DEPARTMENT OF ECOLOGY
State of Washington

Quality Assurance Project Plan

Lead and Cadmium in School Supplies, 2021

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Quality Assurance Project Plan

Lead and Cadmium in School Supplies, 2021

by Kari Trumbull

April 2022

Approved by:

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EAP: Environmental Assessment Program, Department of Ecology

1.0 Table of Contents

List of Tables

2.0 Abstract

In partnership with the Washington State Attorney General's Office, the Washington State Department of Ecology will investigate lead and cadmium in school supply products. School supply products include pencil pouches/cases, book covers, backpacks, and other supplies marketed and sold as school supplies for use by a child 12 years of age or younger. Products that are available to Washington state residents in summer 2021, coinciding with the beginning of the next school year, will be purchased online and/or in retail stores.

3.0 Background

3.1 Introduction and problem statement

Children are at greater risk from exposure to toxic chemicals than adults, because they eat, drink, and breathe more in relation to their body size, and because exposure can occur through common development behaviors, such as biting, chewing, or sucking on toys and other products. Everyday use of products may increase a child's contact with toxic chemicals.

In children, lead is known to cause damage to the brain and nervous system resulting in slow growth and development, learning and behavior problems, along with hearing and speech problems (CDC, 2020a).

Lead has been used in products including paint, ceramics, pipes and plumbing materials, solders, gasoline, batteries, ammunition, and cosmetics (EPA, 2021). Lead compounds are used in plastic, such as polyvinyl chloride (PVC), as stabilizers to make plastic softer and more flexible (CDC, 2020b). Lead may also be found in paint on toys imported from other countries or older toys made in the United States.

Cadmium and cadmium compounds are known carcinogens (ATSDR, 2012). Long-term exposure to lower levels of cadmium in air, food, or water leads to a buildup of cadmium in the kidneys and damage to the kidneys. Other long-term effects include lung damage and fragile bones.

Cadmium is used in pigments for plastics, ceramic, glass, and enamels; as a stabilizer for PVC; and in alloys and coatings on steel and other non-ferrous metals (ATSDR 2012).

The Product Testing program at the Washington State Department of Ecology (Ecology) regularly conducts studies to support the Washington Children's Safe Products Act (CSPA), Chapter 70A.430 Revised Code of Washington (RCW). Studies are designed to select, purchase, and analyze children's products for the presence of restricted toxic chemicals and Chemicals of High Concern to Children (CHCCs).

CSPA sets limits on the use of lead and cadmium (among other chemicals, e.g. six phthalates and five flame retardants[1]) in children's products offered for sale, sold, or distributed in Washington state. CSPA limits the use of total lead at 90 parts per million (ppm) and total cadmium at 40 ppm in children's products. The law also requires manufacturers to report if their children's

[1] In 2017 CSPA was amended to include limits on five flame retardants in children's products and residential upholstered furniture.

products contain any of the CHCCs listed in Chapter 173-334 Washington Administrative Code (WAC).

At the federal level, the Consumer Product Safety Commission (CPSC) administers, and has primary responsibility for enforcing, the Consumer Product Safety Improvement Act (CPSIA). The CPSIA sets its own limits on lead and cadmium (among other chemicals, e.g. phthalates, other metals) in certain categories of children's products (CPSC, 2021a).

Under CPSIA, children's products must not contain more than 100 ppm total lead content in accessible parts. Also, no children's products may contain a concentration of lead greater than 90 ppm in paint or any similar surface coatings. A limit of 75 ppm of soluble cadmium content is required for accessible substrates in toys, including accessible glass, metal, and ceramic toys or small parts of toys (or 50 ppm for modeling clays that are part of toys).

The Product Testing Program at Ecology initially conducted a study in 2015, then partnered with the Washington State Attorney General's Office to conduct additional studies in 2017, 2018, and 2019 to assess the levels of lead and cadmium in school supply products (see Section 3.2.2).

The Attorney General's Office and Ecology partnered again in 2021 to continue investigating lead and cadmium in school supply products for this study. Products include pencil pouches/cases, book covers, backpacks, and other supplies marketed and sold as school supplies for use by children 12 years of age or younger. Products available to Washington state residents will be purchased online and/or in retail stores. This quality assurance project plan (QAPP) describes the procedures for conducting this 2021 product testing study for lead and cadmium in school supplies.

3.2 Study area and surroundings

Products available to Washington state residents, including those purchased in-store and online, will be assessed for inclusion in this study. The practice of purchasing products from larger chain stores and online is used to generally reflect merchandise sold and available to residents across Washington state.

3.2.1 History of study area

Products purchased and collected during this study will be limited to the selection of currently available products in Washington stores and online at the time of the acquisition.

3.2.2 Summary of previous studies and existing data

Ecology's Product Testing program regularly conducts studies to evaluate children's products for the presence of restricted toxic chemicals and CHCCs to support CSPA (RCW 70A.430 and WAC 173-334).

In 2014 and 2015, Ecology designed a study around seven seasonal events to assess products that may be more readily available or only available during holidays and specific times of year. During the 2015 Back to School seasonal study, three pencil pouches and two book covers were found to exceed the CSPA limit of 90 ppm for lead (Trumbull et al., 2017). Cadmium was also tested for and was not detected above the 40 ppm CSPA limit in these five school supply products. Ecology's 2015 study demonstrated that certain school supplies that appeared to be marketed to children contained high concentrations of lead.

In 2017, the Washington State Attorney General's Office and Ecology partnered to conduct a follow-up study to evaluate school supply products similar to those found to contain lead in the 2015 study (Sekerak, 2017). The study focused on testing for lead and cadmium in the five pencil pouches/cases and book covers from the 2015 study, if available, and additional school supply products that were manufactured by the same companies, sold by the same retailers, or appeared to have a similar function or purpose.

A total of 60 product component samples were tested from 45 school supply products in the 2017 study. Of the 60 product component samples, 31 samples (from 23 of the 45 products) contained either lead, cadmium, or both metals above the CSPA limits of 90 ppm for lead and 40 ppm for cadmium. All five of the original 2015 Back to School study products were purchased, tested, and found to contain similar levels of lead as they did in 2015.

In 2018, the Attorney General's Office and Ecology again partnered to perform follow-up testing for lead and cadmium on school supply products previously tested in 2015 and 2017 (Sekerak, 2019). The 2018 study prioritized follow-up testing on pencil pouches/cases and book covers that were previously found to contain lead and cadmium above the CSPA limits and were still available for sale in Washington state.

A total of 76 product component samples were tested from 47 school supply products in the 2018 study. Of the 76 product component samples, 67 samples (from 38 of the 47 products) contained either lead, cadmium, or both metals above the CSPA limits.

In 2019, the Attorney General's Office and Ecology again partnered to perform follow-up testing for lead and cadmium on school supplies tested in the 2015, 2017, and 2018 studies, if available, and to investigate new school supply products for children (Trumbull, 2019).

