DEPARTMENT OF
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State of Washington

Quality Assurance Project Plan

Chemicals of High Concern to Children in Children's Clothing, Footwear, and Accessories

December 2014

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Publication Information

Each study conducted by the Washington State Department of Ecology (Ecology) must have an approved Quality Assurance Project Plan. 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 the final report of the study to the Internet.

This Quality Assurance Project Plan is available on Ecology's website at https://fortress.wa.gov/ecy/publications/SummaryPages/1403125.html

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Ecology's Activity Tracker Code for this study is 14-068.

Quality Assurance Project Plan

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EAP: Environmental Assessment Program

1.0 Title Page and Table of Contents

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2.0 Abstract

The Washington State Department of Ecology (Ecology) will conduct a study in 2014 to evaluate the presence of chemicals of high concern to children (CHCCs) in children's clothing, footwear, and accessories. This study is being carried out to provide data in support of Ecology's enforcement of Washington State's Children's Safe Products Act (CSPA) legislation. The CSPA legislation restricts levels of cadmium, lead, and phthalates in children's products and requires manufacturers to report to Ecology if a product contains a CHCC.

Ecology will purchase approximately 300 articles of children's clothing, footwear, and accessories and send a subset of those products for laboratory testing of CHCCs. Fifty samples will be sent to the laboratory for analysis of metals (antimony, arsenic, cadmium, cobalt, lead, mercury, and molybdenum) and an additional fifty samples will be sent to the laboratory for analysis of phthalates (DEHP, BBP, DEP, DnHP, DIDP, DINP, DMP, DBP, and DnOP[1]). Ecology will select samples for laboratory analysis of metals and phthalates based on X-ray fluorescence (XRF) screenings. Samples to be analyzed for phthalates will be selected based on high levels of chlorine (>15%), which would indicate presence of polyvinyl chloride. Fifty samples will also be tested for ethylene glycol, styrene, methyl ethyl ketone, octamethylcyclotetrasiloxane and 4-nonylphenol.

A final report summarizing findings will be published in 2015. All data will be entered into a publicly available database on Ecology's website.

[1] DEHP = di-2-ethylhexyl phthalate; BBP = butyl benzyl phthalate; DEP = diethyl phthalate; DnHP = di-n-hexyl phthalate; DIDP = diisodecyl phthalate; DINP = diisononyl phthalate; DMP = dimethyl phthalate; DBP = dibutyl phthalate; DnOP = Di-n-octyl phthalate.

3.0 Background

In 2008, Washington State passed the Children's Safe Products Act (CSPA) to address the risk of toxic chemicals in children's products (RCW 70.240). This law restricted the use of lead, cadmium, and phthalates in children's products[2] and required the Departments of Ecology (Ecology) and Health (DOH) to develop a list of chemicals of high concern for children (CHCC). Manufacturers are required to report to Ecology if one of their products contains a chemical from this list. For more information on CSPA, visit http://www.ecy.wa.gov/programs/swfa/cspa/.

The CSPA Reporting Rule requires manufacturers to report on CHCCs in products on a phased-in schedule according to the type of product and size of manufacturer[3]. Manufacturers are separated into size categories by annual aggregate gross sales. The largest manufacturers started reporting in August 2012 on Tier 1 products (mouthable products for children ≤ 3 years). Reporting for Tier 2 products began in February 2013, which includes products targeted to children between 3 and 12 years old, and intended for prolonged contact (>1 hour) with a child's skin. Tier 3 products (short duration contact products) were next in line to be reported by the largest manufacturers (August 2013). The second largest manufacturing class began reporting on a similar phased-in schedule in February 2013. Successively smaller manufacturers will begin reporting each year through 2016.

The reporting rule requires manufacturers to notify Ecology if a product component contains a CHCC concentration of (1) any amount greater than practical quantitation limits (PQLs) defined by Ecology (2012), if the chemical was intentionally added to the product, or (2) 100 ppm or higher, if the chemical is present as a contaminant.

Ecology regularly conducts studies in support of agency efforts to ensure manufacturer compliance with CSPA legislation. In 2014 Ecology's Environmental Assessment Program will conduct a study to measure frequently reported CHCCs in children's clothing, footwear, and accessories. Ecology will test samples of the children's products for metals (antimony, arsenic, cadmium, cobalt, lead, mercury, and molybdenum), phthalates (DEHP, BBP, DEP, DnHP, DIDP, DINP, DMP, DBP, and DnOP[4]), ethylene glycol, MEK, styrene, D4, and 4-nonylphenol.

3.1 Study Area and Surroundings

The CSPA Reporting Rule and restrictions on lead, cadmium, and phthalates apply to any children's product sold in Washington State. Ecology will purchase products "off the shelf" from Puget Sound area stores and through on-line retailers that are representative of products sold across the state.

[2] Washington State restrictions on lead, cadmium, and phthalates are largely preempted by the federal Consumer Product Safety Improvement Act.

[3] Washington Administration Code (WAC) 173-334

[4] DEHP = di-2-ethylhexyl phthalate; BBP = butyl benzyl phthalate; DEP = diethyl phthalate; DnHP = di-n-hexyl phthalate; DIDP = diisodecyl phthalate; DINP = diisononyl phthalate; DMP = dimethyl phthalate; DBP = dibutyl phthalate; DnOP = Di-n-octyl phthalate.

3.1.1 Logistical problems

It is possible that the laboratory will encounter issues with analysis of CHCCs in footwear and accessories. The lab anticipates possible underreporting of results due to inefficient extraction of the plastic matrices. Severe matrix effects may also affect the ability to detect and/or quantitate the analytes of concern. Laboratory results could be highly qualified if these issues occur.

