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ECOLOGY
State of Washington

Quality Assurance Project Plan

Parabens and Metals in Children's Cosmetic and Personal Care Products

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Publication Information

It is Washington State Department of Ecology policy to have an approved Quality Assurance Project Plan for all Agency-sponsored sampling events. The plan describes the objectives of the study and the procedures to be followed to achieve those objectives. After completing the study, Ecology will post a report of the study to the Internet.

The plan for this study is available on the Department of Ecology's website at www.ecy.wa.gov/biblio/1207021.html.

Author and Contact Information

Alex Stone
P.O. Box 47600
Hazardous Waste and Toxics Reduction Program
Washington State Department of Ecology
Olympia, WA 98504-7600

For more information contact: Communications Consultant, phone 360-407-6834.

Washington State Department of Ecology - www.ecy.wa.gov/

- Headquarters, Olympia 360-407-6000
- Northwest Regional Office, Bellevue 425-649-7000
- Southwest Regional Office, Olympia 360-407-6300
- Central Regional Office, Yakima 509-575-2490
- Eastern Regional Office, Spokane 509-329-3400

Quality Assurance Project Plan

Parabens and Metals in Children's Cosmetic Products

February 2012

Approved by:

Signature: _____ Date: _____
Joshua Grice, Client, W2R Program

Signature: _____ Date: _____
John Williams, Client, W2R Program

Signature: _____ Date: _____
Alex Stone, Author / Project Manager, HWTR-HQ

Signature: _____ Date: _____
Ken Zarker, Author's Section Supervisor, HWTR-HQ

Signature: _____ Date: _____
Samuel Iwenofu, HWTR Quality Assurance Officer

Signature: _____ Date: _____
Carol Kraege, Client, W2R Program

Signatures are not available on the Internet version.
W2R: Waste 2 Resources Program
HWTR-HQ: Hazardous Waste and Toxics Reduction Program

Table of Contents

List of Figures and Tables

Page

Figures

Tables

Abstract

The Washington State Department of Ecology's Waste 2 Resources (W2R) and Hazardous Waste and Toxics Reduction (HWTR) Programs are conducting a study to evaluate presence of four parabens used as preservatives and nine potentially hazardous metals in children's cosmetics and personal care products. The study is being conducted in response to the upcoming reporting rule for the Children's Safe Product Act (CSPA) and is being supported with funding from the Washington State Attorney General's Office.

Children's products will be tested for four parabens and nine toxic metals. The phthalate esters include:

- Methyl paraben (CAS 99-76-3).
- Ethyl paraben (120-47-8).
- *n*-Propyl paraben (CAS 94-13-3).
- Butyl paraben (two isomers):
  - *n*-Butyl paraben (CAS 94-26-8).
  - *iso*-Butyl paraben (CAS 4247-02-3).

The nine metals include:

- Antimony
- Arsenic
- Chromium
- Cobalt
- Copper
- Lead
- Mercury
- Molybdenum
- Zinc

It is Washington State Department of Ecology (Ecology) policy to have an approved Quality Assurance Project Plan (QAPP) for all sampling events. The plan describes the objectives of the study and the procedures to be followed to achieve those objectives. After completion of the study, a report describing the study results will be posted to the Internet.

Background

Parabens are a class of chemicals added to consumer products primarily as a preservative. Parabens are the most widely used preservatives in cosmetics. Traditionally, more than one paraben is used in each product and parabens are often used in combination with other preservatives (USFDA, 2012). Cosmetics that may contain parabens include makeup, moisturizers, hair care products, and shaving products, among others. Most major brands of deodorants and antiperspirants do not currently contain parabens. (USFDA, 2012)

All parabens are esters of para-hydroxybenzoic acid (CAS 99-96-7). The four major esters used in cosmetics and personal care products are:

- Methyl paraben (CAS 99-76-3).
- Ethyl paraben (CAS 120-47-8).
- *n*-Propyl paraben (CAS 94-13-3).
- Butyl paraben (two isomers):
    - *n*-Butyl paraben (CAS 94-26-8).
    - *iso*-Butyl paraben (CAS 4247-02-3).

