

TAB E



BUREAU OF HOME FURNISHINGS AND THERMAL INSULATION

3485 ORANGE GROVE AVENUE, NORTH HIGHLANDS, CA 95660-5595

TELEPHONE: (916) 574-2041

FAX: (916) 574-2449



November 19, 1999

Dale Ray, Furniture Flammability Project Manager
U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 East-West Highway
Bethesda, MD 20814

Dear Mr. Ray:

In October 1975, the California Bureau of Home Furnishings and Thermal Insulation began enforcement of Technical Bulletin 117 (TB 117), a mandatory flammability standard for upholstered furniture sold in California. The purpose of this standard is to limit or slow-down the propagation of an upholstered furniture fire, reducing the risk of death or injury by providing the increased opportunity for detection and escape. California's standard has been a major factor in the reduction of death and injury due to furniture fires in this state.

Since TB 117 was developed, there have been many advances in product materials, fire retardant technology, fire test procedures, and manufacturing practices. In light of those advances, we recognize the need to modernize this 24-year old standard.

Therefore, the Bureau is initiating efforts to formally revise and update California Technical Bulletin 117. The Bureau's goal is a revised standard that offers greater protection for California consumers from upholstered furniture fires while utilizing the best practices of the furniture industry. It is our intention that the updated standard be practical, economically feasible, and scientifically sound.

This is a significant and complex undertaking, which requires the input and assistance of industry, consumers, government, fire safety organizations and other interested parties. At this time, as we plan our research, we do not presume what the outcome will be. We can say that the process of updating the standard will be driven by sound science and objective research methods.

We look forward to working with you on this important consumer protection initiative and welcome your comments. John McCormack, the Bureau's Technical Coordinator, will be leading this project. John can be reached at (916) 574-2057, or e-mail at John_McCormack@dca.ca.gov, or I can be contacted at (916) 574-2157, or e-mail at Karen_Hatchel@dca.ca.gov.

Sincerely,

KAREN E. HATCHEL
Bureau Chief



U.S. Consumer Product Safety Commission
Washington, DC 20207

December 20, 1999

Ms. Karen Hatchel, Chief
Bureau of Home Furnishings & Thermal Insulation
3485 Orange Grove Ave.
North Highlands, CA 95660-5595

Dear Ms. Hatchel,

Thank you for your November 19, 1999 letter announcing the Bureau's initiative to revise and update California Technical Bulletin 117 on upholstered furniture flammability, and inviting the CPSC staff to be involved in that activity. It was a pleasure speaking to you on the phone about the Bureau's efforts. The CPSC staff would certainly like to participate. We have developed an excellent working relationship over the past several years with John McCormack, Said Nurbakhsh and the other BHF technical staff. As a part of this working relationship, we will continue to share the results of our regulatory development work, including laboratory testing and other technical analyses. We can also submit comments on flammability, chemical and economic issues as appropriate.

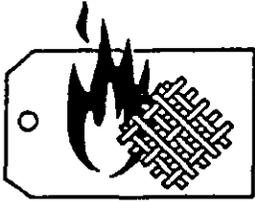
I would also like to take this opportunity to thank you again for participating in the ongoing interlaboratory study of the CPSC draft test method for small open flame ignition of upholstered furniture. I appreciate all the cooperation and technical expertise the Bureau has provided as CPSC has moved forward to develop a possible nationwide standard. Please feel free to contact me at 301-504-0962 ext. 1323 (e-mail: dray@cpsc.gov) regarding any of the issues involved in the TB-117 update project.

Sincerely,

A handwritten signature in black ink, appearing to read "Dale R. Ray", with a long, sweeping underline that extends to the right.

Dale R. Ray
Project Manager, Upholstered Furniture
Directorate for Economic Analysis

cc: J. McCormack



California Department of Consumer Affairs
Bureau of Home Furnishings & Thermal Insulation

UPDATE
Technical Bulletin 117 Revision

**American Furniture Manufacturers Association
Upholstered Furniture Flammability Seminar
March 6, 2001**

In October 1975, the California Bureau of Home Furnishings and Thermal Insulation began enforcement of Technical Bulletin 117 (TB 117), a mandatory, flammability standard for upholstered furniture sold in California. The purpose of the standard was to limit or slow the propagation of upholstered furniture fires caused by small open flame or smoldering sources, reducing the probability of death or injury by providing an increased opportunity for detection and escape. Over the last 25 years, California's TB 117 standard has been a major factor in the reduction of death, physical injury and property loss due to furniture fires in this state. It has also indirectly influenced the fire resistance quality of upholstered furniture sold in other states and several large national furniture suppliers routinely comply with TB 117 for all domestic product sales.

Since the original development of TB 117 over 25 years ago, there have been tremendous changes in the upholstered furniture industry. Advances in availability and fire performance of product materials, fire retardant technologies, manufacturing practices and the sophistication and accuracy of fire-testing protocols, have made clear the need to modernize this standard.

In October 1999, the Bureau announced that it was initiating a formal revision and update of the Technical Bulletin 117 standard. The Bureau's goal is a revised standard that offers greater protection for California consumers from upholstered furniture fires. The Bureau's intention is that the revised standard also be practical, straightforward and economically feasible. And as we proceed, the process of updating the standard will continue to be driven by sound science and objective research methods.