3.1.2 History

Ecology stores data reported by manufacturers on CHCCs in their product components in a database that is available to the public (https://fortress.wa.gov/ecy/cspareporting/). Manufacturers report chemical concentrations in intervals (e.g. "<PQL - 100 ppm" or "100 - 500ppm"). The database captures the category of product (i.e., sleepwear or musical toy), the material the product component is made of, and the function that the chemical serves in the product. As of August 2014, over 18,000 product components have been reported in the database. The 15 top-reported chemicals containing any amount over the PQL reported from August 2012 through August 2014 are graphed in Figure 1.

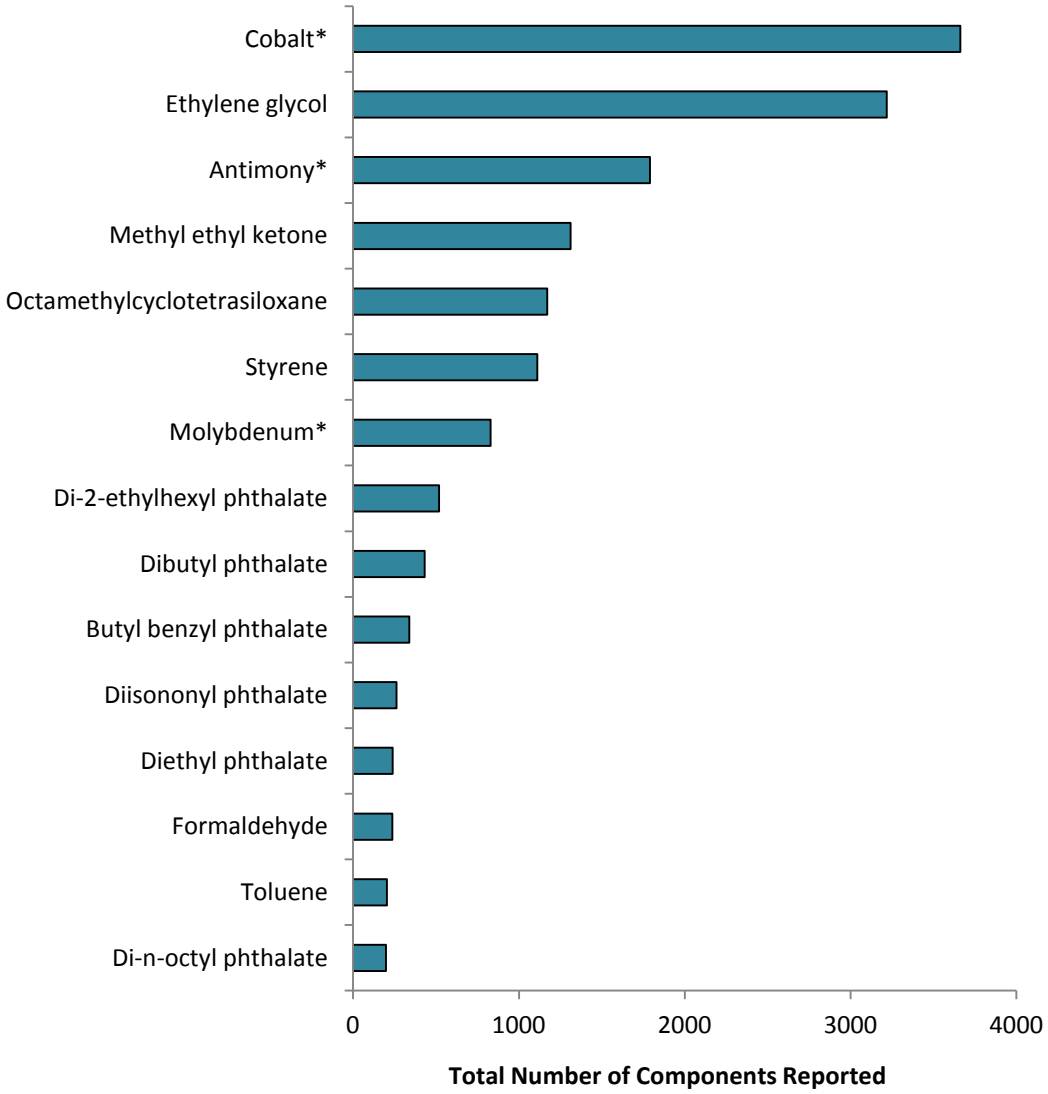

Figure 1. The Number of Components Reported Containing a Chemical >PQL, for the 15 Most-Reported Chemicals.

**includes respective metal compounds*

The metals cobalt and antimony, as well as ethylene glycol, methyl ethyl ketone (MEK), octamethylcyclotetrasiloxane (D4), and styrene, were the most commonly reported chemicals in children's products. The majority of the reports for these chemicals, with the exception of cobalt, were in the concentration range of 100 – 500 ppm. Cobalt was recorded most often between the PQL and 100 ppm. Phthalates were most often reported in the <PQL – 100 ppm and the 100 – 500 ppm ranges, while molybdenum was most commonly reported in products between 1,000 and 5,000 ppm.

Fifty percent of the components reported in the database between August 2012 and August 2014 fell in the category of children's clothing. This may be due to the fact that many clothing manufacturers chose to report early, instead of waiting for the phased in schedule. Figure 2

displays the percentage of chemical reports in the clothing, footwear, and personal accessory segments (combined), by chemical.