These chemicals are widely used as preservatives in cosmetics and in such personal care products as shampoos, hair and shaving products, facial and skin cleansers, and lotions. (CDC, 2012)

Numerous studies have indicated humans are exposed to large amounts of parabens. Ye et al. (2006) using data from a small sample of U.S. adults, reported methyl and *n*-propyl paraben were detected in 99% and 96% of urine specimens, respectively. Paraben values ranged from 43.9 µg/L for the methyl ester to 0.5 µg/L for butyl paraben at the low end. Calafat et al. (2010) reported similar values using NHANES 2005-2006 sample data. They also reported that females had three times higher levels of methyl paraben and seven times higher levels of *n*-propyl paraben than males. Similar results have been reported in the European Union. Frederiksen et al. (2011) reported that the main four groups of parabens were detected in 80% or more of the urine specimens from a small sample of Danish males.

Concerns have been raised concerning potential estrogenic effects of parabens. Although parabens have been shown to be weak estrogenic compounds compared with other synthetic estrogens, the high levels of parabens to which humans are exposed may compensate for their weak estrogenic activity (DOH, 2012). In addition, parabens have demonstrated adverse effects on sperm production and testosterone levels following oral exposure (DOH, 2012). The European Union identified four of the parabens on Washington's Chemicals of High Concern to Children (CHCC) list as Category 1 potential endocrine disruptors, i.e. chemicals that have shown 'Evidence of endocrine disruption activity' (Stone and Delistraty, 2010). The EU determination was prior to the implementation of the REACH (Registration, Evaluation, Authorisation of Chemicals) regulations and is currently being re-evaluated. As reviews of each chemical are completed, any found to be of sufficient concern will be added to the substances of very high concern (SVHC) list. Recent evidence, however, is suggesting a link between

parabens and breast cancer. (Barr, 2012) The EU information and an extensive review of the literature were sufficient to place parabens on Washington's CHCC list.

The use of toxic metals in cosmetic applications has not been extensively researched although some concern has been raised by environmental groups concerning the presence of low levels of toxic metals in some cosmetic applications (Campaign for Safe Cosmetics, 2012). In a limited study, the environmental group, Environmental Defense (2011), found arsenic, cadmium and lead in 20%, 51% and 96% of cosmetics tested above reportable limits, respectively.

There is little information in the U.S. scientific literature on metals in cosmetics. Nnorom et al. (2005) reported that chromium and, at a lower level, cadmium and lead were found in facial makeup sold in Nigeria. In a report to the European Commission, Piccinini et al. (2011) found lead above 1 mg/kg in 37% of lipsticks tested. Heavy metal impurities in cosmetics have been an on-going issue and Health Canada has published draft guidance on resolving heavy metal contamination issues in cosmetics (Health Canada, 2012). As products become more widely distributed in the international marketplace, similar metals may be found in U. S. cosmetics.

The Children's Safe Product Act (CSPA), passed by the Washington State legislature in 2008, (Children's Safe Product Act, 70.240 RCW) requires manufacturers to report the presence of six toxic metals in all components of children's products. For cosmetics, this includes not only the cosmetic product itself, but also the container holding the cosmetics. Ecology will analyze cosmetics and personal care product components, both contents and containers, for the six heavy metals on Ecology's CHCC list and lead. Lead is included as it is part of the original CSPA and now being regulated by the Consumer Product Safety Commission.

The CSPA Reporting Rule was finalized in June of 2011 and implements the reporting requirements under the CSPA. Under the rule, companies making children's products must report beginning August 2012 on 66 specific or classes of chemicals if found in children's products (Appendix A). The list includes chemicals that have primarily either been found in children's products or have been documented to be present in human tissues. Four parabens, their parent compound p-hydroxybenzoic acid and six metals are included in this list. Certain children's products containing these compounds will have to be reported to Ecology. Reporting requirements will begin with the largest manufacturers who make products intended for mouth or skin contact or any product that is mouthable for children 3 and under. Other manufacturers will report using a phased-in schedule included in the rule.

Two additional metals (copper and zinc) are also being analyzed in children's products. Copper and zinc have been identified as potentially having a major impact upon the Puget Sound (Ecology, 2011). Concerns have been raised about the use of these metals in products as a potential source to the Puget Sound.