Revision of the TB 117 standard has proven to be a significant and complex undertaking. The major focus of our research has been to improve the resistance of upholstered furniture to small open flame. However, the impact of any changes in open-flame standards will be measured against the effect on smoldering performance, so that smolder resistance is not compromised. Research efforts relating to the revision of TB 117 are continuing. Though we have made significant progress in our goal of revising this standard, much work remains to be done and the research will continue.

The initial phase of our research has led to the following preliminary conclusions:

Component Tests - Minimum performance standards for component filling materials will continue as a critical element of the TB 117 standard. The pass-fail criteria for some components, especially synthetic (polyester) fibers, must be made more stringent. Once the components have been shown to meet minimum standards, they must then be tested in a composite mockup configuration with the actual fabrics to be used in furniture construction. The composite tests may consist of the actual, finished product or a mockup composite consisting of the fabric to be used and the complying filling materials in the order of layering used in the furniture.

Composite Tests - These tests have the greatest level of predictability for upholstered furniture fire performance. Research to date indicates that once filling components have met a more effective, minimum component standard, the range of available fabrics meeting a composite test may be widened and the need for F.R. backcoating of fabrics may drop significantly.

Upholstery Fabrics - The revised standard must assess the performance of the upholstery fabric, as the first point of ignition, as well as the various classes of filling materials. Upholstery fabric plays a critical role in the development of an open-flame or smoldering furniture fire and is the first line of defense against ignition and propagation. In some cases, fabric alone, if sufficiently flammable, may pose a major fire hazard on its own, even when placed over effective fire-resistant materials. However, the entire burden of the revised standard must not be placed on the upholstery fabric. It must also assess the synergies that occur between fabrics and filling materials, as commonly used for furniture construction. To focus solely on the performance of individual components, such as fabrics or fillings, does not address the synergies inherent in combinations of material components used in the construction of finished furniture.

Synthetic Fibers - Furniture flammability testing and research has clearly demonstrated that there are significant interactions between various individual components used in a furniture composite. Testing of individual components, no matter how severe such tests may be, does not address the behavior of these materials in a composite. A clear example of such interactions or synergies is the behavior of synthetic battings. Polyester and other synthetic battings, even non-fire retardant formulations, do not burn when individually exposed to an open flame. They simply melt or vaporize away from the flame source and stop burning. These same materials, however, when used below a fabric, can burn vigorously and cause the burning of the entire composite. Thus, the fabric acts as a secondary ignition source or "wick", depending on the type of fabric, and causes the batting and consequently, the entire composite, to burn. Therefore, the true fire performance of materials such as synthetic fiber battings, should be assessed in a component test, employing a cotton fabric substrate which assesses the melting and wicking of the polyester.

Improved performance of filling materials and the use of a simple composite test to measure fabric-fill interactions will be key elements of the revised Technical Bulletin 117. As this project progresses, the Bureau will continue to seek the input and assistance of a broad spectrum of entities, including furniture manufacturers and suppliers, industry associations, government regulatory agencies, fire safety organizations, and consumer groups. Working together, we can produce an improved standard that achieves a level of consumer protection worthy of our efforts.

TAB F

**UPHOLSTERED
FURNITURE
ACTION
COUNCIL**

**Box 2436
High Point, NC 27281
(919) 885-5065**



MISSION STATEMENT

ON

UPHOLSTERED FURNITURE FLAMMABILITY

August 1, 2000 R

The Upholstered Furniture Action Council (UFAC) is the voluntary program designed to make residential upholstered furniture more resistant to ignition from smoldering cigarettes which are the leading cause of upholstery fires in the home. UFAC involves all elements of the furniture industry including suppliers, manufacturers and retailers. Since the implementation of its construction criteria in 1978, this program has made a significant contribution to the 78.6% reduction in cigarette fires in upholstered furniture. That is due in large part to the broad-based research that UFAC historically has conducted on upholstered furniture flammability.

In recent months, there have been a number of significant developments on the upholstered furniture flammability issue. The textile industry has completed its study that raised questions about the efficacy of the U. S. Consumer Product Safety Commission's (CPSC) draft test method calling for fire retardant treatment of all upholstered furniture. Both the General Accounting Office and the National Academy of Sciences have completed reports raising added questions about the direction of the CPSC's current regulatory project. The Louisiana State Fire Marshal's Task Force has released its report raising further serious questions about both the CPSC approach and California Technical Bulletin 117 as presently constituted. The California Bureau of Home Furnishings has announced its intent to review and update Technical Bulletin 117. The emerging theme from these developments appears to be a recognition that a "flame-proof" upholstery product is not realistic. However, there is an opportunity for additional research that could result in an upholstery product that would be more resistant to open flame as well as smoldering ignition.

Consistent with its past history, UFAC is committed to supporting government and private sector research based on three criteria: safe, effective and saleable. To be "safe," a solution must not introduce new risks to consumers, workers or the environment nor undermine the existing level of resistance to cigarette ignition. To be "effective," a solution must reduce the number of residential fires involving upholstered furniture and must not create a false sense of security to the consumer. To be "saleable," a solution must result in furniture that is attractive, comfortable, durable and affordable. A solution that meets the criteria of safe, effective and saleable could form the basis for an industry-supported standard for residential upholstered furniture.

