



United States

**Consumer Product Safety Commission**

# **FY 2023 Status Report: Organohalogen Flame Retardant Chemicals Assessment**

June 2023

*This report was prepared by the CPSC staff.  
It has not been reviewed or approved by,  
and may not necessarily reflect the views of,  
the Commission.*

# Table of Contents

<b>Introduction</b> .....	<b>3</b>
<b>Background</b> .....	<b>3</b>
<b>Staff Plan</b> .....	<b>3</b>
Table 1: Recommended Activities for Undertaking Subclass-Based Risk Assessments of OFRs [As presented in the FY 2020 Staff Plan, pp. 24-26] .....	5
<b>Project Work Initiated in FY 2021</b> .....	<b>6</b>
FY 2021 Contracts.....	7
Table 2: FY 2021 Contracts.....	7
<b>FY 2022 Project Activities</b> .....	<b>8</b>
FY 2022 Contracts.....	9
Table 3: FY 2022 Contracts.....	10
<b>FY 2023 Project Activities</b> .....	<b>11</b>
FY 2023 Contracts.....	12
<b>Next Steps</b> .....	<b>13</b>
Table 4: Staff Updates to: Recommended Activities for Undertaking Subclass-Based Risk Assessments of OFRs [originally presented in the FY 2020 Staff Plan, pp. 24-26] .....	15
<b>FY 2024 Contracts</b> .....	<b>16</b>
<b>Summary</b> .....	<b>17</b>

# Introduction

This report presents an overview and status for CPSC staff's project to complete analyses of organohalogen flame retardants (OFRs) in specified consumer products. These analyses can support rulemaking decisions or other regulatory options.

## Background

In 2015, several organizations and individuals petitioned the CPSC (Petition HP 15-1) to ban the use of additive OFRs, as a class, in durable infant or toddler products, children's toys, childcare articles, or other children's products (other than car seats), residential upholstered furniture, mattresses and mattress pads, and the plastic casings of electronic devices. In 2017, the Commission voted to grant the petition, to direct staff to convene a Chronic Hazard Advisory Panel (CHAP), and to complete a scoping and feasibility study in cooperation with the National Academy of Sciences, Engineering, and Medicine (NASEM). NASEM established a committee of experts to address the charge and published the committee's report, "A Class Approach to Hazard Assessment of Organohalogen Flame Retardants," in May 2019.<sup>1</sup> For FY 2020, the Commission directed staff to develop a process for assessing the risks of OFRs in consumer products. Subsequently, staff completed a report to the Commission (Staff Plan),<sup>2</sup> outlining options and recommendations for proceeding with the project in FY 2021 and beyond, subject to availability of resources. In FY 2021, staff proceeded with several activities, largely through contractors, to begin work on the project.

Staff's initial estimate to complete the required analyses for all 14 OFR subclasses was approximately \$18.6M over several years. This estimate includes significant uncertainty, due to anticipated challenges related to inadequate data for subclasses and the chemicals within those subclasses, as outlined in the NASEM report and staff plan. As the project proceeds and analyses are completed, the uncertainty will be reduced, and the work that still needs to be completed for each subclass will be defined better.

## Staff Plan

This section summarizes the key parts of the FY 2020 Staff Plan that inform the specific activities currently underway. In brief, the Staff Plan outlined work that initially would establish procedures for class-based risk assessment of each OFR subclass, refine the chemicals and analogs for multiple OFR subclasses, identify data sources, and determine available toxicity, chemical use, and exposure information.

---

<sup>1</sup> Available at: <https://www.nap.edu/catalog/25412/a-class-approach-to-hazard-assessment-of-organohalogen-flame-retardants>.

<sup>2</sup> CPSC Staff "Project Plan: Organohalogen Flame Retardant Chemicals Assessment," July 1, 2020. Available at: <https://www.cpsc.gov/s3fs-public/OFR-plan-report-package-final.pdf>.

Furthermore, staff's plan described a series of tasks that would support completing subclass-based hazard (toxicity), dose-response, and exposure assessments for use in class-based risk assessment for each OFR subclass. Staff proposed that initial steps would include:

(1) completing literature surveys to identify readily available toxicity and exposure information; (2) conducting market and use research to identify economic data describing how OFR chemicals are used in products; and (3) generating an updated OFR inventory that documents OFR and analog chemicals and their associated physical-chemical properties. Work on these steps would be performed largely by contractors.