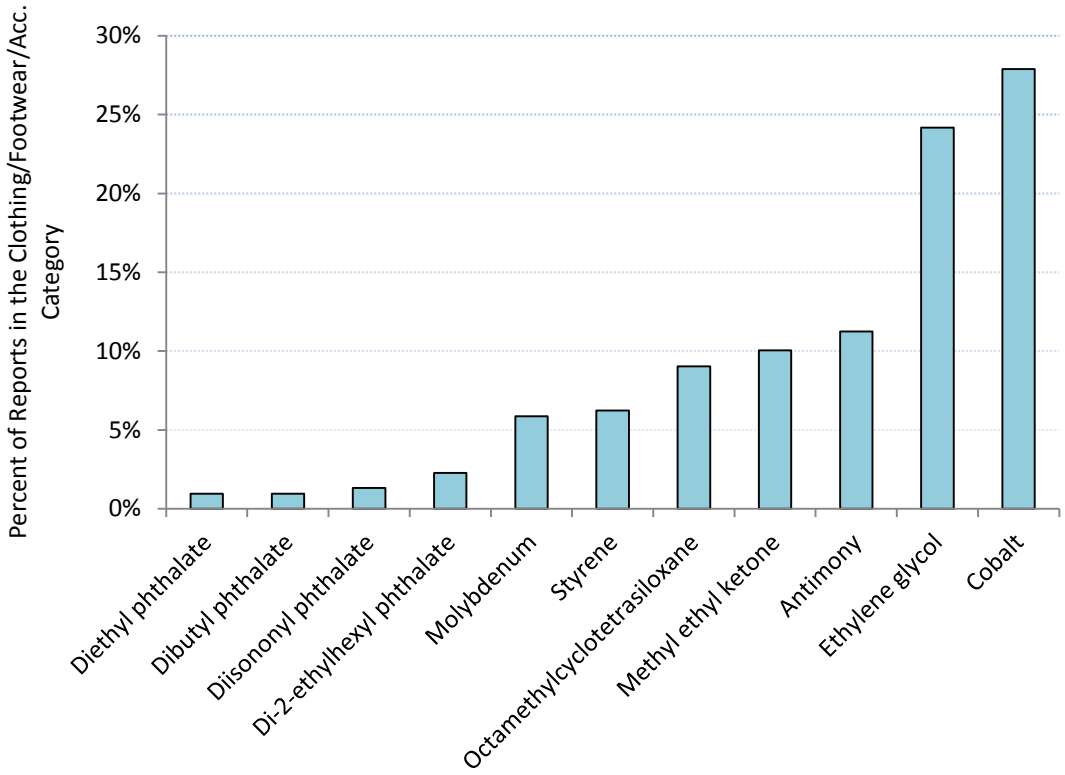

Figure 2. Percentage of Manufacturer Reports in the CSPA Database that were in the Clothing/Footwear/Accessories Category.

The metals cobalt and antimony were reported frequently in children's clothing and footwear. Manufacturers reported the presence of cobalt in clothing and footwear primarily as a coloring/pigment agent. Antimony was reported most often as a contaminant, having no function, in children's clothing and footwear products. This is likely a reflection of the use of antimony trioxide as a catalyst in the process of making polyester.

Ethylene glycol is also used in the manufacture of polyester textiles. Manufacturers reporting to Ecology stated it was present in clothing and footwear as a contaminant with no function. MEK, D4, styrene, and 4-nonylphenol were also reported by manufacturers as a contaminant in clothing and footwear products, with some reports stating the chemicals were used as solvents, softeners, or hardeners. Solvents and surfactants are used in many steps of the clothing manufacturing process.

Manufacturers reported the presence of phthalates as plasticizers in children's clothing, footwear, and accessories in the CSPA reporting database. Phthalates are added to polyvinyl chloride (PVC) plastic and PVC-based inks to impart flexibility. PVC plastics can also be used to make footwear and accessories, such as soft plastic sandals, and PVC-based inks are sometimes used in

plastisol prints on t-shirts and other apparel. The presence of phthalates in footwear and clothing has been documented by others (Tonning et al., 2010; Brigden et al., 2012).

3.1.3 Parameters of interest

This study will analyze children's clothing, footwear, and accessories for metals (antimony, arsenic, cadmium, cobalt, lead, mercury, and molybdenum), phthalates (DEHP, BBP, DEP, DnHP, DIDP, DINP, DMP, DBP, and DnOP[5]), ethylene glycol, styrene, methyl ethyl ketone, octamethylcyclotetrasiloxane (D4) and 4-nonylphenol.

The presence of these chemicals in products does not necessarily pose an exposure threat to the child using the product. However, the chemicals discussed above are included on the CHCC list because research has shown them to have reproductive, developmental, endocrine-disrupting, or carcinogenic effects (Ecology, 2011). Ecology collects information under CSPA to gain an understanding of how chemicals are being used in children's products and to determine what, if any, further actions may be needed to ensure that children's products are safe.

3.1.4 Results of previous studies

Ecology began independently testing children's and consumer products in 2012 to assess manufacturer and retailer compliance with CSPA legislation and other consumer product laws. Metals, phthalates, parabens, and volatile organic compounds were analyzed in Tier 1 and Tier 2 products and packaging by Stone (2014a,b,c,d). Mathieu and Bookter (2014) also tested metals and phthalates in Tier 3 children's products.

Other studies have been conducted to evaluate bisphenol A in baby bottles and sports bottles (Mathieu, 2013) and PBDEs and other flame retardants in consumer products (van Bergen and Stone, 2014).