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Position Statement on:

Residential Upholstered Furniture and Mattress Fire Performance.

Overview

Objective: To reduce the incidence of fire deaths and injuries associated with residential upholstered furniture and mattresses.

The API is concerned about deaths and injuries from fires involving residential furniture and mattresses and supports a combination of approaches to further the Objective. Approaches should address development of a technically sound, effective national standard for residential furniture and mattresses as well as fire safety education and product labeling.

Resolved

- API supports a joint industry effort, the objective of which is to address fire safety of both residential upholstered furniture and mattresses.
- API favors the adoption of a national standard by a government authority that is effective for fire safety and saving lives. An effective standard should be technically sound and appropriate for product performance.
- The national standard should address the following concepts:
 - Test selection and design should address the actual hazard.
 - The final test should be a performance-based test representative of upholstered furniture and/or mattress constructions in residential use.
 - All residential upholstered furniture must meet the same test requirements regardless of the materials used in construction.
 - All residential mattresses must meet the same test requirements regardless of the materials used in construction.
 - The test criteria and procedures should be practical.
 - Appropriate labeling provisions should be included.
- To address residential fire safety concerns, including those associated with upholstered furniture and mattresses, API supports education on:
 - fire safety;
 - the use of fire and smoke detectors and fire suppressant systems; and
 - proper handling of potential ignition sources.



AMERICAN TEXTILE
MANUFACTURERS INSTITUTE

AMERICAN TEXTILE MANUFACTURERS INSTITUTE
Policy Statement on Residential Upholstered Furniture Flammability

February 2001

The American Textile Manufacturers Institute (ATMI) has an impressive record of involvement in and long-time commitment to consumers in the areas of textile flammability and fire safety. ATMI is the national trade association of the U.S. textile industry. Member companies operate in more than 30 states and process nearly two-thirds of all textile fibers consumed by plants in the United States.

The CPSC's Project on Upholstered Furniture Flammability

The Consumer Product Safety Commission (CPSC) is developing a regulation for upholstered furniture flammability that will require upholstery fabrics to serve as fire barriers to protect foam, filling materials and other components of furniture from fires started by small open flame sources. The CPSC has taken this approach without consideration of the combustion characteristics of all furniture components.

ATMI does not believe this course of action will accomplish the agency's stated goal of reducing deaths and injuries that result from residential upholstered furniture fires caused by small open flame sources, and will limit consumer choice of upholstery fabric. ATMI has voiced its concerns to the CPSC and continues to contribute to the rulemaking process to inform and educate the commission on this important consumer issue.

ATMI's Position on Upholstered Furniture Flammability

The upholstery fabrics sector of the U.S. textile industry has been serving its customers for more than two centuries by producing products that meet the performance and styling needs of consumers all over the world. ATMI member companies that produce upholstery fabrics are concerned about the number of deaths (about 80 annually) and injuries involving residential upholstered furniture fires caused by small open flame sources, and want to see those numbers reduced even further. To that end, ATMI is working toward a comprehensive standard, including all upholstered furniture components, for small open flame ignition that::

- is based on sound scientific research,
- is repeatable and technically feasible,
- is economically viable for both the industry and the consumer,
- is based on treating upholstered furniture as a synergistic combination of foam, filling materials, fabric and other components, and
- allows consumers access to the diverse array of upholstery fabrics available in the marketplace.



UFACSM

UPHOLSTERED
FURNITURE
ACTION
COUNCIL

P.O. Box 2436
High Point, NC 27261
(336) 885-5065
Fax (336) 885-5072

January 15, 2001

Mr. Ronald L. Medford
Assistant Executive Director
Hazard Identification and Reduction
U.S. Consumer Product Safety Commission
Washington, DC 20207

Dear Ron:

In early August, UFAC released its Mission Statement on Upholstered Furniture Flammability announcing its intent to develop a voluntary standard to address the risk of injury from small open flame ignition of upholstered furniture provided that standard could meet certain conditions. Since then, several developments have taken place. The most important of these was the formation of a Small Open Flame Technical Committee (SOFTC) comprised of the technical staff of several associations which have been meeting informally since 1998 as the Intra-Industry Coalition to discuss developments on small open flame ignition of upholstered furniture. The coalition includes industry associations representing furniture, upholstery fabrics, fibers, polyurethane foam, plastics, and cotton as well as designers, decorative fabric jobbers, and fabric retailers.

SOFTC was formed to pursue viable technical solutions to reduce the likelihood of deaths and injuries associated with upholstered furniture fires started by small open flames. The committee's objective is to develop a test method that consistently, reproducibly, and quantitatively predicts the performance of actual upholstery fires when upholstered furniture is exposed to small open flame ignition sources such as matches, lighters, and candles.

SOFTC has a two-step plan. First, it hopes to develop a bench scale composite test that predicts the behavior of burning furniture. At present, SOFTC is evaluating a method based on weight loss over time. Second, it is discussing component tests that would relate to the composite test. It is hoped that the Committee's work will lead to the development of a certification program, similar to the UFAC program, where suppliers certify their products as meeting specific performance standards as determined by the tests.

