cosmetic products that have been identified as priority products or product types marketed to or used primarily by people of color. Ecology will closely follow the suggested brands and product examples from the priority product list and purchase items recommended in Appendix A. Ecology will conduct an online search of the priority products to look for availability at retail chain stores and plan purchasing events accordingly. Ecology may purchase a product using the online platform from the same retail store if the product (1) is currently not available in any retail store in the Puget Sound area of Washington, and (2) can be received within the purchasing window (See Table. 2).

Ecology will purchase and send up to 50 unique product samples to MEL for analysis. Ecology will purchase up to:

- 10 lipstick products that cost under $10 to test for lead, cadmium, and arsenic.
- 10 skin lotion products, 10 leave-in hair conditioners, and 10 hair styling gel and cream with a formaldehyde releaser (DMDM Hydantoin[3]) as one of the listed ingredients to be tested for formaldehyde content.
- 10 darker shade powder-based foundations under $20 to test for formaldehyde, lead, cadmium, and arsenic. Ecology will also try to find products that have talc listed as an ingredient; however, having talc listed as an ingredient is not a requirement.

[3] DMDM Hydantoin is the most common name used but other possible synonyms are listed in Appendix A

Ecology may purchase multiples of each product to ensure enough sample is provided for all testing parameters. Ecology will ensure that the multiple of a product purchased represents the same item by confirming, at a minimum, the same tint or color described in the package.

7.2 Field data collection

Any advertisements, photos of product marketing, and other information that may be gathered during study purchasing events will be recorded and uploaded or scanned into the PTDB. Specific protocols are outlined in SOP PTP001 Product Collection and Sample Processing.

7.2.1 Sampling locations and frequency

Ecology will purchase products from large retail chains that have physical stores in Washington State and that do not specialize in one type of merchandise. Ecology may purchase from any store that meets the above criteria such as, but not limited to, Walmart, Target, Fred Meyer, and Costco. Products may also be purchased from online platforms made available by these stores. For online purchases, Ecology may purchase merchandise made available by third-party sellers on the platform only if there are no other alternatives available for a particular product or product type.

Ecology will scope specific products from the priority list online to identify availability in retail stores and/or online. In-store and online purchases will then be coordinated to minimize the frequency of product purchasing events. Staff will record retail locations of products purchased in the Product Documentation Log (Section 8.7) and in the Product Testing Database (PTDB).

7.2.2 Field parameters and laboratory analytes to be measured

The analytes in product component samples for this study are listed in Table 9. The product component samples containing the analytes may be composed of complex matrices that are solids, semi-solids, liquids, or cream-based.

Table 9 Analytes to be measured.

Analyte Group	Analyte Name	Abbrevia-tion	CAS Registry Number
Metal	Lead	Pb	7439-92-1
Metal	Arsenic	As	7440-38-2
Metal	Cadmium	Cd	7440-43-9
Organic	Formaldehyde	H-CHO	50-00-0

CAS = Chemical Abstracts Service

7.3 Modeling and analysis design

Not applicable to this study.

7.3.1 Analytical framework

Not applicable to this study.

7.3.2 Model setup and data needs

Not applicable to this study.

7.4 Assumptions underlying design

Products used in a study reflect current on-the-market products at the time of purchase and not previous in-use products that consumers have had exposure to. Manufacturing formulations are subject to change in response to changes in the regulatory environment. Similar or same products may generate different analytical lab results depending on when the product was manufactured (Trumbull, 2022).

7.5 Possible challenges and contingencies

Some products purchased may not have enough weight necessary for analysis. Samples may also be lost while processing the products. Ecology will purchase multiples of the same product (see Section 7.1) to fulfill the weight requirements for analysis. The cost of buying multiples is factored into the budget (see Table. 6).

For metals testing, the FDA found in previous studies that most of the cosmetic products manufactured within the U.S. have lead levels below 10 ppm (FDA, 2022b). The metals analytes in cosmetics manufactured in the U.S. might be close to, or below, our target reporting limit of 1 ppm.

7.5.1 Logistical problems

Ecology will make every effort to purchase cosmetic products in the list in Appendix A; this list was generated after consultation with community and social justice organizations. However, if the product is not available for purchase online or in retail stores, similar product types of different brands may be considered.

7.5.2 Practical constraints

Limitations in receiving products through online purchases may occur due to unforeseen product unavailability and/or shipping delays after purchase. Some product purchases may need to be cancelled if the products are on back-order and not to be received within the proposed timeframe. Products may be reordered through a different online retailer or purchased at a retail store if it can be achieved within the purchase timeline mentioned in this QAPP (see Table 2).