3.1.5 Regulatory criteria or standards

Ecology's CSPA enforcement officer will review the data from this study to determine whether manufacturers are in compliance with the CSPA Reporting Rule and restrictions on lead, cadmium, and phthalates in children's products. These regulations are described in Section 3.0.

[5] DEHP = di-2-ethylhexyl phthalate; BBP = butyl benzyl phthalate; DEP = diethyl phthalate; DnHP = di-n-hexyl phthalate; DIDP = diisodecyl phthalate; DINP = diisononyl phthalate; DMP = dimethyl phthalate; DBP = dibutyl phthalate; DnOP = Di-n-octyl phthalate.

4.0 Project Description

4.1 Project goals

This study is being carried out to:

- Assess the presence of metals, phthalates, ethylene glycol, MEK, styrene, D4, and 4-nonylphenol in children's clothing, footwear, and accessories.
- Provide data to Ecology's CSPA Enforcement Officer so that manufacturer compliance can be determined.

4.2 Project objectives

To meet project goals, Ecology staff will carry out the following objectives:

- Purchase and conduct XRF screenings on approximately 300 articles of children's clothing, footwear, and accessories bought from on-line and in-person retailers.
- Select 50 product samples, based on XRF measurements, for laboratory analysis of metals.
- Send an additional 50 samples to the laboratory for analysis of phthalates[5]. Samples with high levels of chlorine (>15%) will be chosen for this analysis.
- Send 50 samples to the laboratory for analysis of ethylene glycol, styrene, methyl ethyl ketone, D4, and 4-nonylphenol. Ecology will select product components for these analyses based on a review of the CSPA manufacturer database and a literature review. These samples may or may not be the same products analyzed for metals or phthalates.

4.3 Information needed and sources

The CSPA manufacturer reporting database will be reviewed prior to product collection to guide selection of retailers and products to target. Large manufacturers that do not appear to have reported to Ecology for the chemicals and product types of interest will be given priority. A literature review of existing product testing data will also be completed to help provide a basis for product collection. Sources such as the Danish Environmental Protection Agency "Surveys on Chemicals in Consumer Products" will be reviewed (e.g., Rasmussen et al., 2013; Tonning et al., 2010).

4.4 Target population

Products purchased for screening will consist of children's clothing, footwear, and accessories. Clothing articles will be made up of cotton or polyester, in several different categories (Figure 3). T-shirts and other garments containing a plastisol print will be targeted for analysis of phthalates. Footwear and accessories made with soft flexible plastic will also be selected for phthalates analysis.

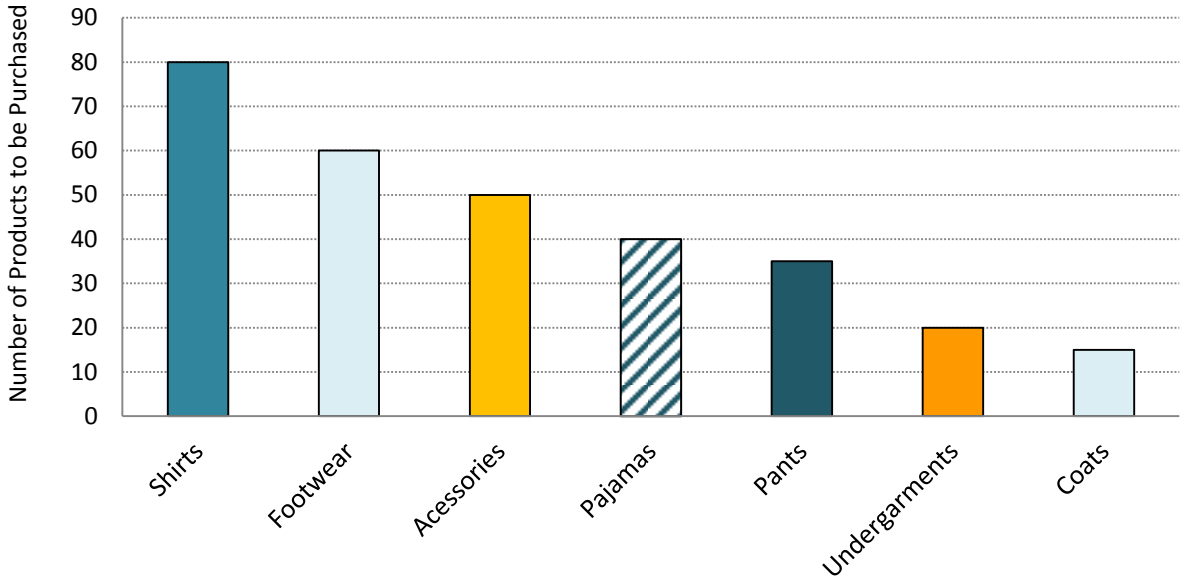

Figure 3. Types of Products Anticipated for Collection.

4.5 Study boundaries

Ecology staff will purchase products "off the shelf" from Puget Sound area stores and through on-line retailers. Large chain retailers and discount stores will be targeted. The practice of statewide distribution by most of the retail chain stores ensures that products purchased from Puget Sound area stores are representative of products sold across the state.

4.6 Tasks required

Approximately 300 children's products consisting of clothing, footwear, and accessories will be purchased from retailers in the Puget Sound area and through internet retailers selling to Washington State consumers. Products will be brought back to Ecology headquarters, isolated into separate components, and screened for metals and chlorine using an XRF analyzer. Component samples will be selected for laboratory analysis based on XRF screenings for metals and phthalates. Samples sent for analysis of ethylene glycol, styrene, methyl ethyl ketone, D4, and 4-nonylphenol will be selected based on a review of Ecology's manufacturer database and other sources listed in Section 4.3.