The committee's previous research work has proven small flame ignition to be a very complex scenario. Any process they ultimately recommend will not be a "quick fix" because there are no "quick fixes" in furniture flammability. As you might expect, this project will take many months to complete. The committee is currently collecting materials and lining up the test laboratories to conduct the first round of tests. The bench scale test must accurately, consistently, and reproducibly predict full-scale performance as well as actual performance in real-world fires.

The committee recognizes three important weaknesses of today's modern fire testing methodology: First, none of the present test methods have been reconciled with what actually happens in real-world fire scenarios, either qualitatively or quantitatively. Second, the precision of today's fire tests is reprehensibly poor with testing errors commonly exceeding 50% to 100%. Finally, computer models, which are claimed to be the answer to calculations involving fire scenarios, are only as good as the data driving the models. As noted above, the precision of the data is quantitatively lacking.

Additional time will be required to develop tests for individual components that accurately reflect the results of the composite tests. Our industry is only interested in providing furniture made under test method results which accurately, provably, and consistently predict performance when exposed to small open flame ignition. We have no interest in pursuing methods that give consumers a false sense of security but have no demonstrable impact on real-world fire safety.

In light of our industry's commitment to support research that could result in upholstery products that would be more resistant to open flames as well as smoldering ignition, we believe SOFTC's work is an exciting development. It is our hope that their approach will lead to a solution that can form the basis for a standard for residential upholstered furniture that our industry can support. As you know, we remain committed to supporting approaches that can be demonstrated to be safe, effective, and saleable to our customers.

Sincerely,



Ed Gerken, Chairman

c CPSC Chairman Ann Brown
CPSC Commissioner Thomas Hill Moore
CPSC Commissioner Mary Sheila Gall



Position Statement on Residential Furniture and Mattress Flammability

May 21, 2001

Since its formation in 1980, the Polyurethane Foam Association (PFA), through its various fire safety efforts and its members' technologies, has been instrumental in helping to educate the users of flexible polyurethane foam (FPF) about the safe use and storage of the product and thereby contribute to reducing loss of life, injuries and property damage due to fires.

As the key comfort component in household furnishings products, FPF has been vital to United States mattress manufacturers by helping them comply with the Federal Flammability Standard for Mattresses (FF4-72) and by helping the residential upholstered furniture industry build products that comply with the voluntary UFAC performance standard. The efforts of the mattress and upholstered furniture industries, along with a reduction in the number of smokers, have been effective in helping to significantly reduce the incidence of household fire fatalities resulting from smoldering ignition by cigarettes. While smoldering ignition remains the most common cause of fires that originate in household furnishings products, it is important to achieve a further reduction in the number of fires that originate in household furnishings ignited by small open flame sources such as matches, disposable lighters and candles.

In addressing small open flame ignition fires with home furnishings, all of the flammable components present in the composite item play an important role. In the case of a smoldering heat source, which burns through the outer layers of a composite, FPF helps reduce the chance of ignition. But, with a small open flame ignition source, those same outer layers can become significant fuel sources contributing to involvement of the composite product. Thus, to properly address ignition by small open flame, the burning characteristics of the composite product must be considered.

PFA position on residential mattress flammability by small flame ignition source

PFA supports the efforts of the Sleep Products Safety Council and the Consumer Product Safety Commission, which are engaged in research with a goal of developing a composite, end product performance-based small open flame ignition standard. PFA members are providing technical counsel and sample materials as part of the research process.

PFA position on residential upholstered furniture flammability

PFA is a member of the Intra-Industry Coalition and is participating in the Coalition's Small Open Flame Technical Committee (SOFTC) in its work to identify a small-scale, composite product bench test that correlates with the real world fire performance of residential upholstered furniture. A possible product of that research could be the creation of a component performance standard that suppliers could certify their products against.

PFA position on small open flame testing

With both residential mattress and residential upholstered furniture flammability testing, PFA will support any resulting small open flame ignition test protocol that is:

- Based on the composite performance of the finished piece including all items of assembly. Mattress testing should include bed clothing*
- Appropriate to the risk of small open flame ignition,
- Without bias toward any component,
- And, reproducible and technically feasible.

*Bed clothing (bedclothes) is defined as mattress covers, sheets, blankets, comforters, pillowcases and similar articles

Products that comply with any resulting test protocol should be:

- Commercially viable and saleable,
- And, effective in resisting ignition by small open flame without compromising smoldering ignition performance.

PFA position on fire prevention and fire safety education

PFA believes that broad educational efforts conducted on an ongoing basis can be effective in preventing household fires. In addition to educational efforts, the installation and use of fire detection (smoke, heat and CO detectors) and suppression systems (extinguishers and sprinklers) are also important elements of a successful fire safety program.

TAB G

proposes to amend 14 CFR part 71 as follows:

PART 71— DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, *Airspace Designations and Reporting Points*, dated September 10, 1997, and effective September 16, 1997, is to be amended as follows:

Paragraph 6002 The Class E airspace areas listed below are designated as a surface area for an airport.