Copper and zinc are toxic to aquatic species and particularly the development of fish. As indicated in a report from the US Fish and Wildlife Services:

> *Mixtures of zinc and copper are generally acknowledged to be more-than-additive in toxicity to a wide variety of aquatic organisms*…'

The aquatic organisms impacted by zinc and copper include oysters and both marine and freshwater fish among others. (Eisler, 1993)

Prior to the submission of the first phase of manufacturer reporting, Ecology's HWTR and W2R Programs will begin analyzing children's cosmetic and personal care products for the 4 parabens and 9 metals. The 9 metals consist of the 6 potentially toxic metals in the CSPA (antimony, arsenic, cadmium, cobalt, molybdenum, and mercury) and copper, zinc and lead.

Project Description

Ecology's W2R and HWTR Programs will measure the concentration of parabens (identified in Table 2) and metals (Table 1) in children's cosmetic and personal care products. The objective of the study will be 1) to assess the levels of parabens and the metals of interest that are required to be reported under the CSPA and 2) to evaluate methods for paraben analysis in these product matrices. This information may be used to verify compliance with the rule.

Children's cosmetic and personal care products will be purchased in two samping events. The first will be the spring of 2012 and the second after August1st of 2012. Samples suspected to contain parabens will be sent to a contract laboratory for analysis. Components will also be screened with an XRF analyzer for metals of interest and those samples containing sufficient metals of interest will be sent to Manchester Environmental Laboratory for analysis.

Sampling Process Design (Experimental Design)

Approximately 200 children's cosmetic and personal care products over the two sampling events will be purchased from local stores and internet retailers for testing. Special emphasis will be placed on products designed to be applied to the skin or ingested. The products will be separated into three components; packaging, containers and product. For example, a container of children's lip gloss will be separated into packaging, product (lip gloss itself) and container (the device used to store and apply the product). Depending upon its construction, the container could be separated into different components as identified in the CSPA rule. Sometimes the container is part of the product and each product will be evaluated on a case-by-case basis. Packaging is not covered under the CSPA but will be retained for potential analysis under a separate QAPP as four toxic metals are restricted by Washington's toxic in packaging legislation.

Individual components of the container, if appropriate, and the product itself will be screened with an XRF for the metals of concern to determine if laboratory analysis is warranted. It is anticipated that approximately 50 container or product samples will be forwarded to the laboratory for metals analysis and approximately 100 samples will be sent for paraben analysis, budget allowing. Since an XRF cannot detect parabens, other information will be used to determine whether a product is likely to contain parabens. Potential sources include product labels, product databases from government and non-governmental organizations (NGO) sources, internet searches, etc.

Items will be sent to the laboratory if they violate screening criteria (outlined below) during the XRF analysis or are selected for low-level analysis. Laboratory analyses will be completed by

inductively coupled plasma mass spectroscopy (ICP-MS) (metals), cold vapor atomic absorption (CVAA) (mercury), and high performance liquid chromatography-mass spectroscopy (HPLC/MS) (parabens).

Product Selection

Products selected for analysis will be 1) Tier 1 products as outlined by the CSPA Reporting Rule or 2) products containing parabens using product label information or information on the historical presence of parabens in specific types of cosmetic or personal care products.

Under the CSPA Reporting Rule tiered approach, Tier 1 products are those intended to be put into a child's mouth, applied to their skin, or for a child less than 3 any mouthable product. Tier 1 products must be reported first. Tiers 2 – 4 include products intended for prolonged direct skin contact, short-duration direct skin contact, and no intended skin contact, respectively. Product analysis will be restricted to Tier 1 products unless sufficient samples cannot be obtained. Products in other Tiers will then be considered for analysis. For example, lip gloss and other cosmetic and personal care products that, when applied, are likely to be applied to the skin, ingested or mouthed by children under 3 will be a higher priority than other children's cosmetic and personal care products.

Product Screening

Products will be screened using a portable XRF gun following the XRF manufacturer's recommendations and adaptations of ASTM method F 2617-08 *Standard Test Method for Identification and Quantification of Chromium, Bromine, Cadmium, Mercury, and Lead in Polymeric Material Using Energy Dispersive X-ray Spectrometry* (ASTM, 2008) or US EPA SW-846 Method 6200 *Field Portable X-Ray Fluorescence Spectrometry for the Determination of Elemental Concentrations in Soil and Sediment* (US EPA, 2012), as appropriate.

