United States
Consumer Product Safety Commission

Memorandum

TO: Jason Levine, Executive Director

DATE: July 13, 2022

THROUGH: Duane Boniface, Assistant Executive Director, Office of Hazard Identification and Reduction
Mary Kelleher, Associate Executive Director, Directorate for Health Sciences

FROM: Kristina M. Hatlelid, Ph.D., M.P.H., Project Manager, Division of Toxicology and Risk Assessment, Directorate for Health Sciences

SUBJECT: FY 2022 Status Report: Progress Toward Organohalogen Flame Retardant Chemicals Assessment

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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 will 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.[1] 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),[2] 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.

Furthermore, staff's plan described a series of tasks that would support completing class-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 using 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

[1] Available at: https://www.nap.edu/catalog/25412/a-class-approach-to-hazard-assessment-of-organohalogen-flame-retardants.
[2] 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.

conceptual models, class-specific PECO statements (Population, Exposure, Comparison, Outcome), and analysis plans that describe subsequent work.

As noted in the FY 2021 OFR project status report, in FY2021, staff proceeded with a collaboration with the National Institutes for Environmental Health Sciences (NIEHS), including the Division of the National Toxicology Program (DNTP), to begin a literature search project to take advantage of NIEHS/DNTP 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, this collaboration largely replaces the literature search activity as originally outlined in the 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's recommended process for assessing the risks of OFRs 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 recommends completing class-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 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 recommendations for undertaking class-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 Class-Based Risk Assessments of OFRs [As presented in the 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.

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 one manuscript, "Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory," published in *Nature Scientific Data*.[3] Staff currently is preparing a second publication, "Development of Refined Flame Retardant Quantitative Structure Use Relationship (QSUR) Models." 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 the Staff Plan, staff identified several options for specific activities in FY 2021. Staff recommended a set of seven specific activities that staff will conduct, with support from contractors and interagency collaborations. Table 2 lists these recommended FY 2021 activities and indicates the staff's involvement, along with contractors and other federal agency staff.

[3] 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.

Table 2: Staff Recommended FY 2021 Activities [As presented in the Staff Plan, pp. 27-31]			
Activity	**CPSC Staff**	**Contract**	**Interagency**
1. Initial Scoping and Scale-Up	X	X	X
2. Scope Document Development	X	X	
3. OFR Market and Use Research	X	X	X
4. Expedited Scope Document Development to Support Hazard and Exposure Assessment Activity	X		X
5. Hazard and Exposure Assessment Literature Search to Support Class-Based Risk Assessment	X		X
6. Exposure Assessment Scoping Activities	X	X	
7. Product Exposure Testing Plan	X	X	X

The initial scoping and scope document development activities (Activities 1 and 2) were intended to be performed by conducting the subclass-specific literature surveys. In FY 2021, staff initiated a contract to support the initial scoping and scale-up activity (Activity 1). This contract included conducting the literature survey for two OFR subclasses and developing a process guide for documentation and consistency in follow-up work. Staff is using the work conducted under this contract to complete the scope documents for the first two subclasses.

Staff's original plan was to stagger the literature surveys and scope document development over 2 or 3 fiscal years, to devote some of the available FY 2021 resources to other parts of the project during this year. Specifically, staff's recommended Activities 4 and 5 were intended for staff to expedite the development of the scope document for one subclass, which then would be used to support a contractor to work on the next steps in the hazard and exposure assessment for the subclass. That is, staff anticipated completing one scope document, so that a contractor could begin the resource-intensive work on the hazard and exposure literature search and the associated data analyses.

However, while kicking-off a collaborative effort with NIEHS and DNTP staff, staff realized that a more efficient process would be to shift the expected effort for Activity 5 from a contractor to the

NIEHS/DNTP collaboration to take advantage of NIEHS/DNTP staff's extensive knowledge and expertise in this area. In addition, the NIEHS/DNTP work is being performed largely using NIEHS/DNTP funding. Therefore, instead of staggering the literature surveys, using CPSC funding from multiple fiscal years, staff initiated two contracts for Activity 2, to complete the literature surveys for the remaining 12 OFR subclasses. These two contracts, which separated the associated subtasks for literature surveys for administrative and logistical reasons, together, will complete all work for the literature surveys for 12 subclasses. As OFR subclass literature surveys are completed, staff will begin to draft the associated scope documents.

Staff also initiated a contract for the OFR market and use research (Activity 3). This contract, for all 14 OFR subclasses, provided the market and use information to be included in the class-specific scope documents. This work is especially critical for understanding the uses or potential uses of OFRs in consumer products and for conceptualizing exposure pathways.