Staff's plan then described the scope documents for each OFR subclass that will integrate the information collected in the initial steps. Scope documents also will include exposure conceptual models, class-specific PECO statements (Population, Exposure, Comparison, Outcome), and analysis plans that describe subsequent work.

In FY 2021, staff proceeded with a collaboration with the National Institutes for Environmental Health Sciences (NIEHS), including the Division of Translational Toxicology (DTT) (formerly known as the Division of the National Toxicology Program), to begin a literature search project to take advantage of NIEHS/DTT staff's extensive knowledge and expertise in this area. This project will provide much of the information that staff had originally planned to obtain through work performed by contractors after completing each scope document. Therefore, the collaboration, begun in FY 2021, largely replaces the literature search activity as outlined in the original staff plan. Information from these activities and the subsequent analyses will be used to complete toxicity, dose-response, and exposure analyses to support risk assessments for specific consumer products that may contain chemicals from specified OFR subclasses.

In the Staff Plan, staff described a process for assessing the risks of OFRs that incorporates established basic principles of risk assessment for chemicals in consumer products and incorporates the NASEM committee's report on a class-based hazard assessment approach to be applied to the identified subclasses. Staff notes that the process for a class-based assessment may differ from a risk assessment for a single chemical. The process includes steps for assessing potential human health effects associated with the chemicals, evaluating exposure to the chemicals from their use in consumer products and other sources, and characterizing the risks to consumers.

The Staff Plan calls for completing subclass-specific draft risk assessments for each OFR subclass and then submitting each to peer review. Following peer review and any necessary updates, staff will complete subclass-specific final risk assessments.

The Staff Plan indicates that there will be decision points for staff as the work progresses for each subclass, for example after completion of scope documents, and then after completion of draft risk assessments. These decisions will consider the adequacy of the available hazard information and exposure data; the potential for collecting or generating additional data, if knowledge gaps are identified; and whether proceeding with evaluations related to specific OFR subclasses is warranted.

The Staff Plan identified for undertaking subclass-based risk assessments of OFRs for each OFR subclass in selected types of products through several activities (summarized below in Table 1). These foundational activities, performed by CPSC staff with contractor support, are

intended to set up and support the overall project as it proceeds through the risk assessment process and through time. These activities will help provide an organizational framework for the project and build efficiencies.

**Table 1: Recommended Activities for Undertaking Subclass-Based Risk Assessments of OFRs [As presented in the FY 2020 Staff Plan, pp. 24-26]**

Recommendation	Description
Develop and maintain a list of OFR chemicals	Adopt a class-based approach using 14 subclasses. Update and maintain NASEM OFR class lists and associated analog substances, acknowledging that OFR chemicals within each subclass can be refined as new OFR chemicals are identified.
Initiate a scope document for each OFR class	Class-specific scope documents will summarize available toxicity and exposure data and other information for staff to determine whether there is sufficient information available, for the class, to conduct a class-based risk assessment, and to document technical approaches that may be used for filling data gaps.
Use a combination of approaches to proceed on multiple activities related to scoping and completing class-based risk assessments	Staff recommends, following completion of scope documents, initiating work on class-based risk assessments, and identifying data needs and pursuing generation of new toxicity and/or exposure data for OFR classes, as informed by available information and science policy decisions.
Consider the use of NAM [new alternative methods] data as an approach to estimate toxicity	In the absence of sufficient toxicity information on some members of a class, NAM data, in conjunction with human or animal toxicity data for other class members or close analogs, could help in reaching science-based conclusions for a class. When no human, animal, or NAM data are available for any class member or close analog, staff recommends generating new toxicity data, using either traditional methods or NAMs, as appropriate.
Develop and maintain a set of procedures and best practices	Staff recommends documenting procedures for identifying, searching, and extracting data from toxicity and exposure databases to inform literature surveys, as well as developing criteria for tools to identify, screen, evaluate, extract, and integrate data for use in class-based risk assessments.
During scoping, identify all uses of OFR chemicals	Determine which OFRs are used, or have been used recently in consumer products, which OFRs have industrial or commercial applications only, and which OFRs have been phased out of use. Understanding the market profile, uses, and trends of OFRs is an important part of characterizing exposure and risks, and can inform prioritization of OFR classes for risk assessment.
Update the project plan	Staff will incorporate lessons learned from scoping and risk assessment activities, and may establish science-policy recommendations, such as for decisions related to the use of NAM data in hazard assessments under the FHSA.

In the next sections, staff presents an update on work started in FYs 2021, 2022, and 2023, and planned future work.