4.7 Practical constraints

No practical constraints are anticipated for this project.

4.8 Systematic planning process

Not applicable.

5.0 Organization and Schedule

5.1 Key individuals and their responsibilities

Table 1 lists the people involved in this project. All are employees of the Washington State Department of Ecology. Table 2 presents the proposed schedule for this project.

Table 1. Organization of project staff and responsibilities.

Staff (all are EAP except client)	Title	Responsibilities
Josh Grice W2R Program Phone: 360-407-6786	EAP Client	Clarifies scope of the project. Provides internal review of the QAPP and approves the final QAPP.
Callie Mathieu Toxics Studies Unit SCS, EAP Phone: 360-407-6965	Project Manager	Writes the QAPP. Coordinates with laboratory. Conducts QA review of data, analyzes and interprets data. Writes the draft report and final report.
Christina Wiseman HWTR Program Phone: 360-407-7672	Sampling Lead	Purchases products, conducts XRF screening of products, and sends samples to laboratory. Enters data into Product Testing Database.
Dale Norton Toxics Studies Unit SCS, EAP Phone: 360-407-6765	Unit Supervisor for the Project Manager	Provides internal review of the QAPP, approves the budget, and approves the final QAPP.
Will Kendra SCS, EAP Phone: 360-407-6698	Section Manager for the Project Manager	Reviews the project scope and budget, tracks progress, reviews the draft QAPP, and approves the final QAPP.
Joel Bird Manchester Environmental Laboratory Phone: 360-871-8801	Director	Approves the final QAPP.
William R. Kammin Phone: 360-407-6964	Ecology Quality Assurance Officer	Reviews and approves the draft QAPP and the final QAPP.

EAP: Environmental Assessment Program
EIM: Environmental Information Management database
QAPP: Quality Assurance Project Plan
SCS: Statewide Coordination Section
W2R: Waste 2 Resources

5.2 Special training and certifications

Ecology staff conducting the XRF screening will be trained in using the XRF analyzer, according to standard operating procedures (van Bergen, 2014).

5.3 Organization chart

See Tables 1 and 2.

5.4 Project schedule

Table 2. Proposed schedule for completing field and laboratory work, data entry into Product Testing Database, and final report.

Product collection and laboratory work	Due date	Lead staff
Product collection completed	10/2014	Christina Wiseman
XRF screening completed	11/2014	Christina Wiseman
Laboratory analyses completed	02/2015	
Product Testing Database (PTDB) entry		
	Due date	Lead staff
Lab data loaded	03/2014	Christina Wiseman
PTDB QA review	04/2015	Callie Mathieu
Data entry complete	05/2015	Christina Wiseman
Final report		
Author lead / Support staff	Callie Mathieu (lead) / Christina Wiseman	
Schedule		
Draft due to supervisor	05/2015	
Draft due to client/peer reviewer	06/2015	
Final (all reviews done) due to publications coordinator	07/2015	
Final report due on web	08/2015	

5.5 Limitations on schedule

No schedule limitations are expected for this project.

5.6 Budget and funding

The product collection and laboratory costs estimated for this project totals $100,530. Table 3 shows the estimated costs for this project.

Table 3. Project budget and funding.

Product/Parameter	Number of Samples	QC Samples*	Cost per Sample	Subtotal
Product Collection	300	---	$12	$3,600
Cryomilling	50	---	$100	$5,000
Metals	50	8	$200	$11,600
Phthalates	50	8	$375	$21,750
Ethylene glycol	50	8	$200	$11,600
Styrene	50	8	$100	$5,800
Methyl ethyl ketone	50	8	$100	$5,800
D4	50	8	$360^	$20,880
4-Nonylphenol	50	8	$250	$14,500
			total:	$100,530

*QC samples in this table include those that are not provided free of charge (matrix spikes, lab duplicates, and cryomill rinseates).
^D4 price includes 25% MEL contract fee.

6.0 Quality Objectives

6.1 Decision Quality Objectives (DQOs)

Decision quality objectives are not necessary for this project.

6.2 Measurement Quality Objectives (MQOs)

Quality objectives for this project are to obtain data of sufficient quality for confident quantification of the target chemicals in products and to ensure that results are comparable between product matrices. Objectives will be achieved through careful attention to the sampling, sample processing, measurement, and quality control procedures described in this plan.

Table 4 shows the measurement quality objectives (MQOs) for laboratory analysis of the target analytes. MEL, or the contract laboratory, will be expected to meet these criteria. However, analyses on consumer products are heavily matrix-dependent and MQOs cannot always be achieved. 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	Bias		Precision		Instrument performance	Sensitivity
	LCS (% recov.)	Matrix Spikes (% recov.)	Lab Duplicates (RPD)	Matrix Spike Duplicates (RPD)	Surrogate Standards (% recov.)	Lowest Concentration of Interest (ppm)
Metals	85 - 115%	75 - 125%	≤ 20%	≤ 20%	n/a	1.0
Phthalates	50 - 150%	50 - 150%	≤ 40%	≤ 40%	50 - 150%	5.0
Ethylene Glycol	50 - 150%	50 - 150%	≤ 40%	≤ 40%	n/a	20
Styrene	70 - 125%	60 - 140%	≤ 40%	≤ 40%	50 - 150%	1.0
MEK	70 - 125%	60 - 140%	≤ 40%	≤ 40%	50 - 150%	1.0
D4	70 - 125%	60 - 140%	≤ 40%	≤ 40%	50 - 150%	50
4-Nonylphenol	50 - 150%	50 - 150%	≤ 40%	≤ 40%	50 - 150%	50

* MQOs for D4 are anticipated. Actual MQOs may vary based on contract lab.