The remaining two main FY 2021 activities (Activities 6 and 7) are related to understanding potential exposures to OFRs that may be present in consumer products and will result in information to be included in the scope documents. In FY 2021, staff began to outline consumer product and human exposure characteristics for OFR subclasses and consumer products. This work will also use information from the literature survey and market and use research contracts as that work is completed in FY 2022 and FY 2023. These activities also benefited from collaborations with EPA staff. Staff expects continued interagency collaboration in the area of exposure assessment.

FY 2021 Contracts

Table 3 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 and for two contracts, into FY 2023.

Table 3: 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	In progress (completion Q1 FY 2023)
4. Complete literature surveys, 12 subclasses	University of Cincinnati IDIQ task order	$459,200	In progress (completion Q3 FY 2023)
	Total:	$1,401,124	

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, is performing the initial subtasks for literature surveys. Completion of this work will be followed by the remaining literature survey subtasks for each OFR chemical subclass. This contract was initiated in FY 2021 (August 2021) and will conclude in early FY 2023 (December 2022).

Contract 4: This contract will use the work performed in Contract 3 to complete the literature surveys for 12 OFR chemical subclasses. Subtasks will include 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 (April 2023).

FY 2021 Interagency Collaborations

As mentioned, staff has continued long-standing collaborative relationships with our colleagues from a number of federal agencies and programs. Of note, staff has continued interaction and collaborations with staff of various EPA offices, as well as staff of the NIEHS, especially the DNTP and the Health Assessment and Translation group. In addition to cultivating our existing relationships, 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 assessment, obtaining and analyzing large amounts of data, applying new toxicology methods, and understanding consumer product-specific chemical exposure pathways.

CPSC staff's collaboration with DNTP staff is directly contributing to the OFR project. DNTP 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, DNTP 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 class-specific scope document to identify specific results of the DNTP project that will be used in the subsequent toxicity analyses for each OFR subclass.

Staff has met with EPA economists who have experience with flame retardant economic data and market use information. CPSC staff will continue to engage with EPA economists as staff's current market and use research contract proceeds and will ask for their review of draft staff and

contractor reports. Staff has established a formal MOU with EPA's Office of Research and Development to facilitate collaboration and data-sharing.

In addition, CPSC's statutory membership (under the Toxic Substances Control Act) in EPA's Interagency Testing Committee (ITC) 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 we 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.[4] EPA extended the submission deadline for this rule as it relates to the 30 OFR chemicals into FY 2022.[5]

FY 2022 Project Activities

As described in the Staff Plan, assessing the risks associated with the presence of OFRs in consumer products is a multiyear, multi-activity project. Work in FY 2022 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.

As described above, staff is collaborating with EPA staff in several ways. Staff is currently following up with EPA staff as they sort through the relevant health and safety data submitted in response to the TSCA reporting rule. With the recent completion of the OFR market and use research, staff will seek EPA staff's review and advice on the information, as we begin to use the research in our analyses and plan next steps. As the project moves forward, staff will continue to seek EPA staff's review and advice on market and use information. In addition, staff will collaborate with EPA staff on research related to exposure to OFR chemicals present in various consumer products or components of products. Staff will continue ongoing discussions with EPA staff, 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 DNTP will complete a scoping review for hazard data for all the OFR subclasses. Because NIEHS/DNTP's focus and expertise is in reviewing and analyzing

[4] 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.
[5] 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.

data related to hazard (*i.e*., toxicity and mechanistic data), the results of NIEHS/DNTP's initial work on identifying exposure data sources have been transferred to CPSC staff for the next steps that involve categorizing and extracting the detailed information for use in subsequent analyses. This work, performed by DNTP (hazard data) and CPSC staff (exposure data), with contractor support, will support staff's literature search and analysis activities for each OFR subclass as we proceed to documenting those steps in scope documents and then initiating the planned work.

In addition to identifying data to be used in subsequent analyses, the NIEHS/DNTP OFR hazards scoping review project also will help identify gaps in the available toxicity data that could be addressed through initiating toxicological studies within NIEHS/DNTP 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/DNTP to identify OFR subclasses and chemicals for which generating new data likely would advance the class-based hazard assessment process, especially considering data that could be obtained in shorter timeframes.

In FY 2021, staff initiated several activities through contracts and task orders. Two of these activities were completed in mid FY 2022, and two will proceed into FY 2023, as noted in Table 3. Staff will continue 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.

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 2022, staff is continuing to coordinate the many tasks and activities involved in the contracts and interagency collaborative efforts. 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 the technical reports page of the CPSC website. 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.