7.5.3 Schedule limitations

Complications in the laboratory digestion and extraction processes due to complex product matrices may cause a need for reanalysis of a sample. However, time constraints may limit the possibilities for reanalyzing a sample. In such cases, results may be accepted with qualifications.

Due to the compressed timeline of the project, MEL staff responsible for data validation will conduct a Stage 2B data validation on the entire set of data with a Stage 4 validation on either 1 laboratory batch or 10%, whichever is higher for the data. The initial Stage 4 validation for at least 1 laboratory batch or 10% will be conducted on each analyte class tested. The client may request a third-party data validation at a later date and time, if needed.

8.0 Field Procedures

8.1 Invasive species evaluation

Not applicable to this study

8.2 Measurement and sampling procedures

Product collection, recording product and sample component data in the Product Testing Database, sample processing, and sample processing methods are outlined in Ecology's Product Testing SOPs:

- Ecology's Product Testing SOP (PTP001) for Product Collection and Sample Processing, Version 2.1 (Wiseman, 2021).
- Ecology's Product Testing SOP (PTP002) for Database Data Entry and Data Entry Quality Assurance, Version 2.1 (Wiseman, 2022).

8.3 Containers, preservation methods, holding times

Sample containers, minimum quantity, storage and preservation, and holding times for sample matrices are shown in Table 10. Hand-reduced lab samples will be stored in certified clean wide-mouth glass jars with Teflon-lined lid. Solids, powders, and semi solids (soft solids that can be cut using a scissor or knife) will be hand-reduced and transferred to pre-cleaned glass jars provided by MEL. Liquid and semi-liquid (homogeneous cream based) samples will be sent to the lab in their original sealed containers.

Multiple bottles of the same product may be used as one sample for liquid samples that do not have enough weight. Such samples will be individually labeled with both the MEL sample ID and the product testing sample ID, and consolidated into one sample bag. The sample bag will also be labeled with the MEL sample ID and product testing sample ID. (See Section 8.5)

All samples to be analyzed for formaldehyde will be processed the day before the courier transports the samples to MEL. All processed samples will be sent to the lab at reduced temperatures. The processed samples will be stored in a cooler with blue ice packs and placed in the walk-in cooler in Ecology's Chain of Custody (COC) room.

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

Parameter	Matrix/ Source Code	Minimum Quantity Required	Container	Preservative	Holding Time
Metals: Lead, Cadmium, Arsenic	CP/ PC	2.5 grams	Original container/ 4 to 8 oz. glass jar	Ambient to reduced temperature	1 year
Formaldehyde	CP/ PC	2.5 grams	Original container/ 4 to 8 oz. glass jar	Ambient to reduced temperature	1 year

CP: Consumer Products
PC: Personal Care Products

8.4 Equipment decontamination

All tools used in the preparation of product components into lab samples will be decontaminated using cleaning procedures described in SOP PTP001 Product Testing SOP for Product Collection and Sample Processing.

8.5 Sample ID

For product testing samples, unique Ecology identification numbers (ECY IDs) are auto-generated by the Product Testing Database (PTDB) during the product and component data-entry process. Product testing ECY IDs combine information from the store or collection location, purchase or collection event number, unique product in the study, and component or sample number of the product. For example, AM-36-1-2 corresponds to: AM for Amazon, 36 for the 36th time Ecology purchased from Amazon, 1 for a unique product in the purchase, and 2 for the second sample or component from the product.

Product component samples sent to the analytical lab for analysis will include a MEL ID number generated from a seven-digit work order number for the study sample set, followed by a dash and a two-digit number specific for each sample in the set (e.g., 1234567-01).

The product testing sample ID and MEL sample ID number will be recorded on the sample containers and on the chain of custody (COC) form.

8.6 Chain of custody

Ecology staff will follow specific protocols outlined in SOP PTP001 Product Collection and Sample Processing for storage of products and samples, and for shipment of product component samples to the lab. COC will be maintained for all samples throughout the study. All samples will be stored in locked cabinets in Ecology's product testing processing room until shipped to the analytical lab.

Product component samples may be analyzed by Manchester Environmental Laboratory (MEL) or a contracted laboratory. If a contract lab is used, Ecology staff will use the contracted lab's COC form for samples being shipped to their analytical lab. If a contract lab does not provide their own COC form, Ecology will use MEL's Laboratory Analyses Required (LAR) form as the COC document. For samples being sent to MEL, Ecology staff will place the product component samples inside the walk-in cooler of the COC room and notify MEL's sample receiving staff with an email to schedule pickup for the next business day.