## Project Work Initiated in FY 2021

The activities summarized above in Table 1, which include general and specific tasks, will occur at different points throughout the project.

In FY 2021, staff addressed the first item, “Develop and maintain a list of OFR chemicals,” in collaboration with Environmental Protection Agency (EPA) staff, to refine a Quantitative-Structure-Use-Relationship (QSUR) model to predict the probability that a chemical is a flame retardant or an OFR. Staff documented this work in FY 2022, by completing a manuscript, “Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory,” published in *Nature Scientific Data*.<sup>3</sup>

The second item in Table 1, “Initiate a scope document for each OFR class,” has begun now that portions of the supporting literature survey work have been completed and provide the necessary information. In FY 2021, staff initiated a contract to support the initial scoping and scale-up activity. This contract included conducting the literature survey for two OFR subclasses and developing a process guide for documentation and consistency in follow-up work. Subsequently, staff initiated two contracts to complete the literature surveys for the remaining 12 OFR subclasses.

As noted above, a collaborative effort with NIEHS and DTT staff replaces the literature search activity that was originally outlined in the staff plan as work that would be done after completing each subclass scope document. This collaboration takes advantage of NIEHS/DTT staff’s extensive knowledge and expertise in this area, and is being performed using NIEHS/DTT funding. DTT staff has long studied the toxicity of selected flame-retardant chemicals (including at the request of CPSC staff) and has interest in class-based assessments and in approaches to identify and evaluate large amounts of data relevant to human health assessments. In the current collaboration, DTT staff, with a support contractor, is performing a scoping review of the OFR subclasses. This work will provide the foundation for the literature search part of the project that is briefly described above and is discussed in detail in the CPSC Staff Plan. Staff will use the initial literature survey and analysis plan detailed in each subclass-specific scope document to identify specific results of the DTT project that will be used in the subsequent toxicity analyses for each OFR subclass.

Also in FY 2021, related to the sixth item in Table 1, staff initiated a contract for the OFR market and use research for all 14 OFR subclasses. Staff deemed this work to be especially critical for understanding the uses or potential uses of OFRs in consumer products and for conceptualizing exposure pathways.

---

<sup>3</sup> Bevington, C., Williams, A.J., Guider, C., Baker, N.C., Meyer, B., Babich, M.A., Robinson, S., Jones, A., Phillips, K.A. (2022) Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory. *Sci Data* 9, 295. <https://doi.org/10.1038/s41597-022-01351-0>.

In addition to the collaboration with DTT, staff has continued interaction and collaborations with staff of various EPA offices. Staff met with EPA economists who have experience with flame retardant economic data and market use information and established a formal MOU with EPA's Office of Research and Development to facilitate collaboration and data-sharing.

In addition, CPSC's statutory membership in EPA's Interagency Testing Committee (ITC) under the Toxic Substances Control Act, 15 U.S.C. § 2603(e)(2)(A)(ix), has provided staff with the opportunity to participate in the process that allows EPA to obtain otherwise unpublished and unavailable health and safety studies. During FY 2021, staff worked with EPA and the ITC to complete the process for adding 30 OFR chemicals to the Priority Testing List (PTL), and supported EPA's rulemaking proceeding under the Toxic Substances Control Act (TSCA) and the TSCA Health and Safety Data Reporting rule seeking specified existing health and safety data on PTL chemicals from industry stakeholders.<sup>4</sup> EPA extended the submission deadline for this rule as it relates to the 30 OFR chemicals into FY 2022.<sup>5</sup>

### FY 2021 Contracts

Table 2 lists the OFR project activities being completed by contractors, using funding available for FY 2021. All of these contracts were initiated in FY 2021 as reported in the 2021 OFR project status report, with performance of the work extending into FY 2022 for each, and for two contracts, into FY 2023.

**Table 2: FY 2021 Contracts**

Contract/Task Order	Contractor	Cost	Status
1. Literature surveys and Guide, 2 OFR subclasses	University of Cincinnati IDIQ task order	\$249,690	Completed
2. OFR Market and Use Research	Industrial Economics Incorporated	\$427,046	Completed
3. Identify data sources for Literature Surveys, 12 remaining subclasses	University of Cincinnati IDIQ task order	\$265,188	Completed
4. Complete literature surveys, 12 subclasses	University of Cincinnati IDIQ task order	\$459,200	In progress (completion Q3 FY 2023)
<b>Total:</b>		\$1,401,124	

<sup>4</sup> See <https://www.federalregister.gov/documents/2021/06/29/2021-13212/health-and-safety-data-reporting-addition-of-20-high-priority-substances-and-30-organohalogen-flame>.