In the 2019 study, 76 product component samples were tested from 76 school supply products (only one product component or composite of components from an individual product was tested as a sample). Of the 76 product component samples, 72 samples (from 72 of the 76 products) contained either lead, cadmium, or both metals above the CSPA limits. Many school supply products that appeared the same or very similar to the products tested in the previous 2015, 2017, and/or 2018 studies were still available for purchase and found to contain either lead, cadmium, or both metals above the CSPA limits.

3.2.3 Parameters of interest and potential sources

Lead and cadmium will be analyzed in product samples of school supplies.

Lead has been used in products, including paint, ceramics, pipes and plumbing materials, solders, gasoline, batteries, ammunition, and cosmetics (EPA, 2021). Lead compounds are used in plastic, such PVC, as stabilizers to make plastic softer and more flexible (CDC, 2020b). Lead may also be found in paint on toys imported from other countries or older toys made in the United States before lead paint was banned in 1978 (CPSC, 1977). Lead is also used in making alloys with other metals.

Lead and lead compounds are probable human carcinogens, based on evidence from studies in humans and more evidence from animal studies (ATSDR, 2020). Lead toxicity targets the nervous system, whether it enters the body through breathing or swallowing. At high levels of exposure, lead can severely damage the brain and kidneys and ultimately cause death. Kidney tumors have developed in laboratory animals that had been given large doses of some lead compounds.

In children, lead is known to cause damage to the brain and nervous system, resulting in slow growth and development, learning and behavior problems, along with hearing and speech problems (CDC, 2020a).

Cadmium is used in pigments for plastics, ceramic, glass, and enamels; as a stabilizer for PVC; and in alloys and coatings on steel and other non-ferrous metals (ATSDR, 2012).The greatest use of cadmium is in nickel-cadmium batteries.

Cadmium and cadmium compounds are known carcinogens (ATSDR, 2012). Long-term exposure to lower levels of cadmium in air, food, or water leads to a buildup of cadmium in the kidneys and damage to the kidneys. Other long-term effects include lung damage and fragile bones. Cadmium damages male and female reproductive organs and produces lung cancer and other cancers by multiple routes of exposures in laboratory animals. Young animals exposed to cadmium before birth have shown impaired growth and neurobehavioral effects.

3.2.4 Regulatory criteria or standards

Information provided in this section focuses on the regulatory environment for lead and cadmium in children's products in Washington state and U.S. federal law.

Washington state's CSPA sets limits on the use of lead and cadmium (among other chemicals, e.g. six phthalates and five flame retardants[2]) in children's products sold in or to those residing in Washington, Chapter 70A.430 RCW. CSPA limits the use of total lead at 90 ppm and total cadmium at 40 ppm in children's products. The law also requires manufacturers to report if their children's products contain Chemicals of High Concern to Children (CHCCs), Chapter 173-334 WAC.

At the federal level, the CPSC administers, and has primary responsibility for enforcing, the Consumer Product Safety Improvement Act (CPSIA). The CPSIA sets its own limits on lead and cadmium (among other chemicals, e.g. phthalates, other metals) in certain categories of children's products (CPSC, 2021a).

Under CPSIA, children's products must not contain more than 100 ppm total lead content in accessible parts. Also, no children's products may contain a concentration of lead greater than 90 ppm in paint or any similar surface coatings. A limit of 75 ppm of soluble cadmium content is required for accessible substrates in toys including accessible glass, metal, and ceramic toys, or small parts of toys (or 50 ppm for modeling clays that are part of toys).

[2] In 2017 CSPA was amended to include limits on five flame retardants in children's products and residential upholstered furniture.

4.0 Project Description

Ecology's Product Testing program has previously conducted studies to assess the levels of lead and cadmium in school supply products (see Section 3.2.2). This QAPP describes the standardized procedures for conducting product testing studies for lead and cadmium to further study the extent to which school supply products contain these chemicals.

Beginning in August 2021, a study will be conducted to assess the levels of lead and cadmium in school supply products. Data from the School Supplies 2021 study will be provided to the Washington State Attorney General's Office.

Ecology will focus the purchasing effort on pencil pouches and pencil cases,[3] book covers, and backpacks previously tested in the 2015 (Trumbull et al., 2017), 2017 (Sekerak, 2017), 2018 (Sekerak, 2019), and/or 2019 (Trumbull, 2019) product testing studies for school supplies. The 2021 study may also include investigations on other supplies marketed and sold as school supplies for use by a child 12 years old or younger. Ecology may purchase school supplies both online and in retail stores.

4.1 Project goals

The School Supplies 2021 study is being conducted with the following goals:

- Assess lead and cadmium concentrations in pencil pouches/cases, book covers, and backpacks that are the same or similar to previously tested school supplies in an Ecology product testing study.
- Assess lead and cadmium concentrations in pencil pouches/cases, book covers, backpacks, and other products sold as school supplies not previously tested in an Ecology product testing study.
- Provide data for the Washington State Attorney General's Office.

4.2 Project objectives

The following objectives will be carried out to meet the 2021 study goals:

- Purchase products sold as school supplies for children 12 years old or younger available for sale in Washington state.
- Analyze lead and cadmium in product component samples from school supply products.

4.3 Information needed and sources

In general, products selected for analysis in a study will be identified based on research of manufacturing processes of products, known to be present in similar products, and from sources such as peer-reviewed journal articles, Safety Data Sheets (SDS), product and ingredient labels, and public databases, such as the Consumer Product Information Database and High Priority Chemicals Data System (previously CSPA Manufacturer Reporting Database).

[3] Pencil pouches and pencil cases will be collectively referred to as pencil pouches/cases for the remainder of this document.

4.4 Tasks required

The study will include the following tasks:

- Purchase up to 50 school supply products available for sale online and/or in retail stores in Washington State.
- Record purchase and product information along with product photos in Ecology's Product Testing Database (PTDB).
- Deconstruct product components from school supply products and prepare for X-ray fluorescence (XRF) screening.
- Screen product components for estimated levels of lead and cadmium using the XRF analyzer.
- Review XRF screening levels of lead and cadmium to identify and prioritize product component samples for lab analysis.
- Process product components from school supply products into samples for lab analysis.
- Submit up to 50 product component samples to Ecology's Manchester Environmental Laboratory (MEL) for analysis of lead and cadmium.
- Submit lead and cadmium laboratory data packages to MEL's Quality Assurance (QA) Coordinator for data verification.
- Enter final lead and cadmium laboratory data in the PTDB.
- Conduct a QA review of the analytical data and PTDB data entries.
- Transfer initial findings to the Washington State Attorney General's Office.
- Analyze study data and write a technical memorandum to accompany the final data set. This memo will document methods, data quality assessment, and results.

