DEPARTMENT OF
ECOLOGY
State of Washington

Addendum #1 to Quality Assurance Project Plan

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

October 2014

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Publication Information

Addendum

This addendum is on the Department of Ecology's website at
https://fortress.wa.gov/ecy/publications/SummaryPages/1207021a.html

This addendum is an addition to an original Quality Assurance Project Plan. It is not a correction (errata) to the original plan.

Original Publication

Quality Assurance Project Plan for Parabens and Metals in Children's Cosmetic and Personal Care Products

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https://fortress.wa.gov/ecy/publications/SummaryPages/1207021.html

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Quality Assurance Project Plan Addendum

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

October 2014

Approved by:

Signature: _____ Date: 1/20/2015

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Samuel Iwenofu, HWTR Quality Assurance Officer

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

Overview

In 2012, the Washington State Department of Ecology (Ecology) initiated a study to evaluate presence of parabens and metals in children's cosmetic and personal care products. Particular emphasis was placed on products known to contain parabens. The results of the study were published in two reports on parabens (Ecology, 2014a) and metals (Ecology, 2014b).

In 2014, the Washington State Legislature (WSL) provided funding to the Washington State Department of Ecology (Ecology) to establish a product testing program. This study builds upon the previous sampling results for parabens and metals by sampling seasonal products. This, study will sample children's products available for the following holidays or specialty sales events over 14 months from November 2014 through December 2015:

- Christmas, 2014.
- Valentine's, Day 2015.
- Easter, 2015.
- Fourth of July, 2015.
- Back-to-School, 2015.
- Halloween, 2015.
- Christmas, 2015.

Paraben product analysis requirements are described in the original Quality Assurance Project Plan (QAPP). Products selected for analysis will meet the definition of a children's product as defined in the Children's Safe Product Act (RCW 70.240). Emphasis will be placed upon children's products produced and sold for the specific holiday season.

Organization and Schedule

Table 1 lists the people involved in this project. All are employees of the Washington State Department of Ecology. Table 2 presents the proposed schedules for this project. The Project Managers will write a summary report for each holiday or specialty shopping event and/or a final report summarizing the results from all the sampling events.

Table 1. Organization of Project Staff and Responsibilities.

Staff (all are HWTR Program)	Title	Responsibilities

Staff (all are HWTR Program)	Title	Responsibilities
Alex Stone Hazardous Waste and Toxics Reduction Program Phone: (360) 407-6758	Co-Project Manager	Writes the QAPP. Oversees project timeline.
Saskia van Bergen Hazardous Waste and Toxics Reduction Program Phone: (360) 407-6609	Co-Project Manager	Oversees project timeline. Conducts QA review of data, analyzes and interprets data. Writes the draft report(s) and/or final report.
Chrissy Wiseman Hazardous Waste and Toxics Reduction program Phone: (360) 407-7672	Sampling Lead	Leads sample collection, processing, and shipment to laboratory. Conducts XRF analysis. Assist with data analysis, result interpretation, and report writing.
Ken Zarker Hazardous Waste and Toxics Reduction Program Phone: (360) 407-6724	Section Manager for the Project Managers	Reviews the project scope and budget, tracks progress, reviews the draft report, and approves the final report.
Samuel Iwenofu Hazardous Waste and Toxics Reduction Program Phone: 360-407-6346	HWTR Quality Assurance Officer	Reviews and approves the draft QAPP and the final QAPP.

HWTR: Hazardous Waste and Toxics Reduction Program
QAPP: Quality Assurance Project Plan

Table 2. Proposed Schedule for Completing Field and Laboratory Work, Data Entry, and Reports.

Field and laboratory work	Due date	Lead staff
Field work completed	November 2015	Chrissy Wiseman
Laboratory analyses completed	February 2016	
Final report		
Author lead / Support staff	Saskia van Bergen/Chrissy Wiseman	
Schedule		
Draft due to supervisor	1 month after sampling completed for specific holiday	
Draft due to client/peer reviewer	2 months after sampling completed for specific holiday	
Final (all reviews done) due to publications coordinator	3 months after sampling completed for specific holiday	

Experimental Design

Target chemicals proposed for testing and recommended practical quantitation limits (PQLs) for each are identical to those established in the Quality Assurance and Project Plan for Parabens and Metals in Children's Cosmetic and Personal Care Products (Ecology, 2012) except where noted below. Not all samples, however, may be tested for both parabens and metals. The XRF screening data will determine which samples are analyzed for metals and samples tested for parabens may not also be tested for metals if there are no metals of interest shown in the screening analysis.

An additional 178 samples will be selected for paraben analysis and 100 samples for metals analysis over the 14 months within the seven holidays identified for this project.