AAL AK E2 Homer, AK

Homer Airport, AK
(Lat. 59°38'42" N, long. 151°28'42" W)
Kachemak NDB
(Lat. 59°38'29" N, long. 151°30'01" W)
Homer Localizer
(Lat. 59°39'07" N, long. 151°27'31" W)

Within a 4.2 mile radius of the Homer Airport and within 1.9 miles either side of the Homer localizer northeast backcourse extending from the localizer to 7.2 miles northeast of the Homer localizer, and within 2.4 miles north and 4.2 miles south of the Kachemak NDB 235° radial extending from the Kachemak NDB to 8.3 miles southwest of the Kachemak NDB. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Supplement Alaska (Airport/Facility Directory).

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

AAL AK E5 Homer, AK

Homer Airport, AK
(Lat. 59°38'42" N, long. 151°28'42" W)
Kachemak NDB
(Lat. 59°38'29" N, long. 151°30'01" W)
Homer Localizer
(Lat. 59°39'07" N, long. 151°27'31" W)

That airspace extending upward from 700 feet above the surface within a 6.7 mile radius of the Homer Airport and within 4 miles either side of the Homer localizer northeast backcourse extending from localizer to 12 miles northeast of the Homer localizer, and within 8 miles north and 4.2 miles south of the Kachemak NDB 235° radial

extending from the Kachemak NDB to 16 miles southwest of the Kachemak NDB.

Issued in Anchorage, AK, on March 9, 1998.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 98-6819 Filed 3-16-98; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

Flame Retardant Chemicals That May Be Suitable for Use in Upholstered Furniture; Public Hearing

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public hearing and request for comments.

SUMMARY: The Commission will conduct a public hearing on May 5-6, 1998 to receive scientific and technical information, such as published or unpublished studies, relating to the toxicity, exposure, bioavailability, and environmental effects of flame retardant ("FR") chemicals that may be suitable for use in residential upholstered furniture, particularly in upholstery fabrics. The Commission seeks written comments and oral presentations from individuals, associations, firms, and government agencies, with substantiated information or technical comments on these topics. The Commission will evaluate the information obtained from the hearing as part of its deliberations on whether to propose a standard to address the hazard associated with small open flame ignitions of upholstered furniture.

DATES: The hearing will begin at 10:00 a.m. on Tuesday, May 5, 1998, and, if necessary, conclude on May 6, 1998. Requests to make oral presentations, and the text of the presentation, must be received by the Office of the Secretary no later than April 21, 1998. Persons planning to testify at the hearing should submit 10 copies of the entire text of their prepared remarks to the Commission no later than April 21, 1998, and provide an additional 50 copies for dissemination on the date of the hearing. Written comments that are in place of, or in addition to oral presentations, must be received by the Office of the Secretary no later than May 5, 1998. Written comments must include the author's affiliation with, or employment or sponsorship by, any professional organization, government

agency, or business firm. All data analyses and studies should include substantiation and citations. The Commission reserves the right to limit the number of persons who testify and the duration of their testimony.

ADDRESSES: The hearing will be in room 420 of the East-West Towers Building, 4330 East-West Highway, Bethesda, MD. Written comments, requests to make oral presentations, and texts of oral presentations should be captioned "Flame Retardant Chemicals" and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland 20814. Comments, requests, and texts of oral presentations may also be filed by telefacsimile to (301) 504-0127 or by e-mail to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: For information about the purpose or subject matter of this hearing call or write Michael A. Babich, Ph.D., Directorate for Epidemiology and Health Sciences, U.S. Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0994, extension 1383; fax (301) 504-0079. For information about the schedule for submission of written comments, requests to make oral presentations, and submission of texts of oral presentations, call or write Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0800, extension 1232; fax (301) 504-0127.

SUPPLEMENTARY INFORMATION: In 1994, the U.S. Consumer Product Safety Commission ("CPSC") initiated a regulatory proceeding to address the hazard of small open flame ignitions of upholstered furniture. 59 FR 30735 (June 15, 1994). Small open flame sources include, for example, cigarette lighters, matches, and candles. Such ignitions of upholstered furniture are associated with an estimated 3,100 fires resulting in an estimated 100 deaths, 460 injuries, and \$50 million in property damage per year in the U.S. The CPSC staff believes that a small open flame performance standard for upholstered furniture could effectively reduce the risk of death, injury, and property loss resulting from small flame ignitions (1).¹

¹ Numbers in parentheses refer to documents listed at the end of this document. The documents are available at the Commission's Public Reading Room, 4330 East-West Highway, room 419, Bethesda, Maryland 20814. For information call the Office of the Secretary at (301) 504-0800.

The small open flame standard that the staff is considering would be a performance standard that specifies a requirement for flame resistance, but would not specify how furniture would have to be constructed to meet the standard. Manufacturers would be free to choose the means of complying with the standard. They could use inherently flame resistant textiles or apply FR treatments. Many different FR chemicals and combinations of chemicals are potentially available. FR chemicals could be incorporated within fibers, applied to the surface of the textile, or applied to the back of the textile in the form of a polymeric coating. Most cover fabrics currently used in upholstered furniture would require treatment with FR chemicals to pass the small open flame standard being considered by CPSC staff. Thus, a small open flame standard could result in the widespread use of FR chemicals in upholstered furniture manufactured for household use.