6.2.1 Targets for precision, bias, and sensitivity

6.2.1.1 Precision

Precision is a measure of the variability in the results of replicate measurements due to random error. Laboratory precision will be assessed through laboratory duplicate analysis. No field replicates are planned for this project. See Table 4 for MQOs.

6.2.1.2 Bias

Bias is the difference between the population mean and the true value. Laboratory bias will be evaluated by analyzing lab control samples and matrix spikes. See Table 4 for MQOs.

6.2.1.3 Sensitivity

Sensitivity is a measure of the capability of a method to detect a substance. The lowest concentrations of interest are listed in Table 4.

6.2.2 Targets for comparability, representativeness, and completeness

6.2.2.1 Comparability

To ensure comparability between projects, product processing, XRF screening, and sampling will be done according the SOP for product testing (van Bergen, 2014).

6.2.2.2 Representativeness

Ecology staff will purchase a large number of products (approximately 300) to help ensure that products collected are representative of those available to consumers. All major retailers in the area will be visited to obtain a wide variety of types of products. Samples selected for laboratory analysis are targeted to samples with a higher likelihood of containing the parameters of interest.

6.2.2.3 Completeness

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

7.0 Sampling Process Design (Experimental Design)

7.1 Study design

Approximately 300 children's products consisting of clothing, footwear, and accessories will be purchased from retailers in the Puget Sound area and through internet retailers selling to Washington State consumers. Products will be brought back to Ecology headquarters, isolated into separate components, and screened for metals and high levels of chlorine using an XRF analyzer. Component samples will be selected for laboratory analysis based on XRF screenings and a review of Ecology's CSPA manufacturer reporting database. Sample numbers and target analytes for laboratory analysis are provided in Table 5.

Table 5. Anticipated Number and Type of Samples to be Analyzed by the Laboratory.

Analyte	Clothing	Footwear	Accessories	Total Number of Samples
Metals[1]	20	15	15	50
Phthalates[2]	20	15	15	50
Ethylene glycol	20	15	15	50
Styrene	20	15	15	50
MEK	20	15	15	50
D4	20	15	15	50
4-Nonylphenol	20	15	15	50

[1]Arsenic, antimony, cadmium, cobalt, lead, mercury, and molybdenum.
[2] Diethyl phthalate, dibutyl phthalate, di-n-hexyl phthalate, butyl benzyl phthalate, di-2-ethylhexyl phthalate, Di-n-octyl phthalate, diisodecyl phthalate, and diisononyl phthalate.

7.1.1 Field measurements

Not applicable.

7.1.2 Sampling location and frequency

Products will be purchased from on-line and Puget Sound retailers over a two week period in late October.

7.1.3 Parameters to be determined

See Table 3 for a list of parameters to be determined.

7.2 Maps or diagram

Not Applicable

7.3 Assumptions underlying design

Ecology staff will purchase products "off the shelf" from Puget Sound area stores and through on-line retailers. Large chain retailers and discount stores will be targeted. The practice of statewide distribution by most of the retail chain stores ensures that products purchased from Puget Sound area stores are representative of products sold across the state.

7.4 Relation to objectives and site characteristics

Not applicable.

7.5 Characteristics of existing data

Ecology's past studies on chemicals in products covered a wide range of product types. This study will be focused solely on clothing, footwear, and accessories. No Ecology studies have analyzed D4 or 4-nonylphenol in product matrices. This study will fill that data gap.

8.0 Sampling Procedures

8.1 Field measurement and field sampling SOPs

Product selection, screening and preparation will follow Ecology's Product Testing SOP (van Bergen, 2014).

8.2 Containers, preservation methods, holding times

Samples will be stored in 8 oz glass jars with no preservation. No holding times have been established for product matrices.

8.3 Invasive species evaluation

Not applicable

8.4 Equipment decontamination

Equipment decontamination is covered in the Product Testing SOP (van Bergen, 2014).

8.5 Sample ID

Sample ID assignment is covered in the Product Testing SOP (van Bergen, 2014).

8.6 Chain-of-custody, if required

Chain of custody will be maintained throughout this project. All products will be placed in locked cages and cabinets between purchasing, XRF screening, and shipment of samples to the laboratory. Ecology staff will use MEL's chain of custody form for samples sent to the laboratory.

8.7 Field log requirements

Photographs, receipts, and store information will be stored in the Product Testing Database upon return from purchasing events.

8.8 Other activities

Product Collection

Ecology staff will purchase products "off the shelf" from Puget Sound area stores and through on-line retailers. Large chain retailers and discount stores will be targeted. The practice of statewide distribution by most of the retail chain stores ensures that products purchased from Puget Sound area stores are representative of products sold across the state.

After products are collected, they will be brought back to Ecology headquarters and assigned a unique sample identification number. Photos and descriptive notes will be recorded. Information such as the type of advertisement used to sell the product and where in the store the product was located will also be recorded to help ensure the product was intended for children within a given age group.

Product Isolation

Ecology staff will remove products from their original packaging and isolate individual product components prior to XRF screening and laboratory testing. Isolation of product components for clothing articles will consist of identifying areas of separate colors, textures, or fabric material and separating them from the rest of the garment. Footwear and accessory components will be identified as any part having a distinct color, material, or function from the rest of the product. Sample preparation will be done on a clean bench lined with aluminum foil by staff wearing powder-free nitrile gloves. All components will be removed with stainless steel tools, e.g., scissors or knives). Tools will be decontaminated at the beginning and ending of each day by scrubbing with Liquinox© and rinsing with deionized water. Between samples, isopropyl alcohol wipes will be used to clean the tools.