<sup>5</sup> See <https://www.federalregister.gov/documents/2021/10/01/2021-21164/health-and-safety-data-reporting-addition-of-20-high-priority-substances-and-30-organohalogen-flame>.

Contract 1: This contract, completed in February 2022, supports the initial scoping and scale-up activity, as outlined in the Staff Plan. The contract included developing process guides for documentation and consistency in follow-up work and performing the literature survey for two OFR subclasses. Staff is using the work conducted under this contract to complete the scope documents for the first two subclasses.

Contract 2: This contract, completed in March 2022, provides market and use information for all 14 OFR subclasses. The final report includes analysis of the diverse OFR chemistries and consumer product applications, describes data for OFR production over time, and summarizes relevant regulations and restrictions for use of OFRs in the United States and internationally. The work provides an understanding of the uses or potential uses of OFRs in consumer products, including children's products, and supports conceptualizing exposure pathways. The report will be used to develop the class-specific scope documents, and it will inform portions of the class-based assessments, especially exposure assessments.

Contract 3: This contract, for all 12 remaining subclasses, performed the initial subtasks for literature surveys. Completion of this work was followed by the remaining literature survey subtasks for each OFR chemical subclass. This contract was initiated in FY 2021 (August 2021) and concluded in December 2022. Staff is using the work conducted under this contract to complete the scope documents for the remaining 12 OFR subclasses.

Contract 4: This contract used the work performed in Contract 3 to complete the literature surveys for 12 OFR chemical subclasses. Subtasks included screening identified scientific literature data sources and reports, constructing data evidence maps, and supporting development of class-specific conceptual models and analysis plans. This contract was initiated in FY 2021 (September 2021) and will conclude in FY 2023 (August 2023).

## FY 2022 Project Activities

Work in FY 2022 continued with contracts and activities initiated in FY 2021, and proceeded with new activities to continue progress towards analysis and assessment of OFR chemicals in consumer products.

In FY 2021, staff initiated several activities through contracts and task orders. Two of these activities were completed in mid FY 2022, and two continued into FY 2023, as noted in Table 2. Additionally, as shown in Table 3, staff initiated four new contract activities in FY 2022. Staff continued the work of administering the ongoing contracts, reviewing deliverables, and ensuring that the outputs and outcomes meet the requirements of the contracts and staff needs.

Also in FY 2022, staff continued interagency collaborations, including the scoping review of the OFR subclasses by DTT staff. The scoping review of OFR subclasses requires a substantial effort to perform a literature search and provide an organization framework for the results. DTT's focus and expertise is in reviewing and analyzing data related to hazard (i.e., toxicity and mechanistic data), and the results of DTT's initial work on identifying exposure data sources



have been transferred to CPSC staff. Staff is now working to categorize and extract the detailed information for use in subsequent analyses, similar to the work DTT staff is doing with the hazard data sources.

In addition to the work by contractors and through interagency collaborations, staff performed a variety of other work on the project. A portion of staff's efforts was to provide the specified data, documents, and other information needed for the contractors to complete their work. Significantly, in FY 2022, staff began to incorporate the work completed by contractors into scope documents for the first two OFR subclasses. Part of each scope document is an initial evaluation of the information available for a subclass, which will inform the analysis plans for the subclass. As the scope documents and analysis plans are completed, staff will draft the next steps for the subclass. Other work performed by staff includes the exposure literature work described above, following the processes used by DTT for the hazard data.

### **FY 2022 Contracts**

In FY 2022, in addition to continuing with the contract work initiated in FY 2021, staff initiated new work through contracts, with funds that had been allocated in the FY 2022 Operating Plan for other chemical hazard work, and with \$750K in the FY 2022 Operating Plan Midyear adjustments approved by the Commission on June 1, 2022. These projects are listed in Table 3 and described below.

These activities are consistent with the contract projects outlined by staff in the FY 2021 OFR project status report, with a focus on developing a guide for read-across methods and tools for class-based evaluations of chemical properties and toxicity and tasks related to class-based exposure assessment for application to OFR subclasses, along with other specific activities that would support planned and ongoing work on this project. Planning for these specific tasks also was informed by the level of available funding and the timeline of funding decisions.