In FY 2022, staff has begun to incorporate the work completed by contractors into scope documents for the first two subclasses with completed literature surveys in FY 2022. 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.

FY 2022 Contracts

In FY 2022, in addition to continuing the work initiated in FY 2021, staff is initiating new work through contracts. Staff began the year planning several projects that could be funded with $1.5M requested for this project (Table 4 and described below). The level of funding provided to the CPSC in the final FY 2022 appropriation did not allow full support for this project. However, on June 1, the Commission approved $750K for OFRs in the FY 2022 Operating Plan Midyear adjustments.

To date, staff has initiated one contract (Contract 1 in Table 4), using funds allocated for other chemical hazard work, given multiple uses for analyses that will result from this contract. Table 4 also lists several other activities that staff had planned to advance this project if funding is approved. Three of these projects (items 2, 3, and 4) were included in the Midyear package and were approved by the Commission. Another two projects (items 5 and 6) would be ready for procurement relatively quickly if additional funding were to become available. These activities include scientific work necessary to support risk assessment of OFRs in consumer products, as well as relatively small contracts that would provide technical support for staff's work and facilitate completion of other parts of the project.

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. Support for an AAAS fellow was not in the original Staff Plan, but staff believes that this would be a cost-effective means of supporting the integration and analysis of data developed for the OFR project.

Table 4: Planned FY 2022 Contracts			
Contract/Task Order	**Contractor**	**Cost**	**Status**
1. Exposure assessment of Polyhalogenated Organophosphates (PHOPs) using human biomonitoring data	University of Cincinnati IDIQ task order	$97,580	Awarded and in progress
2. Read Across Guide and application to one or two subclasses	ICF BPA call order	Estimate: [redacted]	In procurement process
3. Class-based exposure assessment guide	ICF BPA call order	Estimate: [redacted]	In procurement process
4. Scoping Reports for 14 OFR subclasses	ICF BPA call order	Estimate: [redacted]	In procurement process
5. Exposure assessment of Polybrominated Diphenyl Ethers (PBDEs) using human biomonitoring data	ICF BPA call order	Estimate: [redacted] (unfunded)	Possible project if funding were to become available
6. Library/literature support	ICF BPA call order	Estimate: [redacted] (unfunded)	Possible project if funding were to become available
7. AAAS Fellow	AAAS	Estimate: [redacted] (unfunded)	Consider for future fiscal year
	Total:	Estimate: [redacted]	

Contract 1 - 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 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 has been awarded and work is underway.

Contract 2 - 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 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 project is in the Commission-approved Midyear package, and the contract is subject to availability of funding.

Contract 3 - Exposure assessment guide: 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 one or two OFR classes. This project is in the Commission-approved Midyear package, and the contract is subject to availability of funding.

Contract 4 -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 project is in the Commission-approved Midyear package, and the contract is subject to availability of funding.

Contract 5 - Exposure assessment using human biomonitoring data: This contract estimates human exposures to specified OFRs in one subclass (polybrominated diphenyl ethers), using data collected in selected studies of human populations (*i.e.*, biomonitoring data). 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 exposures to certain OFRs in studied populations and will inform staff's analyses of potential exposures to OFRs, specifically from consumer products. This contract currently is unfunded.

Contract 6 - Library/literature support: This work will support staff's access to, and organization of, publications and other data identified in literature search activities that are not otherwise freely available to CPSC. This contract currently is unfunded.

Contract 7 - AAAS Fellow: This proposal would provide a fellow with appropriate scientific education and experience to work with staff on portions of the hazard and exposure assessment work for this project. A fellow would join the CPSC staff OFR team for 1 year. This contract was not funded for FY 2022 but it could be considered for a future fiscal year.

Of these contracts, the highest priority is the read-across guide and application to one or two subclasses (Contract 2 in Table 4). This work is fundamental to providing a solid scientific and technical basis for class-based assessment and the long-term success of the project. Contract 3, concerning exposure assessment in a subclass approach, is also fundamental to providing a solid scientific and technical basis for class-based assessment and the long-term success of the project. Contract 4 will provide significant technical support for staff's completion of subclass scope documents. These three contracts are all included in the Commission-approved Midyear package.

If additional funding were to become available in FY 2022, contracts 5 and 6 could be awarded relatively quickly under the ICF BPA. Contract 5 will further staff's understanding about exposure to OFRs in the PBDE subclass. Contract 6, for library and literature support, will help CPSC staff continue to make progress, both short-term and long-term, by working through literature-searching activities, assisting with information collection, and setting up future work.