8.7 Field log requirements

Each in-store product purchase will be recorded in a bound notebook with pre-numbered pages. A permanent ink pen will be used to record all entries, and any corrections will be made with single line strikethrough, initials, and date. The Product Documentation Log includes the following information:

- Study QAPP Name
- Project Manager (PM) Name
- Collector/Sampler Name

- Collection Date
- Store or Site Name and Address
- Purpose of Product Collection (optional)
- Explanation of Marketing (if applicable)
- Arrival Time at the Product Collection Location
- Number of Products Purchased/Collected
- Location Contact Name, Phone Number, and Email Address
- Miscellaneous/Comments
- Return Time to Ecology

8.8 Other activities

None.

9.0 Laboratory Procedures

9.1 Lab procedures table

Ecology's Manchester Environmental Laboratory (MEL) will conduct both formaldehyde and metals analysis. The lab methods and requested target reporting limits are presented in Table 11.

Formaldehyde samples will be extracted using the U.S. Environmental Protection Agency (EPA) method 8315A-PREP. Analysis for formaldehyde will be performed by gas chromatography-mass spectrometry (GC-MS; EPA 8270E-SIM).

Metal samples will be prepared by EPA Method 3052, less the addition of hydrofluoric acid. Analysis of lead, cadmium, and arsenic will be performed in accordance with EPA Method 6020B.

The target metals reporting limit of 1 ppm is the standard reporting limit established by Ecology for consumer products testing. The 10 ppm target reporting limit for formaldehyde reflects the current capabilities of MEL and is based on the optimization and performance of their method.

Table 11. Laboratory measurement methods

Analyte	Sample Matrix/ Source Code	Samples	Expected Range of Results	Target Reporting Limit^	Sample Prep Method	Analytical (Instrumental) Method
Formaldehyde	CP/ PC	40	<10-1000 ppm	10 ppm	EPA 8315-PREP	EPA 8270E-SIM
Metals: Lead, Cadmium, and Arsenic	CP/ PC	20	<1-100 ppm	1 ppm	EPA 3052*	EPA 6020B

^Individual reporting limits may vary based on specific analyte and matrix type
* Preparation method modified to omit the use of hydrofluoric acid (HF)
CP: Consumer Products
GC-MS SIM: Gas Chromatography - Mass Spectrometry with Selective Ion Monitoring
PC: Personal Care Products
ppm: parts per million

9.2 Sample preparation methods

Solid, semi-solid, and powdered products will be processed into lab samples for analysis using procedures from the Product Testing SOP PTP001.

Liquid and semi-liquid (cream-based homogenous) samples will be sent to the laboratory in their original sealed container. The lab analyst will identify liquid samples in original containers that do not have a seal or a seal that may have been compromised during shipment.

9.3 Special method requirements

MEL developed a method for the extraction and analysis of total formaldehyde[4] in consumer products based on EPA Method 8315A. The performance-based modifications to the preparation

[4] Total formaldehyde here is defined as the free formaldehyde available in the product plus the formaldehyde that may be released from any formaldehyde releaser present in the product, during analysis

technique (EPA 8315A-PREP) include a reduction in sample size and extraction fluids, as well as the addition of surrogates to monitor extraction efficiency. Analysis will be performed by gas chromatography-mass spectrometry (GC-MS; EPA 8270E-SIM) as an alternative to high performance liquid chromatography-ultraviolet/visible detection (HPLC-UV/Vis).

The laboratory preparation method for metal digestion, EPA Method 3052, will be modified to omit the use of hydrofluoric acid.

9.4 Laboratories accredited for methods

MEL is accredited by Washington State's Lab Accreditation Unit (WA-LAU) for:

- Metals analysis using EPA 6020B.
- Formaldehyde analysis using EPA 8270E-SIM.

10.0 Quality Control Procedures

10.1 Table of field and laboratory quality control

Lab quality control (QC) tests will consist of the method blanks, lab control samples, lab control sample duplicates, sample duplicates, matrix spikes, and matrix spike duplicates.

Table 12 displays the lab QC samples required for all analysis. The lab QC samples have associated MQOs (Section 6.2) that will be used to evaluate the quality and usability of the sample results.

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

Parameter	Sample Duplicates	LCS/LCSD	Method Blanks	Matrix Spikes/MSD	Surrogates
Metals	1/batch	1/batch	1/batch	1/batch	N/A
Formaldehyde	1/batch	1/batch	1/batch	1/batch	Each sample

LCS = lab control sample
LCSD = lab control sample duplicate
MSD = matrix spike duplicate
Batch = 20 samples or fewer

10.2 Corrective action processes

The project manager will work closely with the labs, appropriate QA representatives, and any internal or third-party reviewers conducting data reviews to examine data that fall outside of QC criteria. Ecology Headquarters staff will also adhere to appropriate SOPs and study-specific processing and preparation protocols. When 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-sampled, re-analyzed, rejected, or used with appropriate qualifications.

