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Addendum #1 to
Quality Assurance Project Plan

Phthalates and Metals in Children's Products

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Addendum

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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 Phthalates and Metals in Children's Products

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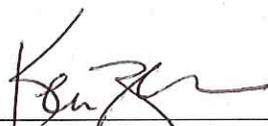
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Quality Assurance Project Plan Addendum

Addendum to Phthalates and Metals in Children's Products

November 2014

Approved by:

Signature: 

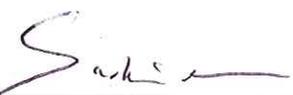
Ken Zarker, Author Supervisor and Client, HWTR-HQ

Date: 1/20/2015

Signature: 

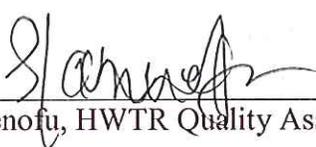
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Date: 1/20/2015

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Saskia van Bergen, Co-Project Manager, HWTR-HQ

Date: 1/20/2015

Signature: 

Samuel Iwenofu, HWTR Quality Assurance Officer

Date: 1/20/2015

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

DEPARTMENT OF ECOLOGY
Hazardous Waste and Toxics Reduction

Overview

In 2012, the Washington State Department of Ecology (Ecology) initiated a study to evaluate presence of phthalates and metals in children’s products. Particular emphasis was placed on products known to contain phthalates. The results of the study were published in three reports on phthalates (Ecology, 2014a; Ecology 2014c) and metals (Ecology, 2014b; Ecology, 2014c).

In 2014, the Washington State Legislature (WSL) provided funding to the Washington State Department of Ecology (Ecology) to establish a product testing program. This additional product testing will build upon previous sampling results for phthalates and metals in children’s products 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.

Phthalate product analysis requirements are described in the original Quality Assurance Project Plan (Ecology, 2012). 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 Project Plan (QAPP) for Phthalates and Metals in Children's Products (Ecology, 2012) except where noted below. Not all samples, however, may be tested for both phthalates and metals. The XRF screening data will determine which samples are analyzed for metals. Samples tested for phthalates may not be tested for metals if there are no metals of interest shown in the screening analysis.

An additional 213 samples will be selected for phthalate analysis and 100 samples for metals analysis over the 14 months within the seven holidays identified for this project. Product Selection and Screening are identical to those established in the QAPP for Phthalates and Metals in Children's Products (Ecology, 2012) except where noted below.

Laboratory Analysis

Manchester Environmental Laboratory (MEL) will conduct the phthalates and 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 200.8.

Phthalates will be measured using GC-MS following Method CPSC-CH-C1001-09.3 (CPSC, 2010)¹. This guidance allows for several different extraction and analysis methods. Proposed sample methods include EPA 3546 for digestion and EPA 8270D for analysis.

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.

¹ United States Consumer Product Safety Commission Standard Operating Procedure for Determination of Phthalates

Table 2. Laboratory Methods and Reporting Limits.

| Analyte | Digestion Method | Instrumentation | Method | RL (ppm) |
|------------|------------------|-----------------|------------|----------|
| Phthalates | EPA 3546* | GC-MS | EPA 8270D* | 5.0 |
| 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 |

*Or equivalent methods allowed under CPSC-CH-C1001-09.3.

^ Alternate digestion method without hydrofluoric acid.

RL: Reporting Limit

EPA: Environmental Protection Agency

GC-MS: Gas Chromatography-Mass Spectroscopy

ICP-MS: Inductively Coupled Plasma-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 |
| Phthalates | \$375.00 | 213 | 30 | \$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 Phthalates 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 Phthalates and Metals in Children's Products (Ecology, 2012) except as noted below.

Measurement of Quality Objectives

MQOs for laboratory analysis of phthalates and 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 1. Measurement Quality Objectives for Laboratory Analyses.

| Analyte | Laboratory Control Samples (recovery) | Matrix Spikes (recovery) | Matrix Spike Duplicates (RPD) | Laboratory Duplicates (RPD) |
|------------|---------------------------------------|--------------------------|-------------------------------|-----------------------------|
| Phthalates | 50 - 150% | 50 - 150% | ≤40% | ≤40% |
| 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 Phthalates 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 phthalate and metal analyses (additional data will be in the product database).
- 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

CPSC, 2010. Test Method: CPSC-CH-C1001-09.3, Standard Operating Procedure for Determination of Phthalates. U.S. Consumer Product Safety Commission Directorate for Laboratory Sciences, Gaithersburg, MD.

Ecology, 2014a. Phthalates in Children's Products, Publication Nr. [14-04-017](#), 46 pages.

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

Ecology, 2014c. Metals and Phthalates in Tier 3 Children's Products, Publication Nr. [14-03-012](#), 41 pages.

Washington State Department of Ecology (Ecology), 2012. Quality Assurance Project Plan: [Phthalates and Metals in Children's Products](#), Publication Nr. 12-07-023, 20 pages.