4.5 Systematic planning process

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

5.0 Organization and Schedule

5.1 Key individuals and their responsibilities

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

Table 1. Organization of project staff and responsibilities.

Staff[1]	Title	Responsibilities
William Sherman Attorney General's Office Phone: 206-442-4485	External Client	Along with other team staff, clarifies scope of the study. Provides review of the QAPP and approves the final QAPP.
Kari Trumbull Toxic Studies Unit SC Section, EAP Phone: 360-407-6093	Project Manager	Writes the QAPP. Leads product sampling strategy, product purchasing, and prioritizing samples for lab analysis. Assists with tracking online purchases, photographing products, sample screening, sample processing, chain-of–custody, and transport of samples to/from the laboratory, as needed. Conducts QA review of lab data and PTDB data entry and study, analyzes and interprets all data, and enters lab data into PTDB. Writes the draft and final technical memorandum.
Prajwol Tuladhar Toxic Studies Unit SC Section, EAP Phone: 360-407-6745	Project Assistant	Assists to prepare the QAPP, product sampling strategy, product purchasing, and prioritizing samples for lab analysis. Leads tracking online purchases (including product packaging and packing receipts), product data entry into internal PTDB, photographing products, sample screening, sample processing, chain-of–custody, and transport of samples to/from the lab. Assists to analyze and interpret data and to write the draft technical memorandum.
James Medlen Toxic Studies Unit SC Section, EAP Phone: 360-407-6194	Unit Supervisor for the Project Manager	Provides internal review of the QAPP, approves the budget, and approves the final QAPP. Tracks project progress, and reviews the draft and final technical memorandum.
Jessica Archer SC Section, 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.
Alan Rue MEL, EAP Phone: 360-871-8801	Director	Reviews and approves the final QAPP.
Christina Frans MEL, EAP Phone: 360-871-8829	Quality Assurance Coordinator	Conducts the internal Ecology data verification process.
Arati Kaza Phone: 360-407-6964	Ecology Quality Assurance Officer	Reviews and approves the draft QAPP and the final QAPP. May perform routine audit of product testing process during the study.

[1]All staff, except the client, are from the Department of Ecology
EAP: Environmental Assessment Program
MEL: Manchester Environmental Laboratory
PTDB: product testing database
QA: Quality Assurance
QAPP: Quality Assurance Project Plan
SC: Statewide Coordination

5.2 Special training and certifications

Ecology staff assisting on product testing studies will have undergone training documented by completing the Product Testing Preparation Staff Training Checklist. Training includes reviewing the study-specific QAPP, current approved product testing standard operating procedures (SOPs), and the location of personal protective equipment and safety equipment (e.g. first aid kit, eye wash station). Product testing training is outlined in Ecology's Product Testing SOP (PTP001) for Sample Collection and Processing, Version 2.1 (Wiseman, 2021).

5.3 Organization chart

Table 1 lists the key individuals and responsibilities.

5.4 Proposed project schedule

Tables 2 – 5 list key activities, due dates, and lead staff for the 2021 study.

Table 2. Schedule for completing product collection, data entry, and screening

Task	Due date	Lead staff
Product purchase complete	September 2021	Kari Trumbull
Product data entry complete	January 2022	Prajwol Tuladhar
Screening complete	February 2022	Prajwol Tuladhar
Product data entry QA complete	March 2022	Kari Trumbull

QA: Quality Assurance

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

Task	Due date	Lead staff
Samples sent to the lab complete	March 2022	Prajwol Tuladhar
All lab analyses complete	April 2022	Heidi Chuhran

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

Task	Due date	Lead staff
Lab data verification complete	May 2022	Christina Frans
Lab data QA reviewed	June 2022	Kari Trumbull
Lab data loaded into internal PTDB	June 2022	Kari Trumbull
PTDB study QA review complete	June 2022	Kari Trumbull
Preliminary data transfer to client	June 2022	Kari Trumbull

QA: Quality Assurance
PTDB: Product Testing Database

Table 5. Schedule for final technical memorandum

Task	Due date	Lead staff
Draft due to supervisor/peer reviewer	July 2022	Kari Trumbull
Draft due to publications team	Aug 2022	Kari Trumbull
Technical memorandum due to AGO	Sept 2022	Kari Trumbull

AGO: Attorney General's Office

5.5 Budget and funding

The estimated study budget is displayed in Tables 6 and 7. Funding for this study is provided by the Attorney General's Office.

Table 6. 2021 Study budget for purchasing products

Activity	Number of Products	Field QC Samples*	Estimated Cost per Product	Subtotal Cost
Purchase school supply products#	50	0	$15.00	**$750.00**

*Product collection and sample processing QC samples are not planned for this study.
#Some products may be purchased in replicate (more than one product of the same product) to provide a sufficient amount of sample for lab analysis and/or field sample duplicates.
QC: Quality Control

Table 7. 2021 Study budget for laboratory analysis

Lab Analysis	Number of Lab Samples	Lab QC Samples*	Estimated Cost Per Sample	Subtotal Cost
Metal: lead, cadmium digestion and analysis	50	9	$100.00	**$5,900.00**

Study Total: $6,650#+

*Quality Control (QC) samples in this table are those not provided free of charge (matrix spike, matrix spike duplicate, and sample duplicate).
#Estimate based up to 50 purchased products and 50 samples plus nine QC samples.
+ Not to exceed $10,000.

6.0 Quality Objectives

6.1 Data quality objectives

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

6.2 Measurement quality objectives

6.2.1 Targets for precision, bias, and sensitivity

Table 8 shows MQOs for analysis of lead and cadmium, expressed in terms of acceptable precision, bias, and sensitivity. MQOs are consistent with previous Ecology school supply studies.

Table 8. Measurement quality objectives

Analyte	LCS (% recovery)	Matrix Spikes (% recovery)	Sample and LCS Duplicates (RPD)	Matrix Spike Duplicates (RPD)	Lowest Concentration of interest (ppm)
Metals: Lead, Cadmium	85-115%	75-125%	≤ 20%	≤ 20%	1.0

LCS: Laboratory control standard
RPD: Relative percent difference
ppm: parts per million

6.2.1.1 Precision

Precision is a measure of the variability in the results of replicate measurements due to random error. Laboratory analysis precision will be assessed through lab duplicate samples for all matrices and analyses. Table 8 shows MQOs for laboratory control standard duplicates and sample duplicates.

6.2.1.2 Bias

Bias is the difference between the sample mean and the true value. Lab analysis bias will be assessed through laboratory control standards. MQOs for percent recoveries are shown in Table 8.

6.2.1.3 Sensitivity

Sensitivity is a measure of the capability of an analytical method to detect a substance above background level and is often described as a detection or reporting limit. The expected lowest concentration of interest for lead and cadmium is shown in Table 8.

6.2.2 Targets for comparability, representativeness, and completeness

6.2.2.1 Comparability

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

6.2.2.2 Representativeness

Products purchased and collected for this study will be representative of those available to Washington state residents and agencies.