**Table 3: FY 2022 Contracts**

Contract/Task Order	Contractor	Cost	Status
5. Exposure assessment of Polyhalogenated Organophosphates (PHOPs) using human biomonitoring data	University of Cincinnati IDIQ task order	\$97,580	In progress (completion Q3 FY 2023)
6. Read Across Guide and application to one or two subclasses	ICF BPA call order	\$386,295.97	In progress (completion Q1 FY 2024)
7. Class-based exposure assessment guide	ICF BPA call order	\$302,136.27	In progress (completion Q1 FY 2024)
8. Scoping Reports for 14 OFR subclasses	ICF BPA call order	\$75,178.55	In progress (completion Q1 FY 2024)
<b>Total:</b>		<b>\$861,190.79</b>	

Contract 5: Exposure assessment using human biomonitoring data. This contract concerns using data from measurements in humans (*i.e.*, biomonitoring data) with other data about chemicals of interest and applying available methods and statistical approaches to understand chemical exposures among human populations. The results of this contract will also support other chemical hazards work. The portion of the work that applies to the OFR project will provide estimates of human exposures to specified OFRs in the polyhalogenated organophosphates (PHOPs) subclass using data collected in selected studies of human populations. The work will identify available datasets for the general population or for selected subgroups, such as children or pregnant women, and perform appropriate analyses to estimate daily exposures. This work will provide estimates of exposures from all sources to the specified OFRs. The results will help staff understand overall levels of exposure to certain OFRs in studied populations and will inform staff's analyses of potential exposures to OFRs specifically from consumer products. This contract was initiated in FY 2022 (April 2022) and will conclude in FY 2023 (July 2023).

Contract 6: Read Across Guide and application to one class: This contract will develop approaches and a process guide for using methods and tools for class-based evaluations of chemical properties and toxicity, including read-across and quantitative structure-activity relationship approaches (QSAR). The contractor will also evaluate analog chemicals and explore the use of information about OFR metabolites or metabolite predictions, which can be used in read-across analyses. The contractor will apply the guide and complete analyses for the first OFR subclasses and associated analogs. This contract was initiated in FY 2022 (August 2022) and will conclude in FY 2024 (December 2023).

Contract 7: Exposure assessment guide and application to two subclasses: This contract will develop approaches and create a process guide for class-based exposure assessment. The work will include applying this guide and piloting the approach for two OFR classes. This contract was initiated in FY 2022 (August 2022) and will conclude in FY 2024 (December 2023).

Contract 8: Scoping Reports for 14 OFR subclasses: technical editing, visualization, and documentation of supporting files: This contract is for services to assist with production of scope documents for 14 OFR subclasses, including technical editing, production and editing of visual aids and figures, and documentation of supporting files and references such as cross-referencing. This contract was initiated in FY 2022 (August 2022) and will conclude in FY 2024 (December 2023).

## FY 2023 Project Activities

Work in FY 2023 and beyond is proceeding for each of the 14 OFR subclasses and will continue to involve work performed by contractors and in coordination with federal agency partners.

Six of the contract projects that started in FY 2021 or FY 2022 continue into FY 2023 (Table 2 and Table 3). In FY 2023, staff is continuing the work of administering the ongoing contracts, reviewing deliverables, and ensuring that the outputs and outcomes meet the requirements of the contracts and staff needs.

Staff is continuing numerous interagency collaborations. DTT's scoping review project is continuing, with current work focused on extracting large amounts of data from the studies identified in the literature search portion of the project. DTT is applying new semi-automated methods to this labor-intensive project to increase through-put and efficiency. The scoping review project and the new tools will help CPSC in the current project and perhaps future projects.

As mentioned above, in FY 2021, staff worked with EPA and the ITC to complete the process for adding 30 OFR chemicals to the PTL, and we supported EPA's TSCA Health and Safety Data Reporting rule that sought specified existing health and safety data on PTL chemicals from industry stakeholders. In early FY 2023, EPA reported to CPSC staff the receipt of 746 submissions for 25 OFRs. Staff has immediate access to many of the reports through a publicly available online portal<sup>6</sup> and can also work with EPA staff to view confidential business information, if needed. Staff is reviewing the submitted data along with other available data from scientific literature and other sources as part of the assessment process.

In addition to cultivating our existing collaborative efforts we are actively identifying other staff from these agencies who have experience with flame retardant chemicals or expertise with other topics relevant to CPSC staff's current project. Topics of common interest include tools, techniques, and approaches for class-based hazard, exposure, and human health risk

---

<sup>6</sup> See <https://chemview.epa.gov/chemview>.

assessment, obtaining and analyzing large amounts of data, applying new toxicology methods, and understanding consumer product-specific chemical exposure pathways.