Possible Toxicity of FR Chemicals

The Commission is interested in information about the possible toxicity of FR chemicals for several reasons. In addressing the hazard associated with the small flame ignition of upholstered furniture, the Commission staff is working to develop a performance standard without creating additional health hazards to consumers or workers or harming the environment. The CPSC staff preliminarily considered the possible toxicity of FR chemicals to consumers. The staff believes that certain FR chemicals could probably be used without presenting a hazard to consumers (2). However, some questions remain, such as whether there is additional information on the chemicals the staff considered, possible hazards posed by new FR chemicals, the environmental impact of FR chemical usage and disposal, and the potential for worker exposure. Another issue is the possible smoke toxicity of FR-treated furniture. Therefore, the Commission is requesting additional information on these issues before considering a proposed rule.

The Federal Hazardous Substances Act ("FHSA") and the Commission's chronic hazard guidelines provide guidance for determining whether a given FR chemical would present a hazard to consumers. 15 U.S.C. 1261 (f)(1)(A); 16 CFR 1500.135. Under the FHSA, toxicity, dose response, exposure, and bioavailability must be considered in assessing the potential hazard to consumers. Toxicity includes acute toxicity, as well as chronic health effects such as cancer, reproductive/

developmental toxicity, and neurotoxicity. 16 CFR 1500.3(c)(ii). The dose response is a measure of the potency of a given FR chemical. Exposure is the amount of FR chemical that may come into contact with consumers. Bioavailability is the amount of FR chemical that is absorbed by the body. A given FR chemical would not present a hazard to consumers unless it is toxic, there is sufficient exposure, and enough is absorbed by the body to exceed the acceptable daily intake. See 15 U.S.C. 1261 (f)(1)(A); 16 CFR 1500.135.

The staff believes that in many cases, the FR chemicals would be applied in the form of a polymeric back-coating. Thus, exposure would depend on the ability of the FR chemical to migrate to the surface of the fabric. The back-coating is expected to reduce exposure because the FR chemical most commonly seen in the FR-treated fabrics to date is incorporated into the polymer and the polymer is on the back of the fabric. However, exposure might occur if the FR chemicals could be extracted during cleaning, or as a result of wear or abrasion or by contact with other liquids.

The CPSC staff reviewed all available data on the acute and chronic toxicity of 16 FR chemicals (2). Based on the available data, the staff determined that 15 of the 16 FR chemicals considered would not present a hazard to consumers. Seven of the chemicals would not be considered "toxic" under the FHSA. Others would not be expected to present a hazard due to low exposure or low bioavailability. However, these conclusions could change if additional information became available that indicated certain chemicals could present a hazard. For some chemicals, only limited information was available on toxicity, exposure, or bioavailability. Furthermore, other FR chemicals not reviewed by the staff may be available for use in upholstered furniture.

A related issue is whether the smoke from FR-treated furniture could be more toxic than the smoke from non-FR-treated furniture. Only the upholstery fabric would be treated with FR chemicals. Although the standard under consideration would require upholstered furniture to resist ignition from a small open flame, the furniture could still ignite in a larger fire. Smoke toxicity must be considered because most fire-related deaths are due to smoke inhalation, rather than burns. The staff reviewed all available data on the smoke toxicity of FR-treated products, and it determined that the smoke from FR-treated products was

generally not more toxic than the smoke from non-FR-treated products (2). However, the Commission seeks additional information on this issue.

Other Uses of FR Chemicals

Although FR chemicals are not currently used in most residential upholstered furniture, they are used in a number of other applications. FR treatments may be used in some commercial grade upholstered furniture, carpets, wall coverings, and automobile and airplane upholstery. FR chemicals are used in other textile products, such as workwear and children's sleepwear, and in a wide variety of plastic containing products, such as printed circuit boards, and television and computer cabinets. FR chemicals are also used in upholstered furniture sold in California and the United Kingdom to comply with certain flammability requirements. Experience gained with these other applications may be relevant to upholstered furniture. The Commission solicits information from those familiar with these applications.

Request for Information

To obtain information relevant to these questions, the Commission will conduct a public hearing on May 5-6, 1998. The Commission solicits written comments and oral presentations of scientific and technical information, including unpublished toxicity studies, from all interested parties on the following topics:

1. FR Chemicals

A. FR chemicals and treatments that are potentially suitable for use in complying with the small open flame standard.

1. Are there any FR chemicals or classes of FR chemicals included in the staff's review (see reference 2) that would not be suitable for upholstered furniture fabrics or barriers?

2. Are there any chemicals that would be suitable for upholstered furniture but were not included in the staff's review?

3. How would each type of FR treatment be applied, that is, incorporated into the fiber, surface treatment, or back coating?

4. With what types of fibers and fabrics can each FR treatment be used?

B. FR chemicals that are currently used in other applications to which consumers may be exposed (such as children's sleepwear, commercial grade furniture, carpet, and wall coverings, automobile and airplane upholstery, and residential furniture sold in California and the U.K).

1. Would any of these chemicals not reviewed by the staff be suitable for upholstered furniture?

2. How does experience gained with these applications address outstanding issues with upholstered furniture?

II. Toxicity

A. Data or analyses, such as unpublished industry-sponsored studies, relating to the toxicity, dose response, bioavailability, or exposure of FR chemicals (both existing studies and those that are planned or underway).