11.0 Data Management Procedures

11.1 Data recording and reporting requirements

Documentation of purchase and collection events will be recorded in the Product Documentation Log (Section 8.7). Study data will be recorded in Ecology's Product Testing Database (PTDB). Study data collected and recorded in the PTDB will include purchase receipts, products purchased (in-store and online), product descriptions, product photos, description of product components, methods used to process product component samples, and lab results.

After analysis is completed by the analytical lab, lab data packages in electronic format will be sent to the project manager and MEL's data validation team. This team will conduct data validation on the analysis. After data verification and validation is complete, the project manager will conduct a QA review of the data and assess results for usability (see Sections 13 and 14). The project manager will upload the final validated and approved data to the PTDB.

11.2 Laboratory data package requirements

After completing the lab analysis, the analytical lab (MEL) will deliver a Level 4 data package in an electronic format to the project manager and MEL's data validation team. MEL will submit lab data in a PDF file format with all required specific content, along with data in EDD format (.csv or .xlsx files). The data package must include all raw data and QA/QC documentation that would be needed to perform a review of the results. The documentation will include bench sheets, calibration reports, chromatograms, and spectra for all calibration standards and samples.

MEL's case narratives will be included to discuss any problems encountered with the analyses, corrective action taken, changes to the requested analytical method, and a glossary for data flags and qualifiers. All sample results and QC data will be included in the case narratives.

11.3 Electronic transfer requirements

Lab case narratives and data packages will be in PDF format, and EDDs will be in a spreadsheet format. Both documents must meet Ecology's product testing formatting requirements. The project manager must approve any alternate formats.

11.4 EIM/STORET data upload procedures

Not applicable to this study. Section 11.1 describes where data will be stored.

11.5 Model information management

Not applicable to this study.

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.

Ecology will audit its product testing process conducted at a minimum of one audit a year.

12.2 Responsible personnel

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

12.3 Frequency and distribution of reports

A draft of report sections on study methods, data quality assessment, and results that are to be included in the joint report provided to the Legislature will be submitted to Ecology's Hazardous Waste and Toxics Reduction Program (HWTR). A draft report summarizing the data findings will include, at a minimum:

- An overview of the study methods with general descriptions of products purchased.
- All the raw data, or a summary of the raw data, to be attached or available on request in an Excel format.
- A summary of lab results.
- Discussion of lab results and data quality.

12.4 Responsibility for reports

The project manager will have lead responsibility for drafting content on study methods, data quality assessment, and results to be submitted to HWTR for the final report. HWTR will be responsible for the final legislative report.

13.0 Data Verification and Data Validation

13.1 Field data verification, requirements, and responsibilities

The project manager will conduct a final review of product purchases and collections, product components, component samples shipped to the lab, and additional product data entered into the PTDB.

13.2 Laboratory data verification

Data verification is the process of evaluating the completeness, correctness, and conformance/ compliance of a specific data set against the method, procedural, or contractual requirements (EPA, 2002). A detailed examination of all lab data sets includes a review for errors, omissions, interpretations, calculations, qualifications, and compliance with all appropriate QC acceptance criteria and contract requirements.

Laboratory staff will generate and submit case narratives, along with the lab data, to the project manager. The narratives will discuss if (1) MQOs were met, (2) proper analytical methods and protocols were followed, (3) calibrations and controls were within limits, and (4) data were consistent, correct, and complete, without errors or omissions (Sekerak, 2016).

The project manager, with guidance of a QA representative as necessary, will verify the final acceptance of lab data. Based on the assessments, the data will be accepted with or without qualifications. Time constraints do not allow for reanalyzing samples at this stage.

13.3 Validation requirements, if necessary

MEL's data validation team will conduct a Stage 2B data validation on the entire set of data with a Stage 4 on either 1 laboratory batch, or 10%, whichever is higher for the data. The initial Stage 4 validation for at least 1 laboratory batch, or 10%, will be conducted on each of the analyte classes tested. The client may request a third-party data validation at a later date, if needed. The acceptability of MEL's data validation team to conduct data validation for this study is explained in the letter attached to Appendix B of this QAPP.

13.4 Model quality assessment

NA

14.0 Data Quality (Usability) Assessment

14.1 Process for determining project objectives were met

After MEL's data validation team completes the data validation process, the project manager will determine data usability and accomplishment of the study objectives. The project manager will examine data from all field and lab procedures to ensure that the data (1) were collected using proper procedures, (2) fall into the expected range of results, and (3) meet reporting limits as described in Sections 8 and 9. The project manager will also determine if the data satisfies the MQOs and QC procedures described in Sections 6 and 10.