6.2.2.3 Completeness

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

6.3 Acceptance criteria for quality of existing data

Not applicable to this study.

6.4 Model quality objectives

Not applicable to this study.

7.0 Study Design

7.1 Study boundaries

School supply products available to Washington state residents, either in-store or online, may be purchased for selection in the 2021 study (section 3.2). Product selection of school supplies marketed and sold for use by children will remain consistent with the strategy used in previous Ecology's product testing school supply studies (Trumbull et al., 2017; Sekerak, 2017; Sekerak, 2019; Trumbull, 2019). School supplies with the following characteristics will be considered for purchase:

- Brightly colored.
- Decorated or embellished with features that might appeal to a child (age 12 years or younger).
- Contain childish themes or are sized more appropriately for use by a child.

School supply products that were detected to contain lead or cadmium[4] in previous Ecology's product testing school supply studies will be prioritized for purchasing. Products from the same manufacturer of the priority products may be purchased in place of original products if the original products are unavailable. Other school supply products not previously assessed for lead and cadmium may be investigated after a reasonable effort has been made to collect the priority products.

The purchase of children's school supplies online and/or in-store will begin in the weeks following the July 4th holiday when retailers increase types of merchandise geared toward the upcoming school year. For in-store purchases, an assessment of the retail store location will include vulnerable communities.

Products purchased for the study will be documented in the product testing database (section 8.5) then deconstructed into product components for XRF screening (section 9.2). XRF screening levels for lead and cadmium will be used to prioritize specific component samples (for example, a metal zipper or fabric case material) to send for lab analysis. Multiple component samples, representing different components from one product, may be submitted to the lab for testing. Product components selected for lab analysis will be processed into product component samples (section 9.2), then sent to the analytical lab for lead and cadmium analysis.

[4] Detections above the Children's Safe Products Act limits of 90 ppm for lead and 40 ppm for cadmium are used to characterize a product as a priority target product.

7.2 Field data collection

Equity Considerations in Sample Collection

Ecology is committed to the principles of equity and environmental justice and shares the EPA's goal "to provide an environment where all people enjoy the same degree of protection from environmental and health hazards and equal access to the decision-making process to maintain a healthy environment in which to live, learn, and work" (Ecology and EPA, 2019).

Product categories in a study will be evaluated to include products, as available during purchase and collection, that are accessible and/or relevant to diverse ethnic, cultural, and economic groups in Washington State.

7.2.1 Sampling locations and frequency

Products will be purchased from retail stores and/or online through internet retailers, including marketplace sellers, during the product purchasing timeframe. In-store and online purchases will be coordinated to minimize the frequency of product purchasing events. Locations of products purchased will be recorded in the Product Documentation Log (section 8.7) and in the product testing database.

7.2.2 Field parameters and laboratory analytes to be measured

The metal analytes to be analyzed in product component samples for this study are listed in Table 9. The product component samples containing the analytes may be composed of complex matrices such as metal, plastic, and/or fabric.

Table 9. Analytes to be measured.

Analyte Group	Analyte Name	Abbreviation	CAS Registry Number
Metal	Lead	Pb	7439-92-1
Metal	Cadmium	Cd	7440-43-9

CAS: Chemical Abstracts Service

7.3 Modeling and analysis design

Not applicable to this study.

7.3.1 Analytical framework

Not applicable to this study.

7.3.2 Model setup and data needs

Not applicable to this study.

7.4 Assumptions underlying design

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

7.5 Possible challenges and contingencies

7.5.1 Logistical problems

Limitations in the selection of available products during product purchase and collection may require extending the timeframe and/or planning additional study events. Product unavailability may occur from products that are no longer manufactured or out of stock.

7.5.2 Practical constraints

Limitations in receiving products through online purchases may occur due to unforeseen product unavailability and/or shipping delays after purchase. Some product purchases may need to be cancelled if the products are on back-order and not be received within the proposed timeframe and/or extending the timeframe. Products may be reordered through a different online retailer if available.

7.5.3 Schedule limitations

Limitations in the availability of project assistants' schedule, laboratory digestion and analysis of complex product matrices, and the data verification process of complex data may impact the study and extend the proposed schedule.

8.0 Field Procedures

8.1 Invasive species evaluation

Not applicable to this study.

8.2 Measurement and sampling procedures

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

- Ecology's Product Testing SOP (PTP001) for Product Collection and Sample Processing, Version 2.1 (Wiseman, 2021).
- Ecology's Product Testing SOP (PTP002) for Database Data Entry and Data Entry Quality Assurance, Version 2.1 (Wiseman, 2022a).
- Ecology's Product Testing SOP (PTP003) for the Operation of the Thermo Fisher Scientific Niton XL3t 700 X-Ray Fluorescence Analyzer (XRF), Version 2.0 (Wiseman, 2022b).
- Ecology's Product Testing SOP (PTP004) for the Operation of the Thermo Fisher Scientific Niton XL3T GOLDD+ X-ray Fluorescence Analyzer, Version 1.0 (Wiseman, 2022c).

Product collection may occur by purchasing products in stores or by purchasing products online. Ecology's product testing staff will take a product collection tote containing the necessary tools and equipment to be used for product collection. The tote will include Product Documentation Log (section 8.7); product testing camera; large, medium, and small plastic sample bags to store products' pens and labels; and gloves. Products purchased in stores will be brought back to the Ecology product testing processing room and secured in a locked cabinet.

Online purchasing will be captured using TechSmith Camtasia® Version 2018.0. Products purchased online are delivered to Ecology's shipping and receiving department and stored in a locked location. Packages will be collected by product testing staff then secured in a locked cabinet in the product testing processing room.

Each purchase (in store and online) will be documented and recorded in the product testing database. Products will be photographed, recorded into the product testing database, placed in individual plastic sample bags labeled with a product testing Ecology identification number (ECY ID, see section 8.5), and stored in labeled totes in locked cabinets until sample processing. Gloves will be worn (and replaced by a new pair between handling different products) when separating, recording, and photographing products.

The processing and preparation of products into product component samples for lab analysis is discussed in the sample preparation methods section (section 9.2) of this QAPP.

8.3 Containers, preservation methods, holding times

Sample containers, minimum quantity, storage and preservation, and holding times for sample matrices are shown in Table 10. Hand-reduced lab samples will be stored in certified clean wide-mouth glass jars with Teflon-lined lids.

There are no demonstrated maximum holding times or preservation methods for metals in products and product sample matrices. Samples can be stored at reduced temperatures prior to lab analysis and kept at ambient temperatures until time of disposal, after lab analysis is completed and the final data set is approved by the project manager.

