UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: September 8, 2021

TO: Mary T. Boyle, Executive Director

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 2021 Status Report: Organohalogen Flame Retardant Chemicals Assessment

Introduction

This report presents an overview and status for CPSC staff's project to initiate and complete analyses required to support rulemaking decisions or other regulatory options for hazards related to organohalogen flame retardants (OFRs) in specified consumer products under the Federal Hazardous Substances Act.

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, child care 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 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

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

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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.

Staff Plan

This section summarizes the key parts of the Staff Plan that inform the specific activities currently underway. In brief, the Staff Plan outlines work beginning in FY 2021 to establish procedures for class-based risk assessment of OFRs, refine the chemicals and analogs for multiple OFR classes, identify data sources, and determine available toxicity, chemical use, and exposure information.

Furthermore, staff's plan for completing class-based hazard (toxicity), dose-response, and exposure assessments for use in class-based risk assessment involves completing a series of tasks. First, staff (based largely on work by contractors) will complete literature surveys that identify readily available toxicity and exposure information, conduct market and use research to identify economic data describing how OFR chemicals are used in products, and generate an updated OFR inventory that documents OFR and analog chemicals and their associated physical-chemical properties. Staff will create scope documents for each OFR class to integrate the available information. Scope documents will include exposure conceptual models, class-specific PECO statements (Population, Exposure, Comparison, Outcome), and analysis plans that describe subsequent work. Next, using the information compiled in each scope document, staff (with contractor support) will perform literature searches to identify additional, specific toxicity and exposure data and other information to be used in the subsequent analyses. Completed toxicity, dose-response, and exposure analyses will be used to complete risk assessments for specific consumer products that may contain chemicals from specified OFR classes.

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. 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.

[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.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

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

Staff indicates in the Plan that there will be decision points as the work progresses for each class: 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 classes is warranted.

In the Staff Plan, we identified recommendations for undertaking class-based risk assessments of OFRs 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.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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 develop criteria for tools to identify, screen, evaluate, extract, and integrate data for use in class-based risk assessment.
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.

The activities summarized in Table 1 will take place at different points throughout the project. Staff already addressed the first item, "Develop and maintain a list of OFR chemicals," in an early effort in collaboration with EPA staff to refine a Quantitative-Structure-Use-Relationship (QSUR) model to predict the probability that a chemical is a flame retardant or an

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

OFR. Two publications concerning this work are pending for late 2021, or early 2022. Other activities in Table 1 will occur as the project proceeds.

FY 2021 Project Activities

In the Staff Plan, staff identifies several options for specific activities in FY 2021, details the pros and cons related to the options, and describes staff's recommended approach. 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 interactions with contractors and other federal agency staff.

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) largely consist of conducting the class-specific literature surveys. In FY 2021, staff first initiated a contract to support the initial scoping and scale-up activity (Activity 1). This contract includes conducting the literature survey for two OFR classes and developing a process guide for documentation and consistency in follow-up work. Staff will use the work conducted under this contract to complete the scope documents for the first two classes.

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

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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 class, which then would be used to support a contractor to work on the next steps in the hazard and exposure assessment for the class. That is, staff anticipated completing one scope document, so that a contractor could begin the relatively 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, we 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 will be performed 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 classes. These two contracts separate the associated subtasks for literature surveys for administrative and logistical reasons, and together, these contracts will complete all work for the literature surveys for 12 classes. As OFR class literature surveys are completed, staff will complete the associated scope documents.

Staff also initiated a contract for the OFR market and use research (Activity 3). This contract, for all 14 OFR classes, will provide 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. Where the market and use research identifies data gaps, staff will consider approaches to collecting or developing additional data needed for subsequent analyses.

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 is using information from the literature survey and market and use research contracts (as that work is completed), in conjunction with other available information, to outline consumer product and human exposure characteristics for specific OFR classes and consumer products, or for OFRs more generally. These activities have benefited from collaborations with EPA staff, and staff expects continued interagency collaboration in the area of exposure assessment.