To reiterate, CPSC staff has planned a group of projects to start in FY 2022, and the agency has planned additional projects for several subsequent years totaling approximately $1.5M per year. Without consistent funding, each part of the project necessarily will be delayed, and the overall timeline for completing the class-based assessments to support CPSC regulatory action will be uncertain.

Next Steps

As described in the Staff Plan, assessing the risks associated with the presence of OFRs in consumer products is a multiyear, multi-activity project. If a funding stream is provided, work in FY 2023 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 DNTP will complete a scoping review of hazard data for all the OFR subclasses. This work will support staff's literature search and analysis activities for each OFR subclass as we continue to develop scope documents and then initiate the planned work.

In addition to identifying data to be used in subsequent analyses, the NIEHS/DNTP OFR hazards scoping review project will help identify gaps in the available toxicity data that could be addressed through initiating toxicological studies within NIEHS/DNTP 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/DNTP to identify OFR subclasses and chemicals for which generating new data likely would advance the class-based hazard assessment process, especially considering data that could be obtained in shorter timeframes.

In FY 2021, staff initiated several activities through contracts and task orders. Two of these activities are ongoing in FY 2022 and will conclude in FY 2023. The four new contracts awarded in FY 2022 will continue into FY 2023. 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. In addition to the work by contractors, staff is working on the project. Part of staff's efforts in FY 2022, FY 2023, and beyond goes to providing specified data, documents, and other information the contractors need to complete their work.

For FY 2023, subject to funding, staff will continue to coordinate the tasks and activities involved in the contracts and interagency collaborative efforts. Staff will integrate the work completed by contractors with staff work related to consumer product exposures, to develop the scope documents for each subclass, starting with the literature surveys for the first two subclasses completed in mid-FY 2022. 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.

As indicated (see Table 1), staff recommended in the Staff Plan several general and specific activities for undertaking class-based risk assessments for each OFR subclass in selected types of products (summarized in Table 1). In the following table (Table 5), staff describes how the current and planned activities support the various elements of the Staff Plan.

Table 5: Staff Updates to: Recommended Activities for Undertaking Class-Based Risk Assessments of OFRs [originally presented in the Staff Plan, pp. 24-26]	
Recommendation	**Update**
Develop and maintain a list of OFR chemicals	Completed – to be published.
Initiate a scope document for each OFR class	Underway; with the completed OFR market and use research contract (for all subclasses), and the completed literature survey contract (for 2 subclasses: polyhalogenated organophosphates and polyhalogenated bisphenol aliphatics), CPSC staff will complete scope documents for 2 subclasses by the end of calendar year 2022; staff will complete the remaining 12 scope documents in calendar year 2023.
Use a combination of approaches to proceed on multiple activities related to scoping and completing class-based risk assessments	With contractor support, staff is proceeding with scoping each OFR subclass, and is developing, planning, and performing multiple activities related to hazard (toxicity) assessment and exposure assessment; these activities support each other.
Consider the use of NAM [new alternative methods] data as an approach to estimate toxicity	Staff continues to support 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. Also in 2023, staff will begin activities to support hazard (toxicity) assessment and exposure assessment for the first 2 subclasses (polyhalogenated organophosphates and polyhalogenated bisphenol aliphatics). Staff will use the scope documents to begin planning the work activities for the remaining subclasses, and decisions and planning for specific subclasses will depend on information documented in the scope documents. Staff completed a status report in FY 2021 and again in FY 2022 with this report to update the plan and activities performed in support of the plan.

FY 2023 Contracts

In FY 2023, in addition to continuing the work initiated in FY 2021 and FY 2022, staff will initiate new work through contracts, subject to available funding, as we reach the next steps of the project. If a funding stream is provided, staff would be requesting $1.5M to support contract work in FY 2023. As part of the FY 2023 Performance Budget Request, CPSC's Office of Hazard Identification and Reduction (EXHR) also requested three 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 funding level the FY 2023 Operating Plan will include. Staff is also requesting funds for one or more AAAS fellows to support chronic chemicals hazards, including this OFR project.

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 new 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 2023 would include proceeding with items listed in Table 4 that were not initiated in FY 2022; and 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 classes 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 classes 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 2022, staff continued work to support analyses of toxicity and exposure and to assess risks related to potential hazards associated with organohalogen flame retardants in consumer products. This work has followed the approach outlined in staff's 2020 project plan. Staff continued work through several contracts initiated in FY 2021, to begin identifying and collecting data and other information. Two of these contracts finished in mid-FY 2022. Staff will clear the contractor reports' associated files and make them available to the public. 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 2022, 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, although the

pace of the work will necessarily slow, and staff would likely need to adjust the scope of 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 2023 and beyond, using available agency resources.