If all the specifications are met, the data quality is usable to meet study objectives. If the MQOs have not all been met, the project manager will examine the data to determine whether they are still usable and whether the data quantity and quality are sufficient to meet project objectives. The project manager will determine appropriate corrective actions for data that do not meet the criteria; this may include samples re-sampled, re-analyzed, rejected, or used with appropriate qualification. The project manager will analyze the data and determining how the results will be summarized and documented in the final report.

14.2 Treatment of non-detects

Lab data will be reported down to the reporting limit, with an associated "U" (the analyte was not detected at or above the reported concentration) or "UJ" (the analyte was not detected at or above the estimated concentration) flag/qualifier for non-detects.

14.3 Data analysis and presentation methods

A summary of the data will be presented in the final report. Results will be displayed in tables, graphs, and/or charts.

14.4 Sampling design evaluation

The number and type of samples collected and tested should be sufficient to meet the objectives of the specific study. The results of the study may lead to future study events with different analytes, a larger sample size, and/or a wider variety of products. Additional study events will be described in a QAPP addendum.

14.5 Documentation of assessment

Documentation of assessment will be described in the final report.

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16.0 Appendices

Appendix A. Product Selection for Cosmetics Testing Project

This guideline is provided by Ecology's Hazardous Waste and Toxics Reduction Program (HWTR)

Total number of products: 50 products

- 10 products for metals testing (lipstick)
- 30 products for formaldehyde testing (skin lotion, leave-in hair conditioner, 10 hair styling gel/cream)
- 10 products for metals and formaldehyde testing (powder-based foundation)

Product selection criteria

How are the preferred stores and product lines for each category selected?

Ecology chose all the product types from a larger list of product types generated based on responses in published literature that surveyed product use among groups of women who identified as Asian, Black, Latina, Vietnamese, White, or mixed race (Collins et al. 2021, Dodson et al. 2021, Harley et al. 2016, Helm et al. 2018).

Based on the initial list, Ecology selected specific product types based on a combination of research and input from certain communities:

- Lipsticks were chosen because a partner at Mother Africa (a Kent-based group that supports African refugee and immigrant women and their families in the region) had expressed concern about the potential for lead contamination in lipstick.
- Darker tint foundations were selected because they have previously been identified as a potential source of heavy metal contamination (FDA study) and are an emerging market.
- The hair gels/creams, leave-in conditioners, and skin moisturizers were chosen based on inputs from a group of Latino teens and parents in Tacoma during community outreach led by Ecology on June 22, 2022.

Preferred stores were identified during conversations with the principal investigators of other studies (Collins et al. 2021, Dodson et al. 2021) and through the survey in Tacoma. We also heard from those we surveyed that cost is a definite consideration for them when purchasing these products.

Product Sourcing

- Ecology will purchase all products at Walmart, Target, or equivalent stores
  - We define an equivalent store as any large stores that have physical locations and do not specialize in one type of merchandise
  - These stores frequently offer groceries, clothes, and home goods in addition to cosmetics
  - These stores are typically chains
- We do not require items to be bought from specific locations. Prior research indicates that if an individual Walmart or Target store in WA carries a specific product it is likely also available through the online storefront (and vice versa).

- However, since online storefronts may also carry items from third-party sellers, we would suggest that the purchaser confirm they are buying products offered by the store and not a third party.
- For the 30 products that will be tested only for formaldehyde, we will confirm a specific ingredient is on the label before purchasing. While Target, Walmart, and others do provide ingredient lists for most of their products online, it may not be accurate if the product has been reformulated recently.

Heavy metals: 10 products from 2 categories (20 products total)

Research Question: are there heavy metal contaminants in inexpensive cosmetics used by people of color?

- Prior research indicates heavy metals may contaminate raw materials used in cosmetics. The FDA has recommended limits for some of these heavy metals.
- Non-government and community-based organizations have expressed concern about lipsticks and darker-tint foundations.
- Foundations are increasingly marketed to people with darker skin tones.
- Cost is a clear consideration for individuals when purchasing cosmetics.

10 lipstick products

Requirements:

- Prioritize products under $10; if different shades of the same brand differ in price, prioritize a lower-price shade
- Do not purchase liquid lipsticks or tinted lip balms
- Select one shade per product; do not combine different shades into one sample

Additional information:

- No requirements or preferences for a specific color or matching colors
- Preference brands designed for dark skin and black-owned brands within the low-cost range
- Suggested brands (these are typical brands found in drug stores; not all products must come from these brands):
  - Wet n wild
  - Cover Girl
  - L'Oréal
  - Maybelline
  - Revlon
  - NARS
  - Black Radiance (designed for darker skin tone)
  - Juvia's place (black-owned)

Examples (price info collected on June 28, 2022):