B. Federal, state, and international programs for evaluating new and existing FR chemicals.

1. How can these programs limit the introduction of new hazardous FR chemicals that would be used in upholstered furniture?

2. Are any FR chemicals considered "toxic" or "hazardous" under any current federal or state programs, such as the Environmental Protection Agency ("EPA"), Occupational Safety and Health Administration ("OSHA"), and Department of Transportation ("DOT")?

3. Are any FR chemicals currently on any regulatory lists, such as under the Resource Conservation and Recovery Act ("RCRA"), the Comprehensive Environmental Response,

Compensation, and Liability Act ("CERCLA"), Toxic Release Inventory ("TRI"), or the California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65")?

4. If any are listed, what is the significance, if any, of being on the particular list, with regard to upholstered furniture?

C. Data or analyses relating to the smoke toxicity of FR-treated products, other than what was discussed in the staff toxicity review (including the need for any additional studies).

III. Exposure and Bioavailability

A. Possible consumer exposure to FR chemicals in upholstered furniture.

1. What scenarios and routes of exposure need to be considered to adequately assess consumer exposure to FR chemicals?

2. What must be considered to adequately assess exposure to children in particular?

B. Studies relating to bioavailability of FR chemicals, such as dermal absorption studies, that were not cited in the staff review.

C. Effect of aging and cleaning of furniture on exposure to FR chemicals.

1. Would the back-coating degrade over time? If so, under what circumstances?

2. Would cleaning with aqueous or non-aqueous agents extract FR chemicals?

3. How tightly would various FR chemicals be bound to or within the fabric or back-coating?

4. How would exposure to light, including ultraviolet and infrared, affect exposure to FR treatments?

5. Some FR treatments are considered to have low bioavailability due to high molecular weight. Could these FR chemicals degrade over time?

IV. Occupational Issues

A. Processes likely to be used to apply FR chemicals to the textiles used in upholstered furniture.

B. Effect of FR chemicals or treatments on workers who would be applying them to textiles or during the manufacture of upholstered furniture.

1. In industries where FR chemicals are currently used, what controls exist to protect workers?

2. What federal or state regulations are these industries subject to that are designed to protect workers?

C. Any controls that currently exist to protect workers from exposure to other chemicals or particles in the textile and upholstered furniture industry.

1. What federal or state regulations are textile and furniture manufacturers currently subject to that are designed to protect workers?

2. Would manufacturers be subject to any additional regulations if FR chemicals were introduced?

3. What additional controls, if any, would be required to protect workers from exposure to FR chemicals in these industries?

D. Cost of complying with additional regulations and implementing additional controls to protect workers, resulting from the use of FR chemicals in upholstered furniture, especially for small companies.

IV. Environmental Issues

A. Federal or state environmental regulations to which textile and upholstered furniture manufacturers are currently subject.

1. What environmental controls, if any, currently exist in these industries?

2. What additional federal or state regulations would textile and furniture manufacturers be subject to, if FR chemicals were introduced?

3. What additional environmental controls, if any, would be required?

B. Cost of complying with additional environmental regulations and implementing additional environmental controls, resulting from the introduction of FR chemicals into upholstered furniture, especially for small companies.

C. Federal or state transportation regulations to which FR chemicals

would be subject and the likely cost of complying with them.

D. Any special disposal requirements when household furniture reaches the end of its useful life and any adverse impacts that disposal might have on the environment or human health.

E. If adopted, a small open flame standard could increase the overall production of FR chemicals. Beyond what is addressed in the previous questions, are there any known or likely environmental effects from the manufacture, use, or disposal of FR chemicals for use in upholstered furniture?

List of Relevant Documents

(Documents may be obtained from the Office of the Secretary or from the CPSC's web site at www.cpsc.gov.)

1. Briefing memorandum from Dale R. Ray, Project Manager, Directorate for Economic Analysis, to the Commission, "Upholstered Furniture Flammability: Regulatory Options for Small Open Flame and Smoking Material Ignited Fires," October 24, 1997.

2. Memorandum from Lakshmi C. Mishra, Ph.D., Directorate for Epidemiology and Health Sciences, to Dale Ray, Project Manager, "Toxicity of Flame Retardant Chemicals (FR's) Used in Upholstered Fabrics and the Toxicity of the Smoke from FR-treated Fabrics," October 1, 1997.

Dated: March 11, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 98-6904 Filed 2-16-98; 8:45 am]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Minoxidil Preparations With More Than 14 mg of Minoxidil Per Package

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing a rule to require child-resistant ("CR") packaging for minoxidil preparations containing more than 14 mg of minoxidil in a single package. The Commission has preliminarily determined that child-resistant packaging is necessary to protect children under 5 years of age from serious personal injury and serious illness resulting from handling or



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: April 4, 2001

TO: Dale Ray, Project Manager, Upholstered Furniture

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences *mad*

THROUGH: Lori Saltzman, M.S., Director, Division of Health Sciences *LS*

FROM: Patricia Bittner, M.S., Toxicologist, and Michael A. Babich, Ph.D., *maB*
Chemist, Division of Health Sciences

SUBJECT: Health Sciences Response to Public Hearing Comments on Upholstered Furniture

This memorandum provides the Health Sciences' staff responses to comments made to the U.S. Consumer Product Safety Commission (CPSC) on the use of flame retardant (FR) chemicals that might also be used to meet a flammability standard for upholstered furniture. It responds to comments from oral testimony given at the public hearing on May 5-6, 1998; written comments that were received in response to the Commission's March 17, 1998 Federal Register notice announcing the hearing; written comments received as follow-up to the hearing; and data submitted by a number of companies on specific chemicals. The original comments and transcripts of the May 1998 public hearing are on file in the Office of the Secretary. A complete listing of commenters and their identification numbers can be found in Appendix A.