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

Analyte	Matrix	Minimum Quantity^	Container	Sample Storage and Preservative*	Estimated Holding Time*
Metals: Lead, Cadmium	Metal, plastic, fabric	0.25 to 1 gram	4 to 8 oz. glass jar	Ambient to reduced temperature	1 year

^A greater minimum quantity may be needed for samples with lab sample duplicates and matrix spike/matrix spike duplicate samples.
*No demonstrated maximum holding times or preservation methods have been established for product matrices.

8.4 Equipment decontamination

All tools used in the preparation of product components into samples for XRF screening and processing product components into lab samples will be decontaminated using cleaning procedures from the Product Testing SOP for Product Collection and Sample Processing (SOP PTP001) and outlined below.

Product Testing Tool Cleaning Procedure:

- Tool cleaning is conducted in the Product Testing Preparation Room.
- Clean tools at the beginning of each day or as needed.
- Wear appropriate PPE (e.g. gloves, eyewear, and clean lab coat) while cleaning tools. Nitrile gloves are required for all tool decontamination processes.
- Set up a drying location for clean tools by placing a large piece of aluminum foil covered with Kimwipes™, or other pretested absorbent towels, on the precleaned countertop.
    - Clean countertop and work area surface with dilute 1% Liquinox® and DI water solution followed by a rinse with 24% ethanol in DI water.
- Wash the “Prep Room Clean Tool Bin” with dilute Liquinox® and DI water and rinse with 24% ethanol in DI water prior to use, then line with aluminum foil (dull side up) covered with a layer of Kimwipes™.
    - Use this bin to transport and store clean tools.
- Follow Steps 1 through 6 below to wash each tool individually until all tools are cleaned. Replace gloves, Kimwipes™, and aluminum foil, as necessary throughout the process, to prevent cross contamination.
    - Step 1: Spray a small amount of the dilute Liquinox® onto a clean scrub brush, and scrub each tool thoroughly for at least 30 seconds, or longer if there are visible pieces of product on the tool.

        - Rinse the scrub brush prior to cleaning the next tool, and set in pre-rinsed stainless bowl between uses.
    - Step 2: Rinse the tool, cutting edge up, with cold tap water to remove the cleaning solution, and follow with a DI water rinse.
    - Step 3: Spray trace amounts of a 10% nitric-acid-in-DI-water solution over the entire tool surface, rotating the tool to ensure the acid rinse is thorough, while cold tap water is running in the sink to dilute residual acid.
    - Step 4: Rinse tool thoroughly with DI water.
    - Step 5: Rinse tool with 24% ethanol in DI water solution to expedite drying.
    - Step 6: Place tool on Kimwipes™ layer over aluminum foil to air dry. Cover the tools with Kimwipes™ while air drying to avoid environmental contamination.
        - Place dry tools in the “Prep Room Clean Tool Bin.” Place all tools in the same direction (e.g. handles and cutting edges).
- Continue with the above process until all tools are clean.
- Tools may not be reused between processing different products and must be cleaned again following the above process.

8.5 Sample ID

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

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

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

8.6 Chain of custody

Chain of custody will be maintained for all samples throughout the study. Products collected for the study will be stored in locked cabinets in Ecology’s product testing processing room for the duration of the study. Samples will be stored in locked cabinets in Ecology’s product testing processing room until shipped to the analytical lab. Ecology staff will use the analytical lab’s chain of custody form (or MEL’s chain of custody form if one is not provided by the analytical lab) for shipment of product component samples to the lab.

8.7 Field log requirements

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

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

Advertisements, photos of product marketing, and other information gathered during product purchasing and collection will be recorded and uploaded or scanned into the product testing database.

8.8 Other activities

Web screen captures and web screen recordings will be collected during online purchasing using TechSmith Camtasia® Version 2018.0. This strategy is consistent with previous documentation during previous Ecology school supply studies.

9.0 Laboratory Procedures

9.1 Lab procedures table

Table 11 summarizes the sample matrices, number of samples, expected range of results, and reporting limits, as well as preparation and analytical methods.

It is anticipated that Ecology's Manchester Environmental Laboratory (MEL) will conduct the metal analysis. Samples for this study will be prepared by the U.S. Environmental Protection Agency (EPA) Method 3052, less the addition of hydrofluoric acid. Analysis of lead and cadmium will be performed in accordance with EPA Method 6020B. The procedures described below are consistent with those used in previous Ecology school supply studies.

Table 11. Measurement methods (laboratory).

Analyte	Sample Matrix	2021 Study Sample Number	Expected Range of Results^	Detection or Reporting Limit⁺	Preparation Method	Analytical Method
Metals: Lead, Cadmium	Metals, Plastics, Fabrics	50 samples	1 ppm to 8,560 ppm	1 ppm	EPA 3052*	EPA 6020B

^Based on data from previous Ecology product testing school supply studies.
⁺Individual reporting limits may vary based upon specific analyte and matrix type.
*Preparation method modified to omit the use of hydrofluoric acid (HF).
ppm: parts per million.

9.2 Sample preparation method(s)

The preparation of solid-type (i.e. metals, textiles, and plastics) product components into samples for XRF screening and processing product components into lab samples for lead and cadmium analysis will use procedures from the Product Testing SOPs PTP001 and PTP003 and/or PTP004 and are outlined below.

Solid-type products are deconstructed into individual components that comprise the product then screened using an XRF analyzer. For example, a 3-ring pencil pouch can be separated into at least 6 component samples: the pencil pouch fabric, zipper tape, zipper teeth, zipper slider, zipper pull, and metal grommet. The product components that are of interest for lab analysis are processed into samples. Multiple product component samples from one product may be submitted to the lab for testing.

Solid-type sample deconstruction for XRF screening:

- Wear clean nitrile gloves and a lab coat when handling products.
- Clean stainless steel table with dilute 1% Liquinox® solution and DI water followed by a rinse with 24% ethanol in DI water.
- Place a new piece of aluminum foil, large enough to place under the product that will be processed for a sample, on the table with dull side up.
- Place a layer of Kimwipes™ over the aluminum foil to create a workspace for product deconstruction.
- Set the product stored in an individual sample bag that will be deconstructed next to the clean Kimwipes™ and foil processing area and open the sample bag.

- Get a tool (i.e. scissors) cleaned following the tool cleaning procedure (section 8.4) and place on clean Kimwipes™ and foil processing area.
- Change gloves (change gloves before deconstruction of every product) and remove the product from open bag then place on clean processing area (Kimwipes™ and foil). Minimize excessive handling and contact of the product with gloved hands and the processing surface during product deconstruction.
- Deconstruct product into individual product components using the clean tool to isolate entire components (i.e. zipper slide) or enough of the component for a lab sample (i.e. strip of fabric). Components of a product for deconstruction and isolation are listed in the PTDB during product data entry documentation.
  - If additional components are identified and isolated in the deconstruction of the product that may be of interest to XRF screen, document in the PTDB.
- Place the isolated component into an appropriately sized zip-top sample bag labeled with the product component ID.
  - Thin materials (i.e. plastic and fabrics) should be folded or stacked to at least a centimeter (cm) or as thick as possible when placed in the sample bag.
- Clip together in numerical order all the labeled zip-top sample bags containing the isolated product component and place sample set back into the product sample bag with any remainder of the product.
- After completing deconstruction of a product, remove Kimwipes™ and foil then clean the stainless steel table using 24% ethanol in DI water.
- Replace foil and Kimwipes™ on workspace and gloves then continue the process to deconstruct the next product.
- Products will be placed on a new piece of Kimwipes™ over foil when not stored in individual sample bags.