- Black Radiance Perfect Tone Lip Color, 0.13 oz, $1.69
- Wet n wild Silk Finish Lipstick, Will You Be With Me?, $0.80
- Revlon Super Lustrous Lipstick with Vitamin E and Avocado Oil, $1.35
- Maybelline Color Sensational The Creams, Cream Finish Lipstick Makeup, Blissful Berry, 0.15 oz., $2.74
- L'Oréal Paris Color Riche Collection Exclusive Lipstick, 0.13 oz., $6.80

10 powder based foundations

Will be used for both metals and formaldehyde testing. May need to buy larger amounts

Requirements:

- Prioritize products under $20
- Prioritize products with darker shades
- Prioritize darkest shade available for purchase
- Prioritize products that contain talc as an ingredient
- Select one shade per product; do not combine shades into one sample for individual test.
- Purchase only powder foundations; do not purchase liquid foundation or sticks.

Additional information:

- Suggested brands:
  - Black Opal (black-owned)
  - Black Radiance (designed for darker skin tone)
  - Maybelline
  - L'Oréal
  - Cover Girl
  - Milani

Examples (price info collected on June 28, 2022)

- Maybelline Fit Me Matte + Poreless Pressed Face Powder Makeup, Nutmeg, 0.29 oz. $3.25
- L'Oréal Paris True Match Super-Blendable Powder, C9 Deep Cool $8
- L'Oréal Paris Age Perfect Creamy Powder Foundation, 365 Chestnut
- L'Oréal Paris Infallible 24H Fresh Wear Foundation in a Powder $10
- Black Opal Ultra Matte Foundation Powder, 8 Deep, $10
- Black Radiance Pressed Powder, Café, Deep, $4
- COVERGIRL Outlast Extreme Wear Pressed Powder, 880 Cappuccino $8
- COVERGIRL Simply Ageless Wrinkle Defying Pressed Powder, $10
- COVERGIRL Clean Pressed Powder $6.38
- Milani Conceal + Perfect Cream To Powder Smooth Finish, Caramel Brown $11

Formaldehyde: 10 products each from 4 categories (40 total)

Research Question: Are there unlabeled/incidental formaldehyde in cosmetics marketed to/used by people of color?

- Formaldehyde exposure is associated with increase cancer risk at higher concentrations and an allergic response at lower concentrations.
- Foundations can be worn for many hours at a time, which increases the exposure risk. Powder-based foundations are more likely to be inhaled than liquid foundations.
- Foundations are increasingly marketed to people with darker skin tones

10 powder based foundations

- Use same products purchased for heavy metal testing. If needed, it's acceptable to purchase two pieces from the product with one for metals testing and one for formaldehyde testing.

Research Question: For products that contain formaldehyde-releasing chemicals as preservatives, how much formaldehyde is available in the product?

- Formaldehyde-releasers are typically used in water-based cosmetics to preserve products by emitting formaldehyde.
- The amount of formaldehyde-releaser used (and subsequently the free formaldehyde available) in cosmetic products sold in the US is not well known.
- Allergic reactions to formaldehyde have been reported at concentrations as low as 130 – 200 ppm. Additionally, there are higher rates of contact sensitization to formaldehyde in the USA than in Europe.
- We propose evaluating products that all list the same common formaldehyde-releaser, and that are applied to the skin/scalp for extended periods.
- We identified specific products and brands that are either inexpensive or marketed to people of color.

10 skin lotions

- To the extent possible, store these products in the same environment.

Requirements:

- Purchase products that list DMDM Hydantoin as an ingredient
- Prioritize products with lower prices

Additional information:

- Suggested brands
  - Suave
  - Jergens
  - Gold Bond
  - Goicoechea
  - Lubriderm
  - Equate
  - Keri
  - Palmer's (including stretch mark lotion)
  - Avena (and Avena Instituto Espanol)
  - Luster's
  - Dial
  - Vaseline
  - Pond's
  - OGX

Examples identified (be sure to confirm the actual products contain DMDM Hydantoin before purchasing):

- Suave Skin Solutions Body Lotion Advanced Therapy 32 oz.
- Suave Skin Solutions Body Lotion Cocoa Butter and Shea 32 oz.
- Suave Skin Solutions Body Lotion Revitalizing with Vitamin E, 32 oz.
- Lubriderm Daily Moisture Body Lotion for Dry Sensitive Skin, 16 fl oz.
- Keri Daily Dry Skin Therapy Moisture Original Body Lotion, 20 oz.
- Keri Nourishing Shea Butter & Vitamin E Whole Body Therapy Lotion
- Vaseline Intensive Care hand and body lotion Cocoa Radiant 20.3 oz.