Based on the work staff has initiated in FY 2021, staff will begin to develop scope documents for defined chemical classes. The scope documents are based on the results of the initial literature surveys, with summarized hazard and exposure data, along with information from the market and use research. As described above, scope documents will contain several

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

components with information compiled or generated by CPSC staff and through contractors. For example, a contractor is conducting the literature surveys and producing data evidence maps. Staff will produce the conceptual exposure models, class-specific PECO statements, and analysis plans.

As scope documents are completed for each OFR class, staff will coordinate with the National Institutes for Environmental Health Sciences (NIEHS), including the Division of the National Toxicology Program (DNTP), on literature searches, as informed by the initial literature surveys, and will begin to extract, evaluate, and integrate the data to reach conclusions about the hazards, exposures, and risks of a class or to identify data gaps and additional data needs. In FY 2021, staff established support contracts for literature surveys and for market and use research for tasks that can be done in parallel. Staff also established interagency agreements and collaborations with staff at the Environmental Protection Agency (EPA), NIEHS, and DNTP. DNTP also initiated a project and is funding literature searches for OFRs.

FY 2021 Contracts

Table 3 lists the OFR project activities being completed by contractors, using funding available for FY 2021.

Table 3: FY 2021 Contracts

Contract/Task Order	**Contractor**	**Cost**
1. Literature surveys and Guide, 2 OFR classes	University of Cincinnati IDIQ task order	$249,690
2. OFR Market and Use Research	IEc/ERG	$427,046
3. Identify data sources for Literature Surveys, 12 remaining classes	University of Cincinnati IDIQ task order	$265,188
4. Complete literature surveys, 12 classes	University of Cincinnati IDIQ task order	$459,200
	Total:	$1,401,124

Contract 1: This contract supports the initial scoping and scale-up activity, as outlined in the Staff Plan. The contract includes development of process guides for documentation and consistency in follow-up work. The contract includes conducting the literature survey for two OFR classes. Staff will use the work conducted under this contract to complete the scope

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

documents for the first two classes. This contract was initiated in FY 2021 (December 2020) and will conclude early in FY 2022 (December 2021).

Contract 2: This contract will provide market and use information for all 14 OFR classes. The contract includes analysis of the diverse OFR chemistries and consumer product applications, and it will describe trends over time, as well as international markets. The work will provide an understanding of the uses or potential uses of OFRs in consumer products and support conceptualizing exposure pathways, and it will be used to develop the class-specific scope documents. This contract was initiated in FY 2021 (February 2021) and will conclude early in FY 2022 (November 2021).

Contract 3: This contract, for all 12 remaining classes, will perform the initial subtasks for literature surveys. Completion of this work will be followed by the remaining literature survey subtasks for each OFR chemical class. This contract was initiated in FY 2021 (July 2021) and will conclude in early FY 2023 (June 2022).

Contract 4: This contract will use the work performed in Contract 3 to complete the literature surveys for 12 OFR chemical classes. 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 (August 2021) and will conclude in early FY 2023 (December 2022).

FY 2021 Interagency Collaborations

Staff has continued our long-standing collaborative relationships with our colleagues from a number of federal agencies and programs, including interaction and collaborations with staff from various EPA offices, as well as staff from the NIEHS, especially the DNTP and their Office of Health Assessment and Translation (OHAT). 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 will directly contribute 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

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

collaboration, DNTP staff, with a support contractor, will perform a scoping review of the OFR classes. 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 and exposure analyses for each OFR class.

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 we will ask our EPA colleagues to review 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, and we have set up recurring virtual meetings with staff from several EPA offices for discussion of specific identified topics of mutual interest, and to share information and expertise and foster ongoing collaborations.

Furthermore, CPSC's statutory membership in EPA's Interagency Testing Committee (ITC) provides staff with opportunities to participate in processes that allow 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 completed 8(d) rulemaking seeking specified existing health and safety data on PTL chemicals from industry stakeholders.[3]

In another scientific collaboration, CPSC staff organized and co-chaired a workshop[4] at the Society of Toxicology annual meeting on scientific challenges of regulating OFRs as a class in consumer products. CPSC staff presented during the workshop and participated in the subsequent discussion, which included scientists from EPA, NIEHS, academic institutions, and industry.