XRF screening is conducted in the XRF isolation/shielding box with the isolated product component sample inside a sample bag placed over the measurement window. An image is captured with each XRF scan. Calibration verification standards are scanned before and after every scanning session along with after every 20 unique product component samples scanned. Errors encountered during scanning are documented in the XRF error log (e.g. component sample ID typos and incomplete scans). At the end of the scan session, typed narratives provide a discussion of issues during the XRF screening session. XRF screening data is reviewed and product component samples prioritized for lab analysis based on the lead and cadmium screening levels.

Solid-type sample processing for lead and cadmium analysis:

- Wear clean nitrile gloves and a lab coat when handling products.
- Clean stainless steel table with dilute 1% Liquinox® solution and DI water followed by a rinse with 24% ethanol in DI water.
- Place a new piece of aluminum foil, large enough to place under the product that will be processed for a sample, on the table with dull side up.
- Place a layer of Kimwipes™ over the aluminium foil to create a workspace for sample processing.

- Weigh an empty labeled sample jar and place jar on processing surface with lid set loosely on top of the jar.
- Set the product and/or product component that will be processed for a sample next to the clean Kimwipes™ and foil processing area and open the bag that contains it.
- Get a tool (i.e. scissors) cleaned following the tool cleaning procedure (section 8.4) and place on clean Kimwipes™ and foil processing area.
- Change gloves (change gloves before processing every sample) and remove the product or product component from open bag and place on clean processing area (Kimwipes™ and foil). Minimize handling and contact of the selected product component with gloved hands and the processing surface during processing into sample.
- Hand-reduce the sample of product component to at least approximately 2 millimeter by 2 millimeter (mm) in size into the sample jar using the clean tool.
- Weigh the jar and record the weight of final processed sample on label.
- Product component samples sent to the analytical lab will undergo acid digestion by modified EPA Method 3052 (hydrofluoric acid omitted) followed by analysis for lead and cadmium by EPA Method 6020B using ICP-MS.

9.3 Special method requirements

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

9.4 Laboratories accredited for methods

Ecology's Manchester Environmental Laboratory (MEL) is an Ecology-accredited lab for metal analysis by EPA Methods 3052 and EPA 6020B.

10.0 Quality Control Procedures

10.1 Table of field and laboratory quality control

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

Batches typically consist of matrix matched samples. A set number of lab QC samples are planned in the budget and not to be exceeded. A variety in product component sample matrices may result in more matrix matched batches with fewer samples which may exceed the budget for lab QC samples in order to meet the requirements in Table 12.

The analytical lab will consult with the project manager on the allocation of samples into batches and lab QC samples for each batch when a variety of product matrices are analyzed. The project manager will determine if a batch will include a variety of product matrices with the full set of lab QC samples or smaller matrix matched batches with a limited lab QC sample set. One full lab QC sample set for every 18 samples will be met, at a minimum, regardless of matrix.

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

Analyte	Lab Method Blanks	Lab Sample Duplicates	Lab Control Standards/ Lab Control Standard Duplicates	Lab Matrix Spikes/ Matrix Spike Duplicates
Metals: lead, cadmium	1/batch	1/batch	1 set/batch	1 set/batch

batch: 18 product component samples or fewer and typically matrix matched[5]

10.2 Corrective action processes

Deviations from this QAPP when conducting the described activities – including product purchase and collection, product documentation and data entry in the PTDB, and sample processing – will be discussed in the final technical memorandum. Substantial deviations will be described in a QAPP addendum, pre-approved by Ecology's QA Officer.

Deviations from the specified laboratory methods, QC criteria, or instances in which data results do not meet MQOs will be documented in the case narratives of the lab data packages and data verification package. The deviations will be described in the final technical memorandum. The project manager will determine appropriate corrective actions which may include samples re-sampled, re-analyzed, rejected, or used with appropriate qualification.

[5] Batch sizes will be a maximum of 18 product component samples to adjust for microwave prep method size limitations.

11.0 Data Management Procedures

11.1 Data recording and reporting requirements

Documentation of purchase and collection events will be recorded in the Product Documentation Log (section 8.7). Study data will be recorded in Ecology's internal product testing database (PTDB). Study data collected and recorded in the PTDB includes purchase receipts, products purchased (in store and online) and collected, product descriptions, product photos, description of product components, methods used to process product component samples, laboratory results, and case narratives.

All raw XRF screening data will be initially verified by the analyst for completeness and accuracy (per the applicable SOP: PTP003 and/or PTP004), and the data made available to the project manager for review prior to the lab analysis sample selection process.

Verified XRF screening results are uploaded to the internal PTDB, are available internally through XRF results searches, and can be exported out into Comma Separated Value (.CSV) files. Raw XRF spectrum/data files are stored in the internal PTDB as .NDT file attachments to uploaded XRF batches. Narratives attached to XRF batches provide a discussion of issues encountered during the XRF screening. XRF data are used for internal preliminary screening processes only and are not searchable on the external PTDB.

Laboratory data packages in electronic format will be sent to the project manager after analysis is complete by the analytical lab. The lab data packages will also be sent to the Ecology MEL Quality Assurance (QA) Coordinator for data verification. The project manager will conduct a QA review of the data and assess results for usability after data verification is complete (see Sections 13 and 14). The project manager will upload the final validated and approved data to the internal PTDB.

The project manager will compile and send an initial preliminary data set, in CSV format, to the Attorney General's Office upon completion of the QA review of the lab data and the PTDB study data (sections 12.3 and 12.4). A final data set will accompany the final technical memorandum and transferred to the Attorney General's Office via USB flash drive.

11.2 Laboratory data package requirements

After completing laboratory analysis, the analytical lab (it is anticipated that MEL will conduct the metal analysis) will deliver a Tier 4 Level data package in electronic format to the project manager and MEL's QA Coordinator. The analytical lab will submit lab data as a fully paginated and bookmarked comprehensive PDF format file with all required specific content, along with data in EDD format (.csv or .xlsx files). The data package must include all raw data and QA/QC documentation that would be needed to perform an independent review of the results. The documentation will include benchsheets, calibration reports, chromatograms, and spectra for all calibration standards and samples.