In addition to the work by contractors, staff is performing work on the project. A portion of staff's efforts goes to providing specified data, documents, and other information needed for the contractors to complete their work. In FY 2023, staff is continuing to coordinate the many tasks and activities involved in the contracts and interagency collaborative efforts.

Staff completed drafts of the scope documents for the first two subclasses with completed literature surveys in FY 2022, and is proceeding to complete the scope documents for the remaining 12 subclasses. Part of each scope document is an initial evaluation of the information available for a subclass, which will inform the analysis plan for the subclass. As the scope documents and analysis plans are completed, staff will draft the next steps for the subclass. In addition, consistent with the Staff Plan, staff will continue to provide updates on the implementation of the plan so that the plan stays current.

Furthermore, staff is committed to making completed work available to the public. To date, contractors have completed reports, databases, spreadsheets and workbooks, and other deliverables, as specified in contracts. Staff is working through the processes to clear these reports and files and to prepare them to be uploaded to a new "landing page"<sup>7</sup> on the CPSC website for the OFR project. As the project progresses, newly completed reports will be cleared and uploaded to this page. Staff may prepare notices of availability for Commission consideration for publication in the *Federal Register* for some of these reports to, for instance, inform stakeholders or seek public comment.

## FY 2023 Contracts

In FY 2023, in addition to continuing the work initiated in FY 2022, staff is planning to initiate new work through contracts. Staff proposed several contract projects to be funded through FY 2023 Operating Plan Midyear adjustments.

The approved Midyear contract projects are described here, with additional details provided in Appendix A (FOR OFFICIAL USE ONLY).

These activities are consistent with the contract projects outlined by staff in the FY 2021 OFR project status report, with a focus on developing a guide for class-based dose-response analysis, completing literature search and screening for exposure data, review of and tasks related to class-based exposure assessment for application to OFR subclasses, along with other specific activities that would support planned and ongoing work on this project. Planning for these specific tasks was also informed by the level of available funding and the approvals of the Commission.

Contract 9 (approved subject to availability of funds): Subclass-based Hazard and Risk Assessment (dose-response) Guide and Application: This contract will document and develop possible approaches and processes for subclass-based dose-response analysis. Dose-

---

<sup>7</sup> CPSC web page "Organohalogen Flame Retardant Chemicals Assessment," available at <https://www.cpsc.gov/Business--Manufacturing/Organohalogen-Flame-Retardant-Chemicals-Assessment>.

response analysis provides quantitative estimates of the potency of chemicals. Dose-response analysis is part of quantifying risk in a chemical risk assessment that also involves hazard assessment and exposure assessment. Staff has ongoing work on developing approaches and process for subclass-based hazard assessment and exposure, and will need to develop subclass-based approaches for dose-response analysis in order to move forward with the OFR subclass risk assessments.

Contract 10 (approved subject to availability of funds): Literature Search and Screening: This contract follows the collaboration with NIEHS/DTT staff to identify OFR exposure literature. This work will complete the detailed literature screening and support data extraction from the identified studies. Note, this contract may be split into two related contracts.

Contract 11 (approved subject to availability of funds): Peer Consultation on Guides/Approaches: This contract will facilitate expert review of some of the work done to date. This contract will complete reviews of the guides (approaches and processes) for subclass-based hazard assessment and subclass-based exposure assessment, to be followed by review of the guide for subclass-based dose-response analysis. Because completing work in the OFR project will need to employ new methods or rely on new ways of applying existing methods, staff is seeking expert review and feedback at this point in order to refine the approaches and support successful application of such methods.

## Next Steps

As described in the Staff Plan, assessing the risks associated with the presence of OFRs in consumer products is a complex project, requiring many activities over multiple years. If a funding stream is provided, work in FY 2024 and beyond will proceed for each of the 14 OFR subclasses and will continue to involve work performed by contractors and in coordination with federal agency partners.

As described, staff has collaborated with EPA staff in several ways and will continue to do so. Specifically, staff will collaborate with EPA staff on research related to exposure to OFR chemicals present in various consumer products or components of products, and staff will continue ongoing discussions, specific to human health and exposure evaluations for OFR chemicals. Staff also will continue interactions to share expertise and enhance capabilities in other areas, such as data collection and management, and application and interpretation of data from new toxicology methods.

The current collaboration with DTT will complete a scoping review of hazard data for all OFR subclasses. This work will support staff's literature search and analysis activities for each OFR subclass as we complete scope documents and initiate the planned work.