While ASTM method F 2617-08 is not intended for samples with surface coatings or non-polymeric materials, all samples will be screened following adaptations of the method for qualitative information. In addition, although EPA SW-846 Method 6200 was not intended for the analysis of cosmetics or personal care products, similar procedures can be used to evaluate bulk products.

Target Chemicals

Target metals proposed for testing along with state and federal criteria are shown in Table 1 and paraben esters are listed in Table 2.

Table 1. Washington State and Federal Criteria for Analytes of Interest.

Analytes	**Action levels (ppm)**	
	State[=]	**Federal**
Phthalates	5.0	6,000[a]
Antimony	1.0	60[^]

Arsenic	1.0	25^
Cadmium	1.0	75^
Cobalt	1.0	-
Copper	-	
Lead	-	90+
Mercury	0.5	60^
Molybdenum	1.0	-
Zinc	-	

= State Limit: Draft practical quantitation limits as defined in the CSPA Rule Reporting Guidance, available at: http://www.ecy.wa.gov/programs/swfa/cspa/pdf/cspaguide_pql.pdf, accessed 1/3/2012.
^ Federal Limit: Consumer Product Safety Commission (CPSC) ASTM F963-11, Standard Consumer Safety Specification for Toy Safety
+ Federal Limit: CPSC 16 C. F. R. 1303 restrictions in surface coatings of consumer goods and children's products. Non-soluble portions are limited to 100 ppm in August 2011.

While lead is not required for reporting under the CSPA, it is included in this study because its content in certain products falls under Federal regulation (16 C.F.R. § 1303). Copper and zinc are included because of concerns that these metals in products are impacting the Puget Sound.

Table 2. Specific Paraben Esters Included in the Study.

Phthalate	**CAS Number**
Methyl paraben	99-76-3
Ethyl paraben	120-47-8
n-Propyl paraben	94-13-3
Butyl paraben (two isomers):	
n-Butyl paraben	94-26-8
iso-Butyl paraben	4247-02-3

For screening purposes, products containing half or more of the state action levels in Table 1 will be forwarded to the laboratory for validation (within the limits of the laboratory budget). It should be noted, criteria falling under ASTM F963-11 Standard Consumer Safety Specification for Toy Safety and 16 C.F.R. § 1303 are designed for soluble portions of surface coatings. XRF screening, however, is for total metals. In the instance of more products with detectable levels of metal than the budget will allow, those products with the highest XRF screening concentrations will be sent to the laboratory for additional analysis.

All 9 metals will be analyzed in each sample forwarded to the laboratory if screening levels for a single metal are violated. In addition to products violating the screening standards, multiple samples containing low levels will be forwarded to the laboratory for analysis.

As with metals, samples containing the highest levels of parabens determined from available information such as labels, product databases and other readily-available information will be sent to the laboratory for analysis. The exact number of samples will depend upon the availability of applicable products and budgetary constraints. It is expected, however, that approximately 100 samples will be sent for paraben analysis over the two sampling events.

Organization and Schedule

Table 3 lists the individuals involved in the project and Table 4 contains a schedule.

Table 3. Organization of Project Staff and Responsibilities.

Staff	Title	Responsibilities
Joshua Grice, W2R (360) 407-6786	Client	Clarifies scopes of the project. Provides internal review of the QAPP and approves the final QAPP.
John Williams, W2R (360) 407-6940	Client	Clarifies scopes of the project. Provides internal review of the QAPP and approves the final QAPP.
Alex Stone Senior Chemist HWTR-HQ Program (360) 407-6758	Project Manager	Writes the QAPP. Oversees field sampling and transportation of samples to the laboratory. Conducts QA review of data, analyzes and interprets data. Writes the draft report and final report.
Ken Zarker HWTR-HQ (360) 407-6698	Section Mgr for Project Manager	Reviews the project scope and budget, tracks progress, reviews the draft QAPP, and approves the final QAPP.
Carol Kraege, W2R (360) 407-6906	Section Mgr for the Clients	Reviews the project scope and budget, tracks progress, reviews the draft QAPP, and approves the final QAPP.
Samuel Iwenofu HWTR-SWRO (360) 407-6964	HWTR QA Officer	Reviews the draft QAPP and approves the final QAPP.