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. Work in FY 2022 and beyond will

[3] 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.
[4] Society of Toxicology Annual Meeting 2021. Workshop Session: The Scientific Challenges in Regulating Organohalogen Flame Retardants (OFRs) as a Class in Consumer Products. Chair: Xinrong Chen, Consumer Product Safety Commission, Co-Chair: Linda Birnbaum, NIEHS. https://www.toxicology.org/events/am/AM2021/index.asp.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

proceed for each of the 14 OFR classes 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. As the project moves forward, staff will seek EPA staff's review and advice on market and use information and will collaborate 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 all the OFR classes. This work will support staff's literature search and analysis activities for each OFR class as we proceed to documenting those steps in scope documents and then to initiating the planned work.

In addition to identifying data to be used in subsequent analyses, the DNTP 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 class, or for specific chemicals within classes, will be an ongoing process in a timeframe measured in months and years. Staff will work with NIEHS/DNTP to identify those OFR classes 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 will be completed in early FY 2022, and two will proceed later into FY 2022, or early 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 needs. In addition to the work by contractors, work on the project is being performed by staff. A portion of staff's efforts in FY 2021, FY 2022, and beyond goes to providing specified data, documents, and other information needed for the contractors to complete their work.

For FY 2022, staff will continue to coordinate the many 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 class, starting with the literature surveys for the first two classes that will be completed in early FY 2022. Part of each scope document is an initial evaluation of the information available for a class, which will inform the analysis plan for the class. As the scope documents and analysis plans are completed, staff will draft the next steps for the class. In

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

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 will initiate new work through contracts, task orders, or interagency agreements. This planned work is in the following areas:

1. Read-Across: Develop approach/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). Apply this guide and complete read-across/QSAR for the first two OFR classes and associated analogs.
2. Consumer exposure modeling: After the market-use research is complete, staff will use the resulting information, in conjunction with other relevant studies to complete mechanistic (tier one) modeling for identified OFR-consumer product combinations. This will involve developing exposure scenarios and using existing models to quantify exposures. These estimates will be bolstered by a recently published consensus framework for modeling SVOC (*i.e.*, semi-volatile organic compounds) exposure.[5]
3. DNTP literature search: Apply additional resources for the ongoing project to support completion of screening and evaluating data sources.
4. Exposure Assessments (First Batch): Integrate data from models, product testing, environmental monitoring, and biomonitoring. Use the results of consumer exposure modeling, and available data collected to date, perform targeted supplemental searching for product testing, environmental monitoring, or biomonitoring to refine exposure estimates. Develop a guide documenting the approach used to integrate information from multiple sources together to derive exposure estimates.

<u>Possible late FY 2022 or early FY 2023 Contracts</u>

5. 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

[5] Eichler CMA et al.2021. Assessing Human Exposure to SVOCs in Materials, Products, and Articles: A Modular Mechanistic Framework. Environ Sci Technol 55(1):25-43. doi: 10.1021/acs.est.0c02329.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

short-term testing and could be performed through a nomination to NTP or by contract laboratories.

6. 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.

Summary

In fiscal year 2021, staff began work to support analyses of toxicity and exposure, and assess risks related to potential hazards associated with organohalogen flame retardants in consumer products. This work follows the approach outlined in staff's 2020 project plan. Staff initiated several contracts to begin identifying and collecting data and other information. These contracts will finish in early FY 2022, and staff will use these results to proceed with the next steps of the project. Staff also established and strengthened 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 class that will integrate the information obtained in the initial work and identify the approach to assessing risks to consumers related to the presence of OFR chemicals in consumer products. In addition, staff has begun developing specific tasks that can be performed by contractors in FY 2022 and beyond using available agency resources.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)