In addition to identifying data to be used in subsequent analyses, the DTT OFR hazards scoping review project will help identify gaps in the available toxicity data that could be addressed through initiating toxicological studies within NIEHS/DTT research programs. Staff expects that the analysis of available data and identification of data gaps for each subclass, or for specific chemicals within subclasses, will be an ongoing process in a timeframe measured in months

and years. Staff will work with NIEHS/DTT to identify OFR subclasses and chemicals for which generating new data likely would advance the subclass-based hazard assessment process, especially considering data that could be obtained in shorter timeframes.

Of the four new contracts awarded in FY 2022, three will continue into FY 2024. Staff will continue the work of administering these contracts, reviewing deliverables, and ensuring that the outputs and outcomes meet the requirements of the contracts and staff's needs.

For FY 2024, subject to resources and funding, staff will continue to coordinate the tasks and activities involved in the contracts and interagency collaborative efforts, including providing specified data, documents, and other information the contractors need to complete their work. Staff will integrate the work completed by contractors with staff work related to different parts of the assessment work, and will complete the scope documents for each subclass. Part of each scope document is an initial evaluation of the information available for a subclass, which inform the analysis plans for the subclass, and the next steps for the subclass. In addition, consistent with the Staff Plan, staff will continue to provide updates on the implementation of the plan so that the plan stays current.

As indicated (see Table 1), staff recommended in the Staff Plan several general and specific activities for undertaking subclass-based risk assessments for each OFR subclass in selected types of products. In Table 4, staff describes how the current and planned activities support the various elements of the Staff Plan.

**Table 4: Staff Updates to: Recommended Activities for Undertaking Subclass-Based Risk Assessments of OFRs [originally presented in the FY 2020 Staff Plan, pp. 24-26]**

Recommendation	Update
Develop and maintain a list of OFR chemicals	Completed
Initiate a scope document for each OFR subclass	Underway with the completed OFR market and use research contract, and the completed literature survey contract, CPSC staff will complete scope documents for all OFR subclasses by the end of calendar year 2023. The scope documents will describe the types and amounts of available information across each subclass, which in turn will inform determinations on additional toxicological and exposure data needed.
Use a combination of approaches to proceed on multiple activities related to scoping and completing subclass-based risk assessments	With contractor support, staff is developing, planning, and performing multiple activities related to hazard (toxicity) assessment and exposure assessment. Initial projects include searching and evaluating available published literature and other data sources; completing process guides for subclass-based hazard and exposure assessment, including case studies of subclass-based assessment; and analyzing human biomonitoring data for certain OFRs. These will help staff understand not only overall subclass-based approaches, but also exposures in studied populations, informing staff's analyses of potential exposures to OFRs specifically from consumer products. These activities support each other.
Consider the use of NAM [new alternative methods] data as an approach to estimate toxicity	Staff continues to support the use of NAMs to address data gaps and fill data needs that are identified in the initial scoping activities for each subclass. If new toxicity data are required to proceed with hazard assessments for 1 or more subclasses, NAMs may serve to provide data that would otherwise be produced in more traditional laboratory toxicological testing.
Develop and maintain a set of procedures and best practices	Staff is documenting current and planned work; in addition, several activities include development of process guides that will be used by staff and contractors as work on each subclass is initiated.
During scoping, identify all uses of OFR chemicals	This was completed as part of the OFR market and use research contract.
Update the project plan	Staff plans for all scope documents to be completed in calendar year 2023. Staff will use the scope documents to plan the work activities for each subclass. Decisions and planning for specific subclasses will depend on information documented in the scope documents.  Staff completed status reports in FY 2021 and FY 2022. With this FY 2023 status report, staff continues to update the plan and activities performed in support of the plan.

Staff notes that staff is planning projects to proceed with the OFR assessments in FY 2024 and several subsequent years. Without consistent funding and resources, each part of the project

necessarily will be delayed, and the overall timeline for completing the subclass-based assessments to support CPSC regulatory action will be uncertain.

## FY 2024 Contracts

In FY 2024, in addition to continuing the work initiated in FY 2022 and FY 2023, staff will initiate new work through contracts, subject to available funding, as we reach the next steps of the project. As part of the FY 2024 Performance Budget Request, CPSC's Office of Hazard Identification and Reduction (EXHR) requested \$1.5M to fund these next steps and also requested two additional staff members (FTEs) in Health Sciences to support work on OFRs and other chronic chemical hazards. However, it is unknown at this time what resources the FY 2024 Operating Plan will include.