HWTR-HQ: Hazardous Waste and Toxics Reduction Program-Headquarters.
HWTR-SWRO: Hazardous Waste and Toxics Reduction Program-Southwest Regional Office
QAPP: Quality Assurance Project Plan.
W2R: Waste 2 Resources.

Table 4. Proposed Schedule for Completing Field and Laboratory Work and Reports.

Field and laboratory work	Due date	Lead staff
Field work completed	March 2012	Alex Stone
Laboratory analyses completed	June 2012	
Final report		
Author lead / Support staff	Alex Stone	
Schedule		
Draft due to supervisor	September 2012	
Draft due to client/peer reviewer	October 2012	
Final (all reviews done)	November 2012	
Final report due on web	January 2013	

Sample Collection and Preparation

Items will be obtained in person or through internet retailers by HWTR or W2R staff. Upon collection, photos and descriptive notes on each product will be taken to document the presentation of the product and to assist in determining the age group for whom it is intended. Products will be removed from their original packaging using pre-cleaned stainless steel implements. Photos and descriptive notes on each product screened such as approximate thickness, surface roughness, material makeup, etc. will be recorded. Other information such as the type of advertisement used to sell the product, where in the store the product was located, etc. may be necessary to prove the product was intended for children

All field and laboratory staff handling the products will wear powder free nitrile gloves. Stainless steel tools will be used to deconstruct the product or remove it from its packaging along. All tools used will be cleaned by the following sequence: hot water scrub with liquinox soap, 10% nitric acid rinse, and deionized water rinse.

Products will be separated into to three fractions. Fraction 1 will consist of the product packaging that will be retained for possible analysis under a separate QAPP. Fraction 2 will comprise the cosmetic or personal care product contents. Fraction 3 will consist of the container used to hold the cosmetic or personal care product ingredients. If necessary, Fraction 3 may be further broken down into individual components. Individual components of the product will be screened separately. Items with different colors or base materials will be treated as components. Additionally, individual pieces of products intended to be disassembled will be treated as components. Components targeted for testing will be removed with stainless steel tools (scissors, pliers, saws, etc.) for further testing. All tools will be cleaned using the sequence identified above.

Fractions 2 and 3 will be screened for metals using an XRF. Those components that contain appreciable levels of metals will be sent to Manchester laboratory for analysis, where possible. If Manchester is unable to meet the QAPP requirements, the same procedure described below for paraben analysis will be used to obtain a contract laboratory to provide analysis.

Samples of Fraction 2 will be sent to a contract laboratory for paraben analysis. First choice will be a laboratory under contract to the state to provide analytical data (State Contract 1807). If no laboratory under the state contract is willing to conduct the analyses, the Project Manager will solicit other qualified laboratories to provide analytical services. The Project Manager will be responsible for all laboratory analysis review and evaluation.

Analytical Procedures

XRF Analysis

Individual product components will be screened using a Niton XL3t portable XRF gun (Figure 1) or equivalent following the manufacturers recommendations and adaptations of ASTM method F 2617-08 *Standard Test Method for Identification and Quantification of Chromium, Bromine, Cadmium, Mercury, and Lead in Polymeric Material Using Energy Dispersive X-ray Spectrometry* or EPA SW-846 Method 6200 *Field Portable X-Ray Fluorescence Spectrometry for the Determination of Elemental Concentrations in Soil and Sediment*, as appropriate. The W2R program is currently in the process of purchasing an XRF instrument. Actual instrument details may vary depending upon the Model and Company selected from the bidding process.

Figure 1. Niton Portable XRF

For the initial screening, a reading will be taken for at least 30 seconds on a smooth (or near smooth) area of the product large enough to cover the spectrometer's window and at least 2 mm thick. If the item is less than 2 mm thick it may be folded on to itself until 2 mm depth has been reached (care will be taken to trap minimal air in between folds). For samples of the actual cosmetic material, a portion of the sample will be placed into a new, clean plastic bag and sampled using the EPA methodology for soil or sediment. The sample will meet the same 2 mm depth requirements as for the container components.

If the screening measurement violates criteria, a second longer measurement will be taken (up to 180 seconds). Both measurements will be taken using the appropriate XRF software package (based on sample material). Detection limits are shown in Table 5. After XRF analyses are completed, components will be placed in pre-cleaned I-Chem jars and forwarded to the appropriate laboratory for testing.