- Up & Up Extra Radiance Cocoa Butter Body Lotion
- Up & Up Extra Healing Ultra Dry Skin Moisturizer
- OGX Extra Hydrating Radiant Glow + Argan Oil of Morocco Lotion
- Urban Hydration Rosehip Body Lotion
- Neutrogena Norwegian Formula Moisture Wrap Daily Repair Body Lotion, 15.2 oz.
- 123 SESAME STREET baby lotion (Walmart)
- Pond's Dry Skin Cream Facial Moisturizer - 6.5 oz.
- Olay Regenerist Night Recovery Cream Face Moisturizer, 1.7 oz.
- Teatrical Facial Cream Stem Cells Moisturizer, 8 oz.

10 conditioners (leave-in)

- To the extent possible, store these products in the same environment.

Requirements:

- Purchase products that are leave-in conditioners. These are products marketed to moisturize or strengthen hair, protect hair from damage, and/or help with tangling or frizz. They are also intended to be left on the hair instead of being washed out after a few minutes.
- Purchase products that list DMDM Hydantoin as an ingredient

Additional information:

- Brands that have at least one product that lists DMDM Hydantoin as an ingredient:
  - Aussie
  - Suave
  - TRESemmé
- Brands that market products to people of color (and have at least one relevant product):
  - Africa’s Best
  - Cantu
  - Luster’s
  - Miracle 9
  - ORS
  - Sedal
  - TGIN
  - Urban Hydration

Examples identified (confirm the actual products contain DMDM Hydantoin before purchasing):

- Africa's Best Organics Moisturizing nourishing Mayonnaise Hair Treatment
- Sedal Co-Creations Ceramidas Leave in Styling Conditioner
- Luster's S-Curl Activator Moisturizer
- ORS Oil Moisturizing Hair Lotion
- TGIN Butter Cream Daily Moisturizer with Shea Butter + Vitamin E
- Cantu Daily Oil Moisturizer
- Aussie Miracle Curls Leave-In Cream Pudding
- Tresemme Smooth and Silky Conditioner
- Suave Kids Purely Fun Detangler Spray
- Urban Hydration Aloe Vera & Cucumber Leave-in Spray Conditioner
- Miracle 9 Moisture Therapy Leave-In-Conditioner

10 hair styling gels and creams

- To the extent possible, store these products in the same environment.

Requirements:

- Purchase hair styling products. These include hair gels, hair mousse, edge control creams and other products that are used to style hair. These products typically hold hair strands in place or are used to control frizz. These products can be applied to the hair by hand (as opposed to spray).
- Purchase products that list DMDM Hydantoin as an ingredient

Additional information:

- Brands that have at least one product that lists DMDM Hydantoin as an ingredient:
  - Ampro
  - Aussie
  - Axe
  - Cremo
  - Got 2b
  - Herbal Essences
  - Pantene
  - TRESemmé
- Brands that market products to people of color (and have at least one relevant product):
  - Let's Jam! (Softsheen Carson)
  - Luster's
  - ORS
  - TGIN

Examples identified (confirm the actual products contain DMDM Hydantoin before purchasing):

- Luster's Pink Shea Butter Coconut Oil Smooth & Hold Edge Gel
- Let's Jam! Shining and Conditioning Extra Hold Jar Hair Styling Gel
- ORS Olive Oil Edge Control Nourishing Jar Hair Styling Gel
- TGIN Rose Water Curl Defining Mousse
- Herbal Essences Curl-Scrunching Gel, Totally Twisted
- Aussie Headstrong Volume Gel, Volumizing Hair Gel
- Pantene Flexible Wave Gel for Curly Hair, Non-Sticky Formula
- Got2b Glued Styling Spiking Hair Gel
- Ampro Pro Styl Regular Hold Protein Styling Gel
- TRESemme Frizz Control Hair Gel, Mega Control with Lasting Shine Alcohol-Free for All Hair Types
- AXE Styling Pomade, Clean Cut Look Medium Hold High Shine for Short to Mid-Length Hair

Other information

DMDM hydantoin is the most common name used on personal care labels.
Other synonyms for DMDM hydantoin:

Dantoin DMDMH
DMDMH

Dimethylol dimethyl hydantoin
1,3-bis(hydroxymethyl)-5, 5-dimethyl- 2,4-imidazolidinedione
1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2, 4-dione
1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione(+)
1,3-dihydroxymethyl-5, 5 dimethylhydantoin
1,3-dimethylol-5,5-dimethyl hydantoin
2,4-imidazolidinedione
1,3-bis(hydroxymethyl)-5,5-dimethyl-, 2,4imidazolidinedione
1,3-bis(hydroxymethyl)5,5dimethyl hydantoin

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Appendix B. MEL Independent Validation Letter

STATE OF WASHINGTON
DEPARTMENT OF ECOLOGY
MANCHESTER ENVIRONMENTAL LABORATORY
7411 Beach Drive East • Port Orchard, Washington 98366-8204 • (360) 871-8800 • FAX (360) 871-8850

July 12, 2022

Arati Kaza
Quality Assurance Officer
Department of Ecology

Dr. Kaza,

For the Toxic Chemicals in Cosmetics project, John Weakland and Christina Frans are independent Data Validators for analysis done by Manchester Environmental Lab (MEL), which is consistent with Ecology's internal guidance document on Data verification and validation.