XRF Screening and Sample Selection

All isolated product components will be screened using a Niton XL3 XRF analyzer, following the instrument manufacturer recommendations and procedures described in Ecology's Product Testing SOP (van Bergen, 2014). XRF measurements will be made on components placed inside a bench-top stand for 120-second intervals. A previous Ecology study found that XRF measurements could be useful as a screening tool to identify products that warrant further laboratory analysis of metals, provided the product is separated into isolated components first and measured in a stand for at least 60 seconds (Furl et al., 2012).

Metal and chlorine readings from the XRF analyzer will be used as a screening tool for selection of product components to be forwarded to the laboratory for metals and phthalates. Components with XRF measurements at or above the screening levels in Table 6 will be forwarded to the laboratory for analysis. If more samples contain target elements above the selection criteria, then samples will be prioritized for analysis based on the highest concentrations. Samples will be selected across the range of metals.

Chlorine measurements will be used to identify components that are made of polyvinyl chloride (PVC). Phthalates are sometimes added to PVC as plasticizers, and so selection for laboratory phthalates samples will be based on high levels of chlorine readings. The XRF analyzer can only detect high levels (>15%) of chlorine, indicating presence of PVC, and cannot detect phthalates directly. Therefore, the measurement of high levels of chlorine by XRF will serve as a screening tool only, to prioritize samples selected for laboratory analysis of phthalates.

Table 6. XRF Screening Levels for Metals and Chlorine.

Element	XRF Screening Level (ppm)
Antimony	50
Arsenic	50
Cadmium	20
Cobalt	50
Lead	45
Mercury	NL
Molybdenum	50
Chlorine	150,000*

NL = no limit
* XRF instrument limit of detection for chlorine

Ecology staff will also review the CPSA manufacturer reporting database and existing product testing data in the literature. Product types that have been reported by manufacturers or found by other researchers to contain the chemicals of interest will be selected for laboratory analysis of ethylene glycol, styrene, MEK, D4, and 4-nonylphenol. The database and literature review will also help inform selection of samples for phthalates analysis.

9.0 Measurement Methods

9.1 Field procedures table/field analysis table

Not applicable.

9.2 Lab procedures table

Table 7. Lab Procedures.

Analyte	Samples (number/arrival date)	Expected Range of Results (ppm)	Matrix	RL (ppm)	Preparation Method	Analysis Method	Analysis Instrument
Metals (except Hg)	50, 11/17/14	<1 - 1,000	Fabric	1.0	EPA 3052	EPA 200.8	ICP-MS
			Plastic	1.0	EPA 3052	EPA 200.8	ICP-MS
Metals (Hg)	50, 11/17/14	<1 - 1,000	Fabric	1.0	EPA 3052	EPA 200.8	ICP-MS
			Plastic	1.0	EPA 3052	EPA 200.8	ICP-MS
Phthalates	50, 11/17/14	<5 - 50,000	Fabric	5.0	EPA 3546 mod	EPA 8270D	GC-MS
			Plastic	50	EPA 3546 mod	EPA 8270D	GC-MS
Ethylene Glycol	50, 11/17/14	<20 - 1,000	Fabric	20	lab-specific	EPA 8015C	GC-FID
			Plastic	20	lab-specific	EPA 8015C	GC-FID
Styrene	50, 11/17/14	<1 - 1,000	Fabric	1.0	EPA 3050B mod	EPA 8260C	GC-MS
			Plastic	1.0	EPA 3050B mod	EPA 8260C	GC-MS
MEK	50, 11/17/14	<1 - 1,000	Fabric	1.0	EPA 3050B mod	EPA 8260C	GC-MS
			Plastic	1.0	EPA 3050B mod	EPA 8260C	GC-MS
D4	50, 11/17/14	<50 - 1,000	Fabric	50	lab-specific	lab-specific	GC-MS
			Plastic	50	lab-specific	lab-specific	GC-MS
4-Nonylphenol	50, 11/17/14	<50 - 1,000	Fabric	50	EPA 3546 mod	EPA 8270D	GC-MS
			Plastic	50	EPA 3546 mod	EPA 8270D	GC-MS

9.3 Sample preparation method(s)

Individual component samples selected for laboratory analysis may need to be reduced in size depending on the material of the sample and laboratory requirements. When necessary, staff will reduce the product part in size by cutting the material into approximately 2 cm x 2 cm pieces using stainless steel tools (such as scissors or snips). Chain-of-custody will be recorded throughout sample processing, screening, shipment, and laboratory analysis. Detailed product processing procedures are described in Ecology's Product Testing SOP (van Bergen, 2014).

Samples consisting of plastic will be cryomilled prior to analysis. Cryomilling is the process of reducing a sample to very small particle sizes (~5-50 microns) by lowering the product to cryogenic temperatures and mechanically milling it with a stainless steel magnetic shaker. This process provides a homogenous, finely divided solids sample necessary for efficient extraction. Manchester Environmental Laboratory (MEL) will conduct the cryomilling on all samples where physically possible.

The entire product component that was isolated prior to XRF screening will be placed in the sample jar for laboratory analysis. If the component is too large, a representative section from the upper right hand corner of the material will be selected.