Table 5. Niton Portable XRF LOQs and Expected Range of Results.

Element	Expected Range of Results (ppm)	LOQ (ppm)[+]
Antimony	<LOQ - 300	25
Arsenic	<LOQ - 300	3
Cadmium	<LOQ - 300	15
Chromium	<LOQ - 300	*
Cobalt	<LOQ - 300	15
Copper	<LOQ - 300	15
Lead	<LOQ - 300	4

Mercury	<LOQ - 10	6
Molybdenum	<LOQ - 300	*
Zinc	<LOQ - 300	15

ppm = parts per million
LOQ = Limit of Quantitation
[+] Polyethylene blank, 8 mm aperture, 180 second total analysis time
[*] Detection limits are not specified by the manufacturer for these elements

All samples screened will be assigned a unique identifier and results from the XRF will be transferred to Microsoft Excel spreadsheets.

Laboratory

Table 6 describes digestion and analysis methods along with estimated LOQ's. Metals samples will be prepared following EPA 3052[1] (microwave complete digestion) and measured using ICP-MS or CVAA (mercury).

Paraben samples will be analyzed by a contract laboratory chosen by the Project Manager. Sample extraction and analysis methods used by the contract laboratory will be approved by the Project Manager.

Table 6. Laboratory Methods and Reporting Limits

Analyte	Digestion Method	Instrumentation	Method	RL (ppm)
Antimony	EPA 3052	ICP-MS	EPA 6020	1.0
Arsenic	EPA 3052	ICP-MS	EPA 6020	1.0
Cadmium	EPA 3052	ICP-MS	EPA 6020	1.0
Cobalt	EPA 3052	ICP-MS	EPA 6020	1.0
Copper	EPA 3052	ICP-MS	EPA 6020	1.0
Lead	EPA 3052	ICP-MS	EPA 6020	1.0
Molybdenum	EPA 3052	ICP-MS	EPA 6020	1.0
Mercury	EPA 3052	ICP-MS	EPA 6020	0.1
Zinc	EPA 3052	ICP-MS	EPA 6020	1.0
Parabens	*	HPLC-MS	*	30.0

ICP-MS = Inductively-coupled plasma/mass spectrometry
CV AA = Cold vapor atomic absorption
HPLC-MS = High Performance Liquid Chromatography/mass spectroscopy
* Method will be approved by Project Manager

Budget

The project budget is included in Table 7.

Table 7. Project Budget

[1] Method 3025 provides complete digestion of the plastic matrix that allows the most representative numbers for total metals. Use of hydrofluoric acid (HF) is not necessary for most plastic matrices and is not recommended. Nitric and/or hydrochloric acids as identified in the method are adequate to effect complete dissolution of most plastic matrices.

	# of Samples	Cost per sample	Total
Sample collection	100	$5.00	$500.00
Metals	50	$200.00	$10,000.00
Parabens	100	$350.00	$35,000.00
Total			**$45,500.00**

Quality Objectives

Quality objectives for this project are to obtain data of sufficient quality so that the amount of metals and parabens in children's cosmetic and personal care products can be determined. These objectives will be achieved through careful attention to the sampling, sample processing, measurement, and quality control (QC) procedures described in this plan.

Measurement Quality Objectives

An XRF reading will be taken every 25 samples on standards provided by the manufacturer. Since the XRF analysis is being used as a screening tool only, no measurement quality objectives (MQOs) are outlined. Performance of the portable XRF has been determined in a previous Ecology report (Publication No. 12-03-009) which proves the efficacy of using XRF as a screening tool, particularly for metals. The conclusions from the report will be implemented in this work and all screening will be done using a stand to minimize error.

MQOs for laboratory analysis of metals and parabens are shown in Table 8. It is expected that MEL and contract laboratories will meet these criteria. MQOs falling outside of the acceptance limits will be reviewed by the Project Manager for their usability.

Table 8. MQOs for Laboratory Analyses.