Laboratory Analysis

A contract laboratory will be selected to conduct the paraben analysis following the requirements established in the original QAPP (Ecology, 2012a). Manchester Environmental Laboratory (MEL) will conduct the metals analyses described in Table 2. Project reporting limits are also included in the table. Chain-of-custody will be recorded throughout sample processing, screening, shipment, and laboratory analysis.

Metals samples will be digested via EPA Method 3052 (complete microwave digestion without hydrofluoric acid) and measured using ICP-MS following EPA Method 6020.

Samples consisting of material such as hard plastic may need to be cryomilled prior to analysis. Cryomilling is the process of reducing a sample to very small particle sizes by lowering the product to cryogenic temperatures and mechanically milling it. This process provides a homogenous, finely divided solids sample necessary for efficient extraction. When necessary, MEL will carry out the cryomilling.

Table 2. 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
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
Parabens	*	HPLC-MS	*	30.00

^ Alternate digestion method without hydrofluoric acid.
EPA: Environmental Protection Agency
ICP-MS: Inductively Coupled Plasma-Mass Spectroscopy
* Method will be approved by Project Manager
RL: Reporting Limit
GC-MS: Gas Chromatography-Mass Spectroscopy
CVAA: Cold Vapor Atomic Absorption

Project Budget

The budget for this project is presented in Table 3:

Table 3: Project Budget

Analysis	Cost/analysis	Nr. of analyses	Samples per holiday (7 holidays)	Budget
Metals	$200.00	100	14	$20,000.00
Parabens	$450.00	178	25	$80,000.00
			Total	**$100,000.00**

Quality Control Procedures

Laboratory QC tests planned for the analysis are identical to those established in the Quality Assurance and Project Plan for Parabens and Metals in Children's Products (Ecology, 2012).

Quality Objectives

Quality objectives for this project are identical to those established in the Quality Assurance and Project Plan for Parabens and Metals in Children's Products (Ecology, 2012) except as noted below.

Measurement of Quality Objectives

MQOs for laboratory analysis of metals are shown in Table 4. MEL will be expected to meet these criteria. If the tests MQOs are not met, the analytical laboratory will reanalyze the samples

in question in an attempt to conform to the MQOs. Quality control tests falling outside of MQO acceptance limits, and related data batches, will be reviewed by the project manager for their usability.

Table 4. Measurement Quality Objectives for Laboratory Analyses.

Analyte	Laboratory Control Samples (recovery)	Matrix Spikes (recovery)	Matrix Spike Duplicates (RPD)	Laboratory Duplicates (RPD)
Metals	85 - 115%	75 - 125%	≤20%	≤20%

Data Management Procedures

Data management procedures are identical to those in the Quality Assurance and Project Plan for Parabens and Metals in Children's Products (Ecology, 2012) except as noted below.

Laboratory data and case narratives will be stored with the project manager. Data from this project will also be available in Ecology's Product Testing Database.

Audits and Reports

Audits

MEL must participate in performance and system audits of their routine procedures. Results of these audits will be available upon request.

Report

A report summarizing findings for this project will be published after an internal review period. The final report will include:

- Categorical descriptions of the products screened with XRF.
- Any deviations from the QAPP.
- A summary of XRF and laboratory results of parabens and metals analyses.
- Assessment of levels found that would violate standards in the CSPA or the reporting rule.

Data Verification and Validation

MEL will verify that (1) methods and protocols specified in this project plan were followed, (2) all calibrations, QC tests, and intermediate calculations were performed for all samples, and (3)

the data are consistent, correct, and complete, with no errors or omissions. Evaluation criteria will include the acceptability of procedural blanks, calibration, ion abundance ratios, QC tests, and appropriateness of data qualifiers assigned.

MEL will provide case narratives to the project manager, describing the quality of MEL data. Case narratives should include any problems encountered with the analyses, corrective actions taken, changes to the referenced method, and an explanation of data qualifiers. Narratives will also address the condition of samples on receipt, sample preparation, methods of analysis, instrument calibration, and results of QC tests.

Data Quality (Usability) Assessment

The project manager will assess the quality of the data, based on case narratives and data packages, to determine whether MQOs were met for this study. The project manager will determine whether the data should be accepted, accepted with additional qualification, or rejected and re-analysis considered. Data quality and usability will be discussed in the report(s).

References

Washington State Department of Ecology (Ecology), 2012. Quality Assurance Project Plan: Parabens and Metals in Children's Cosmetic and Personal Care Products, Publication number 12-07-021, 22 pages.

Ecology, 2014a. Parabens in Children's Products, Publication Nr. 14-04-016, 23 pages.

Ecology, 2014b. Metals in Children's and Consumer Products and Packaging, Publication Nr. 14-04-014, 59 pages.

Washington State Legislature (WSL), 2008. Children's Safe Products, Chapter 70.240 RCW.