9.4 Special method requirements

The method for D4 analysis is a non-standard method. MDL studies have been carried out for solids (sediments and fish tissue), but not for fabric or plastic matrices. For this study, the product samples will be analyzed by the method developed for environmental solids. The extraction procedure for sediments will be used. The project manager will review the data to determine whether the data quality meet the goals of this study.

4-nonylphenol is a technical mixture of isomers, which the analytical instrument being used (GC/MS) cannot distinguish between. Therefore, the lab will report a sum of branched isomers under CAS number 84852-15-3, and the linear 4-nonylphenol under CAS number 104-40-5. All results will be qualified "J" as estimates because of the analytical uncertainty of not being able to distinguish individual isomers.

9.5 Lab(s) accredited for method(s)

Manchester Environmental Laboratory will conduct all analyses except for D4. A laboratory accreditation waiver will be obtained for the analysis of D4, as there is currently no accreditation for this parameter in solid matrices.

10.0 Quality Control (QC) Procedures

10.1 Table of field and laboratory QC required

Table 8 outlines the laboratory quality control (QC) samples planned for this project. QC tests will include one method blank, laboratory control sample (LCS), LCS duplicate, matrix spike, and laboratory duplicate per analysis batch of 20 samples or less.

Laboratory QC procedures for cryomilling preparation will include: (1) rinsing the cryomill with deionized water and reagents specified by the laboratory between each sample and (2) testing a rinse blank per batch of 20 samples processed. One cryomill rinseate per batch will be analyzed for metals and phthalates.

Table 8. Quality Control Tests.

Analyte	Cryomill Rinseates	Method Blank	Laboratory Duplicate	Laboratory Control Sample	Matrix Spike	Matrix Spike Duplicate	Surrogates
Metals	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	n/a
Phthalates	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample
Ethylene Glycol	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	n/a
Styrene	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample
MEK	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample
D4	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample
4-Nonylphenol	1/batch	1/batch	1/batch	1/batch	1/batch	1/batch	every sample

XRF QC will include measurement of metal and plastic duplicates and standards (provided by the manufacturer) after every 25 samples, as outlined in the Product Testing SOP (van Bergen, 2014). Since the XRF analysis is being used as a screening tool only, no XRF measurement quality objectives (MQOs) are outlined in this project plan. Ecology staff will follow QC procedures documented in the Product Testing SOP.

10.2 Corrective action processes

The project manager will work closely with the contract laboratory and the MEL QA Officer conducting the data review to examine data that fall outside of QC criteria. The project manager will determine whether data should be re-analyzed, rejected, or used with appropriate qualification.

If a cryomill rinseate blank identifies cross-contamination as a result of carryover in the cryomill, the affected samples will be qualified following the National Function Guidelines for organic data (EPA, 2014). Depending on the degree of contamination, the laboratory may be required to reanalyze the affected samples.

11.0 Data Management Procedures

11.1 Data recording/reporting requirements

All project data will be stored in Ecology's Product Testing Database. The database will hold product descriptions, purchase receipts, photos of products, and laboratory data and case narratives. The data will be viewable by the public through an external search application at: https://fortress.wa.gov/ecy/ptdbpublicreporting/.

11.2 Laboratory data package requirements

MEL will provide case narratives to the project manager, describing the quality of MEL and contract laboratory 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.

11.3 Electronic transfer requirements

Case narratives in PDF format, and electronic data deliverables in an Excel spreadsheet format, will be sent to the project manager via email.

11.4 Acceptance criteria for existing data

Not applicable.

11.5 EIM/STORET data upload procedures

Not applicable. Section 11.1 describes the database where data will be stored for this project.

12.0 Audits and Reports

12.1 Number, frequency, type, and schedule of audits

MEL and contracted laboratories must participate in performance and system audits of their routine procedures. No audits are planned specifically for this project.

12.2 Responsible personnel

Not applicable.

12.3 Frequency and distribution of report

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

- The types of products purchased.
- Results of laboratory analyses.
- Statistical summary of laboratory results.

12.4 Responsibility for reports

See Section 5.1.

13.0 Data Verification

13.1 Field data verification, requirements, and responsibilities

Not applicable.

13.2 Lab data verification

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.

13.3 Validation requirements, if necessary

Not applicable.

14.0 Data Quality (Usability) Assessment

14.1 Process for determining whether project objectives have been met

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 final report.

14.2 Data analysis and presentation methods

The final report will include a statistical summary of the results. Summary statistics, such as minimum, maximum, median, and frequency of detection will be presented in a table.

14.3 Treatment of non-detects

Laboratory data will be reported down to the reporting limit, with an associated "U" or "UJ" qualifier for non-detects. No statistical tests requiring non-detect substitutions will be conducted for this study.

14.4 Sampling design evaluation

The number and type of samples collected will be sufficient to meet the objectives of this project.

14.5 Documentation of assessment

Documentation of assessment will occur in the final report.

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Appendix. Acronyms and Abbreviations

CSPA	Children's Safe Products Act
D4	Octamethylcyclotetrasiloxane
Ecology	Washington State Department of Ecology
MEL	Manchester Environmental Laboratory
MEK	Methyl ethyl ketone
MQO	Measurement quality objective
PVC	Polyvinyl Chloride
QA	Quality assurance
QC	Quality Control
RL	Reporting Limit
SOP	Standard operating procedures

Units of Measurement

ppm	parts per million

Quality Assurance Glossary

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

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

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

Bias: The difference between the population 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 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 is usable for intended purposes.
- J (or a J variant), data is estimated, may be usable, may be biased high or low.
- REJ, data is 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: The term split sample denotes when a discrete sample is further 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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