	Laboratory Control Samples	Matrix Spikes	Duplicates[+]	Method Blanks*
	(recovery)	(recovery)	(RPD)	(ppm)
Antimony	85- 115%	75-125%	±20%	1.0
Arsenic	85- 115%	75-125%	±20%	1.0
Cadmium	85- 115%	75-125%	±20%	1.0
Cobalt	85- 115%	75-125%	±20%	1.0
Copper	85- 115%	75-125%	±20%	1.0
Lead	85- 115%	75-125%	±20%	1.0
Mercury	85- 115%	75-125%	±20%	0.1
Molybdenum	85- 115%	75-125%	±20%	1.0
Zinc	85- 115%	75-125%	±20%	1.0
Parabens	70- 130%	75-125%	±20%	30.0

[*] Metals reporting limits were established by raising soil limits by a factor of 10
[+] Matrix spike duplicates and split duplicates
RPD – Relative Percent Difference
ppm = parts per million

Quality Control Procedures

Field

No field quality control procedures are anticipated for this project.

Laboratory

Table 9 shows laboratory QC samples planned for the project. Split duplicate samples will be used to assess variability in the data due to sample preparation and laboratory procedures.

Table 9. Quality Control Tests.

	Laboratory Control Samples	Matrix Spikes	Matrix Spike Duplicates	Laboratory Duplicates	Split Duplicates†	Method Blanks	Surrogate Recovery*
Elements	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample

† Dependent on amount of sample available

* PBDEs only

Data Management Procedures

XRF data from the screening portion of the project will be transferred to Microsoft Excel spreadsheets and stored with the Project Manager.

Data packages from MEL and any contract laboratory will include case narratives discussing any problems encountered with the analyses, corrective actions taken, changes to the referenced method, and an explanation of data qualifiers. The narrative should address condition of the samples on receipt, sample preparation, methods of analysis, instrument calibration, recovery data, and results from QC samples. This information is needed to evaluate the accuracy of the data and to determine whether the MQOs were met.

Audits

MEL participates in performance and system audits of their routine procedures. Results of these audits are available on request. Similar audits will also be required from any contract laboratory selected for sample analysis and the information will be made available to Ecology upon request.

Report

A final report detailing the findings of the study will be completed. The final report will include:

- Categorical descriptions of the products screened with the XRF (i.e. brands, product names, etc. will not be included)
- Comparison of laboratory results with XRF screening, where applicable.

- Assessment of ability to test children's cosmetic and personal care products for parabens.
- Determination of whether or not the proposed PQL for parabens have been appropriately established.
- Data on specific children's cosmetic and personal care products. Some data may be reserved until any compliance issues are resolved.

Data Verification

The Project Manager will conduct a review of all laboratory data generated by MEL and all contract laboratories. The Project Manager will verify that methods and protocols specified in this QAPP were followed; that all calibrations, checks on quality control, and intermediate calculations were performed for all samples; and that the data are consistent, correct, and complete, with no errors or omissions. Evaluation criteria will include the acceptability of procedural blanks, calibration, matrix spike recoveries, labeled compound and internal standard recoveries, ion abundance ratios, duplicates, laboratory control samples, and appropriateness of data qualifiers assigned. MEL and all contract labs will prepare written data verification reports based on the results of their data review.

A case narrative from all laboratories will meet the requirements for a data verification report for MEL's chemical data.

Data Quality (Usability) Assessment

The Project Manager will examine the data reviews, case narratives, and data packages to assess the usability of the data. To determine if project MQOs have been met, results for laboratory control samples, sample duplicates, matrix spikes, and labeled compound recoveries will be compared to QC limits. The method blank results will be examined to verify there was no significant contamination of the samples. To evaluate whether the targets for reporting limits have been met, the results will be examined for "non-detects" and to determine if any values exceed the lowest concentration of interest. Based on these assessments, the data will be either accepted, accepted with appropriate qualifications, or rejected and re-analysis considered.

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Appendices

Appendix A. Chemicals required by the CSPA rule.