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

11.3 Electronic transfer requirements

Laboratory case narratives and data packages will be in PDF format and EDDs will be in a spreadsheet format that meets Ecology's product testing formatting requirements or alternative format approved by the project manager.

11.4 EIM/STORET data upload procedures

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

11.5 Model information management

Not applicable to this study.

12.0 Audits and Reports

12.1 Field, laboratory, and other audits

Analytical labs must participate in performance and system audits of their routine procedures.

The product testing process conducted at Ecology will be audited at a minimum of one audit a year.

12.2 Responsible personnel

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

12.3 Frequency and distribution of reports

At the earliest point after completion of the QA review of the lab data and the PTDB study data, the project manager will compile and send an initial preliminary data set, in CSV format, to the Attorney General's Office.

A final report summarizing the data and findings will be generated in the Ecology technical memorandum format. The final technical memo will include at a minimum:

- An overview of the study.
- Goals and objectives of the study.
- General description of products purchased or collected.
- Discussion of methods, data quality, usability of the data, and the significance of any problems encountered.
- Summary tables and graphs of laboratory data.
- Discussion of laboratory results.

A final data set will accompany the final technical memorandum and transferred to the Attorney General's Office via USB flash drive. The data set will include spreadsheets of data (in CSV format), photos of products, screen captures, screen-recording videos, and any additional study files.

12.4 Responsibility for reports

The project manager will be the lead responsible for the final technical memorandum, with assistance from the lead project assistant, as available. The project manager will deliver the final technical memorandum, final dataset (in CSV format), web screen recordings, photos, and any additional study files to the Attorney General's Office via USB flash drive.

13.0 Data Verification

13.1 Field data verification, requirements, and responsibilities

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

13.2 Laboratory data verification

Lab data verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. Ecology's MEL QA Coordinator will perform the data verification for the study.

The analytical lab will review lab results prior to submitting the data package in electronic format to the project manager. The lab data package will also be sent to MEL's QA Coordinator for data verification of the data package. The data package will be reviewed following EPA National Functional Guidelines for Inorganic Data Review (EPA, 2020), this QAPP, and QC requirements of EPA Method 6020B.

The QA Coordinator will prepare a case narrative report of the data verification, which includes (1) an overall assessment of data quality, (2) analytical methods were followed, (3) calibrations and controls were within limits, (4) project MQOs were met, and (5) data were consistent, correct, and complete without errors or omissions. After data verification is completed, the project manager will review the report and conduct a QA review of the data to assess results for usability.

13.3 Validation requirements, if necessary

Independent data validation will not be required for this study.

13.4 Model quality assessment

This study does not involve modeling or analysis of existing data.

14.0 Data Quality (Usability) Assessment

14.1 Process for determining project objectives were met

Upon completion of the internal Ecology data verification process by MEL's QA Coordinator or designee, the project manager will assess the data for usability and determine whether study objectives were met. Data from all field and laboratory procedures will be examined to determine whether they were measured with the proper procedures, fall into the expected range of results, and meet reporting limits as described in Sections 8 and 9. Data will also be examined to determine whether all MQOs and QC procedures have been met as described in Sections 6 and 10.

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

14.2 Treatment of non-detects

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

14.3 Data analysis and presentation methods

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

14.4 Sampling design evaluation

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

14.5 Documentation of assessment

Documentation of assessment will occur in the final technical memorandum (see Section 12).

15.0 References

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16.0 Appendix. Glossaries, Acronyms, and Abbreviations

Glossary of General Terms

Ambient: Background or away from point sources of contamination. Surrounding environmental condition.

Anthropogenic: Human-caused.

Acronyms and Abbreviations

AGO	Washington State Attorney General's Office
CAS	Chemical Abstracts Service
CPSC	U.S. Consumer Product Safety Commission
CPSIA	U.S. Consumer Product Safety Improvement Act
CSPA	Washington State Children's Safe Products Act
e.g.	For example
EAP	Ecology's Environmental Assessment Program
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
et al.	And others
i.e.	In other words
MEL	Manchester Environmental Laboratory
MQO	Measurement quality objective
PPE	Personal Protective Equipment
ppm	parts per million
PTDB	Ecology's Product Testing Database
QA	Quality assurance
QAPP	Quality assurance project plan
QC	Quality control
RCW	Revised Code of Washington
RPD	Relative percent difference
SDS	Safety Data Sheet
SOP	Standard operating procedure
WAC	Washington Administrative Code
XRF	X-ray fluorescence

Units of Measurement

mm	millimeter
mg/kg	milligrams per kilogram (parts per million)

Quality Assurance Glossary

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

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

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

Bias: The difference between the sample mean and the true value. Bias usually describes a systematic difference reproducible over time and is characteristic of both the measurement system and the analyte(s) being measured. Bias is a commonly used data quality indicator (DQI) (Kammin, 2010; Ecology, 2004).

Blank: A synthetic sample, free of the analyte(s) of interest. For example, in water analysis, pure water is used for the blank. In chemical analysis, a blank is used to estimate the analytical response to all factors other than the analyte in the sample. In general, blanks are used to assess possible contamination or inadvertent introduction of analyte during various stages of the sampling and analytical process (USGS, 1998).

Calibration: The process of establishing the relationship between the response of a measurement system and the concentration of the parameter being measured (Ecology, 2004).

Check standard: A substance or reference material obtained from a source independent from the source of the calibration standard; used to assess bias for an analytical method. This is an obsolete term, and its use is highly discouraged. See Calibration Verification Standards, Lab Control Samples (LCS), Certified Reference Materials (CRM), and/or spiked blanks. These are all check standards but should be referred to by their actual designator, e.g., CRM, LCS (Kammin, 2010; Ecology, 2004).

Comparability: The degree to which different methods, data sets and/or decisions agree or can be represented as similar; a data quality indicator (USEPA, 1997).

Completeness: The amount of valid data obtained from a project compared to the planned amount. Usually expressed as a percentage. A data quality indicator (USEPA, 1997).

Continuing Calibration Verification Standard (CCV): A quality control (QC) sample analyzed with samples to check for acceptable bias in the measurement system. The CCV is usually a midpoint calibration standard that is re-run at an established frequency during the course of an analytical run (Kammin, 2010).

Control chart: A graphical representation of quality control results demonstrating the performance of an aspect of a measurement system (Kammin, 2010; Ecology 2004).

Control limits: Statistical warning and action limits calculated based on control charts. Warning limits are generally set at +/- 2 standard deviations from the mean, action limits at +/- 3 standard deviations from the mean (Kammin, 2010).

Data integrity: A qualitative DQI that evaluates the extent to which a data set contains data that is misrepresented, falsified, or deliberately misleading (Kammin, 2010).

Data quality indicators (DQI): Commonly used measures of acceptability for environmental data. The principal DQIs are precision, bias, representativeness, comparability, completeness, sensitivity, and integrity (USEPA, 2006).