Although both John and Christina are part of the MEL staff reporting to the Lab Director, neither person is involved in the daily production of data. John Weakland serves as the Data Validation Chemist and is not associated with the analysis of samples or the production of data reports for the lab. His responsibilities are limited to performing validation of final data reports and contracting laboratory serves for analyses not performed at MEL.

While Christina serves as the Quality Assurance Coordinator for the laboratory, she is also not involved in the direct analysis of samples or the production of final data reports for MEL. She has an overarching quality assurance role that provides for separation from direct data production.

Thank you
Alan Rue
Lab Director
Manchester Environmental Lab
Washington State Department of Ecology
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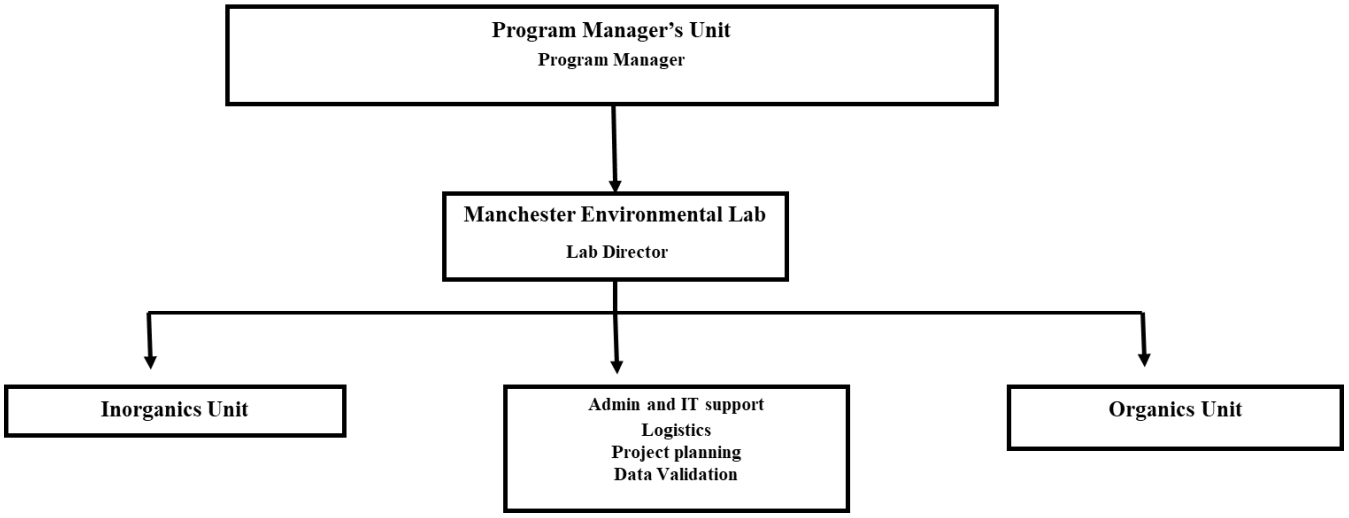
Organizational Chart

Environmental Assessment Program



Appendix C. Acronyms, Abbreviations, and Quality Assurance Glossary

Acronyms and Abbreviations

CAS	Chemical Abstracts Service
CPSC	U.S. Consumer Product Safety Commission
CPSIA	U.S. Consumer Product Safety Improvement Act
CSC	Campaign for Safe Cosmetics
CSPA	Washington State Children's Safe Products Act
DOH	Washington State Department of Health
EAP	Ecology's Environmental Assessment Program
e.g.	For example
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
et al.	And others
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HWTR	Hazardous Waste and Toxics Reduction Program
i.e.	In other words
MEL	Manchester Environmental Laboratory
MQO	Measurement quality objective
PPE	Personal Protective Equipment
ppm	parts per million
PTDB	Ecology's Product Testing Database
QA	Quality assurance
QAPP	Quality assurance project plan
QC	Quality Control
RCW	Revised Code of Washington
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
SDS	Safety Data Sheet
SOP	Standard Operating Procedures
WAC	Washington Administrative Code

Units of Measurement

mm	millimeter
mg/kg	milligrams per kilogram (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, October 26, 1984).

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).

References for QA Glossary

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