CAS	Chemical
50-00-0	Formaldehyde
62-53-3	Aniline
62-75-9	N-Nitrosodimethylamine
71-36-3	n-Butanol
71-43-2	Benzene
75-01-4	Vinyl chloride
75-07-0	Acetaldehyde
75-09-2	Methylene chloride
75-15-0	Carbon disulfide
78-93-3	Methyl ethyl ketone
79-34-5	1,1,2,2-Tetrachloroethane
79-94-7	Tetrabromobisphenol A
80-05-7	Bisphenol A
84-66-2	Diethyl phthalate
84-74-2	Dibutyl phthalate (DBP)
84-75-3	Di-n-Hexyl Phthalate
85-44-9	Phthalic Anhydride
85-68-7	Butyl Benzyl phthalate (BBP)
86-30-6	N-Nitrosodiphenylamine
87-68-3	Hexachlorobutadiene
94-13-3	Propyl paraben
94-26-8	Butyl paraben
95-53-4	2-Aminotoluene
95-80-7	2,4-Diaminotoluene
99-76-3	Methyl paraben
99-96-7	p-Hydroxybenzoic acid
100-41-4	Ethylbenzene
100-42-5	Styrene
104-40-5	4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3
106-47-8	para-Chloroaniline
107-13-1	Acrylonitrile
107-21-1	Ethylene glycol
108-88-3	Toluene
108-95-2	Phenol
109-86-4	2-Methoxyethanol

CAS	Chemical
110-80-5	Ethylene glycol monoethyl ester
115-96-8	Tris(2-chloroethyl) phosphate
117-81-7	Di-2-ethylhexyl phthalate (DEHP)
117-84-0	di-n-octyl phthalate (DnOP)
118-74-1	Hexachlorobenzene
119-93-7	3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine
120-47-8	Ethyl paraben
123-91-1	1,4-Dioxane
127-18-4	Perchloroethylene
131-55-5	Benzophenone-2 (Bp-2); 2,2',4,4'-Tetrahydroxybenzophenone
140-66-9	4-tert-Octylphenol; 1,1,3,3-Tetramethyl-4-butylphenol
140-67-0	Estragole
149-57-5	2-Ethylhexanoic Acid
556-67-2	Octamethylcyclotetrasiloxane
608-93-5	Benzene, pentachloro
842-07-9	C.I. Solvent Yellow 14
872-50-4	N-Methylpyrrolidone
1163-19-5	2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209
1763-23-1	Perfluorooctanyl sulphonic acid and its salts; PFOS
1806-26-4	Phenol, 4-octyl-
5466-77-3	2-Ethyl-hexyl-4-methoxycinnamate
7439-97-6	Mercury & mercury compounds including methyl mercury (22967-92-6)
7439-98-7	Molybdenum & molybdenum compounds
7440-36-0	Antimony & Antimony compounds
7440-38-2	Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) & dimethyl arsenic (75-60-5)
7440-43-9	Cadmium & cadmium compounds
7440-48-4	Cobalt & cobalt compounds
25013-16-5	Butylated hydroxyanisole; BHA
25637-99-4	Hexabromocyclododecane
26761-40-0	Diisodecyl phthalate (DIDP)
28553-12-0	Diisononyl phthalate (DINP)

Appendix B. Glossary, Acronyms, and Abbreviations

Acronyms and Abbreviations

Following are acronyms and abbreviations used frequently in this report.

CPSC	Consumer Product Safety Commission
e. g.	For example
Ecology	Washington State Department of Ecology
et al.	And others
i. e.	In other words
HWTR	Hazardous Waste and Toxics Reduction Program
MEL	Manchester Environmental Laboratory
MQO	Measurement quality objective
NHANES	National Health and Nutrition Examination Survey
Parabens	Esters of para-hydroxybenzoic acid used primarily as a preservative
PBT	persistent, bioaccumulative, and toxic substance
QA	Quality assurance
QAPP	Quality assurance project plan
RPD	Relative percent difference
RSD	Relative standard deviation
SOP	Standard operating procedures
SRM	Standard reference materials
W2R	Waste 2 Resources Program

Units of Measurement

ng	nanogram, a unit of mass equal to 1 billionth of a gram
µg	microgram, a unit of mass equal to 1 millionth of a gram
mg	milligram, a unit of mass equal to 1 thousandth of a gram
g	gram, a unit of mass
kg	kilograms, a unit of mass equal to 1,000 grams.
mL	milliliter, a unit of volume equal to 1 thousandth of a Liter
Liter	Liter, a unit of volume
ng/g	nanograms per gram (ppb)
ng/kg	nanograms per kilogram (ppt)
µg/L	microgram per liter (ppm)
ng/L	nanograms per liter (ppt)
ppm	parts per million
ppb	parts per billion
ppt	parts per trillion
mm	millimeter
s.u.	standard units