In FY 2022, staff established a new multiyear, blanket purchase agreement for toxicological, exposure, and risk assessment services. Staff is setting up a second multiyear blanket purchase agreement for laboratory exposure testing. Staff intends to use these contracts to complete a number of activities that will allow steady progress towards accomplishing many of our goals for this project over the next 5 years, to the extent that funding will allow. If funding is not available to use these contracts, then staff will not be able to make the anticipated progress in this project.

If the requested \$1.5 million funding stream is provided, contract work in FY 2024 would include proceeding with items planned for the current year if they are not funded and initiated in FY 2023. Depending on progress made to date, the contract work will include activities related to analysis of toxicity endpoints in specified subclasses, and analyses of potential exposures from specified products.

Specifically, assuming full funding of \$1.5 million, additional work would include:

1. Hazard analysis: Based on the completed literature surveys and literature searches, as well as other work expected to be completed in the coming months, work will proceed to evaluate and analyze toxicity data for specific OFR subclasses, including the polyhalogenated organophosphates subclass. Analysis will focus on toxicity endpoints of interest that have been identified for each subclass, following well-established procedures for hazard analysis. Different tools, techniques, and approaches may be used to evaluate the quality of available information and to supplement missing or insufficient data.
2. Exposure evaluation: Based on the completed literature surveys and literature searches, as well as other work expected to be completed in the coming months, work will proceed on evaluating and analyzing exposure data for specific OFR subclasses as used or present in specified consumer products. Analyses will follow established exposure modeling and estimating procedures and may use different tools, techniques, and approaches, as appropriate, for the available data and specific consumer products.



3. Targeted exposure testing. Based on information collected to date, staff will identify chemicals within OFR subclasses that lack specified exposure data. Where data gaps cannot adequately be addressed through exposure modeling, staff will identify exposure testing that could inform exposure. Targeted exposure testing may include chemical migration or emission testing of products and could be performed by a contract laboratory or interagency collaboration.
4. Targeted toxicity testing: Based on information collected to date, staff will identify chemicals within OFR subclasses that lack specified toxicity data. Where data gaps cannot adequately be addressed through read-across estimates or other non-laboratory methods, staff will identify toxicity testing that could inform chemical toxicity or mechanisms of action. Targeted toxicity testing may include short-term transcriptomic assays and other short-term testing and could be performed through a nomination to NTP or by contract laboratories.

## Summary

In FY 2023, staff continues working to support analyses of toxicity and exposure and to assess risks related to potential hazards associated with organohalogen flame retardants in consumer products. Already funded work in progress, together with work completed to date will, once completed, will provide documentation of the market and uses for chemicals in each of the 14 subclasses; information on the amounts and types of readily available toxicity and exposure information; analysis of human biomonitoring data for certain OFRs to help in understanding overall exposures in studied populations; and define processes and approaches for use in completing subclass-based assessment.

This work has followed the approach outlined in staff's FY 2020 project plan. Staff continues working through several contracts initiated in FY 2021 and FY 2022, to begin identifying and collecting data and other information. As these contracts have completed, staff has begun to clear the contractor reports' and associated files in order to make them available to the public on a new "landing page" to be established as part of the CPSC website. Staff has begun to use information from the completed contracts to proceed with the next steps of the project. Staff will continue to oversee ongoing contracts through FY 2023 and beyond, and staff expects to initiate several more activities through contracts, subject to available funding. Staff notes that this is a multiactivity, multiyear project that relies in large measure on contractors performing work and supporting CPSC staff work. Thus, timely progress depends on multiple years of reliable and sufficient funding and staffing, such that staff can plan the steps of the risk assessment and carry out those steps without interruption and without needing to revise the plan repeatedly to adopt a smaller scope and longer timeline. Without sufficient funding to support work performed by contractors, CPSC staff can still proceed with the project and make progress. However, the pace of the work would necessarily slow, and staff likely would need to adjust the scope of the project, such as to focus on a smaller number of OFR subclasses.

Staff also continued interagency collaborations that will help federal agencies efficiently use resources and that will advance staff's work on the current project. Staff is proceeding with

developing the scope documents for each OFR subclass. The scope documents will integrate the information obtained in the initial work and identify staff's approaches to assessing risks to consumers related to the presence of OFR chemicals in consumer products. In addition, staff will develop specific activities that can be performed by contractors in FY 2024 and beyond, using available agency resources.