Data quality objectives (DQO): Qualitative and quantitative statements derived from systematic planning processes that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions (USEPA, 2006).

Data set: A grouping of samples organized by date, time, analyte, etc. (Kammin, 2010).

Data validation: An analyte-specific and sample-specific process that extends the evaluation of data beyond data verification to determine the usability of a specific data set. It involves a detailed examination of the data package, using both professional judgment and objective criteria, to determine whether the MQOs for precision, bias, and sensitivity have been met. It may also include an assessment of completeness, representativeness, comparability, and integrity, as these criteria relate to the usability of the data set. Ecology considers four key criteria to determine if data validation has actually occurred. These are:

- Use of raw or instrument data for evaluation.
- Use of third-party assessors.
- Data set is complex.
- Use of EPA Functional Guidelines or equivalent for review.

Examples of data types commonly validated are:

- Gas Chromatography (GC).
- Gas Chromatography-Mass Spectrometry (GC-MS).
- Inductively Coupled Plasma (ICP).

The end result of a formal validation process is a determination of usability that assigns qualifiers to indicate usability status for every measurement result. These qualifiers include:

- No qualifier – data are usable for intended purposes.
- J (or a J variant) – data are estimated, may be usable, may be biased high or low.
- REJ – data are rejected, cannot be used for intended purposes.
  (Kammin, 2010; Ecology, 2004).

Data verification: Examination of a data set for errors or omissions, and assessment of the Data Quality Indicators related to that data set for compliance with acceptance criteria (MQOs). Verification is a detailed quality review of a data set (Ecology, 2004).

Detection limit (limit of detection)**:** The concentration or amount of an analyte which can be determined to a specified level of certainty to be greater than zero (Ecology, 2004).

Duplicate samples: Two samples taken from and representative of the same population, and carried through and steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variability of all method activities including sampling and analysis (USEPA, 1997).

Field blank: A blank used to obtain information on contamination introduced during sample collection, storage, and transport (Ecology, 2004).

Initial Calibration Verification Standard (ICV): A QC sample prepared independently of calibration standards and analyzed along with the samples to check for acceptable bias in the measurement system. The ICV is analyzed prior to the analysis of any samples (Kammin, 2010).

Laboratory Control Sample (LCS): A sample of known composition prepared using contaminant-free water or an inert solid that is spiked with analytes of interest at the midpoint of the calibration curve or at the level of concern. It is prepared and analyzed in the same batch of regular samples using the same sample preparation method, reagents, and analytical methods employed for regular samples (USEPA, 1997).

Matrix spike: A QC sample prepared by adding a known amount of the target analyte(s) to an aliquot of a sample to check for bias due to interference or matrix effects (Ecology, 2004).

Measurement Quality Objectives (MQOs)**:** Performance or acceptance criteria for individual data quality indicators, usually including precision, bias, sensitivity, completeness, comparability, and representativeness (USEPA, 2006).

Measurement result: A value obtained by performing the procedure described in a method (Ecology, 2004).

Method: A formalized group of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, data analysis), systematically presented in the order in which they are to be executed (EPA, 1997).

Method blank: A blank prepared to represent the sample matrix, prepared and analyzed with a batch of samples. A method blank will contain all reagents used in the preparation of a sample, and the same preparation process is used for the method blank and samples (Ecology, 2004; Kammin, 2010).

Method Detection Limit (MDL): This definition for detection was first formally advanced in 40CFR 136, October 26, 1984 edition. MDL is defined there as the minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, and reported to be greater than zero (Federal Register, October 26, 1984).

Percent Relative Standard Deviation (%RSD): A statistic used to evaluate precision in environmental analysis. It is determined in the following manner:

$$\%RSD = (100 * s)/x$$

where s is the sample standard deviation and x is the mean of results from more than two replicate samples (Kammin, 2010).

Parameter: A specified characteristic of a population or sample. Also, an analyte or grouping of analytes. Benzene and nitrate + nitrite are all parameters (Kammin, 2010; Ecology, 2004).

Population: The hypothetical set of all possible observations of the type being investigated (Ecology, 2004).

Precision: The extent of random variability among replicate measurements of the same property; a data quality indicator (USGS, 1998).

Quality assurance (QA): A set of activities designed to establish and document the reliability and usability of measurement data (Kammin, 2010).

Quality Assurance Project Plan (QAPP): A document that describes the objectives of a project, and the processes and activities necessary to develop data that will support those objectives (Kammin, 2010; Ecology, 2004).

Quality control (QC): The routine application of measurement and statistical procedures to assess the accuracy of measurement data (Ecology, 2004).

Relative Percent Difference (RPD): RPD is commonly used to evaluate precision. The following formula is used:

[Abs(a-b)/((a + b)/2)] * 100

where “Abs()” is absolute value and a and b are results for the two replicate samples. RPD can be used only with 2 values. Percent Relative Standard Deviation is (%RSD) is used if there are results for more than 2 replicate samples (Ecology, 2004).

Replicate samples: Two or more samples taken from the environment at the same time and place, using the same protocols. Replicates are used to estimate the random variability of the material sampled (USGS, 1998).

Representativeness: The degree to which a sample reflects the population from which it is taken; a data quality indicator (USGS, 1998).

Sample (field): A portion of a population (environmental entity) that is measured and assumed to represent the entire population (USGS, 1998).

Sample (statistical): A finite part or subset of a statistical population (USEPA, 1997).

Sensitivity: In general, denotes the rate at which the analytical response (e.g., absorbance, volume, meter reading) varies with the concentration of the parameter being determined. In a specialized sense, it has the same meaning as the detection limit (Ecology, 2004).

Spiked blank: A specified amount of reagent blank fortified with a known mass of the target analyte(s); usually used to assess the recovery efficiency of the method (USEPA, 1997).

Spiked sample: A sample prepared by adding a known mass of target analyte(s) to a specified amount of matrix sample for which an independent estimate of target analyte(s) concentration is available. Spiked samples can be used to determine the effect of the matrix on a method’s recovery efficiency (USEPA, 1997).

Split sample: A discrete sample subdivided into portions, usually duplicates (Kammin, 2010).

Standard Operating Procedure (SOP): A document which describes in detail a reproducible and repeatable organized activity (Kammin, 2010).

Surrogate: For environmental chemistry, a surrogate is a substance with properties similar to those of the target analyte(s). Surrogates are unlikely to be native to environmental samples. They are added to environmental samples for quality control purposes, to track extraction efficiency and/or measure analyte recovery. Deuterated organic compounds are examples of surrogates commonly used in organic compound analysis (Kammin, 2010).

Systematic planning: A step-wise process which develops a clear description of the goals and objectives of a project, and produces decisions on the type, quantity, and quality of data that will be needed to meet those goals and objectives. The DQO process is a specialized type of systematic planning (USEPA, 2006).

References for QA Glossary

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