I. Flame Retardant Chemicals--Overall Risk

Issue: FR chemicals and treatments are/are not safe to use on residential upholstered furniture.

A number of comments were received from chemical manufacturers stating that specific flame retardant (FR) chemicals are safe to use for treatment of residential upholstered furniture. The comments addressed either specific FR chemicals produced by individual companies or certain aspects of toxicity. In some instances, data were supplied to support their positions.

Several FR chemical manufacturers commented that their products have been used safely in a variety of products for years with no apparent effects on human health. Ciba Specialty Chemicals Corporation (Ciba) commented that there have been no reports of adverse health effects or other incidents arising from the use of their

Pyrovatex[®] products in consumer settings in the years since the UK imposed fire safety requirements for residential upholstered furniture in 1988. They assert that Pyrovatex[®] has been used in 30 countries for more than 40 years without any incidents of adverse health effects. Similarly, Westex, Inc. (Westex) commented that cotton apparel fabrics treated with the phosphonium salt precondensate/ammonium cure process confer no unusual health risk to wearers over a variety of conditions. American Flamecoat of Southern New Jersey, Inc. (American Flamecoat) stated that they have been involved in every aspect of fire prevention as it pertains to fire retardant chemicals being used on fabrics since 1986 and FR's will reduce the loss of life and property due to fire. Many fire retardants on the market have "passed the toxicity test."

Wolf Corporation commented that cotton batting treated with Boron #10 could be classified as "relatively harmless." The National Cotton Batting Institute stated that boric acid (10%) does not present a hazard to humans when used in occupational or home-use settings and is sold in drugstores over-the-counter for use as an eyewash.

Albemarle Corporation (Albemarle) stated that decabromodiphenyl oxide (DBDPO) is currently used throughout the U.S. to meet institutional, commercial, and transportation fire safety standards and in California to meet standards for residential furniture. Albemarle stated that DBDPO and hexabromocyclododecane (HBCD) are not toxic, and are poorly absorbed and rapidly eliminated from the body. Wallace Forman, a consumer, stated that there now exist 100% non-combustible fire barrier fabrics that can completely protect mattresses, pillows, theatre seats, etc.

The Antimony Oxide Industry Association (AOIA) commented that the issues concerning public health hazards of FR use are overstated and are clearly outweighed by the safety benefits using FR chemicals. They also commented that textile companies already safely handle many chemicals used in softeners, soil and water repellants, dyes, and non-FR latexes; they noted that some textile companies handle FR chemicals for use in commercial and automotive or airline seats, so there is no credibility to the claim that they cannot be handled safely.

Akzo Nobel Chemical Company (Akzo Nobel) commented that the likelihood of exposure from sitting, lying on, or chewing on furniture backcoated with FR chemicals is negligible, because the encapsulation of the chemicals in a polymer limits potential migration and/or release from the fabric.

The University of Surrey, United Kingdom (UK), produced a report that included an assessment of toxic risk on some FRs (antimony trioxide, decabromodiphenyl oxide, melamine, alumina trihydrate, tetrabromobisphenol A, and tris (chloropropyl)phosphate) for the UK Department of Trade and Industry (UK DTI). The report concluded that the presently available data do not indicate significant toxic risk from exposure to flame retardants in upholstered furniture.

Conversely, a number of submitters stated that FR chemicals should not be used to treat residential upholstered furniture, either because the chemicals are toxic or not

enough information is known about their toxicity. The commenters were primarily textile manufacturers or industry groups representing textile and furniture industries and interior decorators. There was also concern expressed that these chemicals would be bioavailable and as such, consumers would be harmed when exposed to them.

Trevira Germany (Trevira), Everfast, Inc. (Everfast), the Coalition of Converters of Decorative Fabrics, and the Decorative Fabrics Association stated that individuals would have continuous exposure to the treated fabrics throughout their manufacture, distribution, and sales and that there is not a full understanding of the potential health effects of such exposure. The American Society of Interior Designers (ASID) stated that they are opposed to government mandates requiring the application of FR chemicals because of the potential health risk to humans from long-term exposures to FR chemicals in end-use products.

The Upholstered Furniture Action Council (UFAC), the American Furniture Manufacturers Association (AFMA), the National Cotton Council, the American Textile Manufacturers Association (ATMI), the Environmental Defense Fund, and Steve Hart, a consumer, stated that there is either insufficient information on both the health effects of FR chemicals and their potential bioavailability, or there is a widespread acknowledgement of the toxicity of many of the chemicals. They believe that toxicity data are missing for many of the FR chemicals proposed for use on upholstered furniture and a complete toxicological data set should be required for each chemical. The Environmental Defense Fund and Steve Hart stated that the Commission should approve no chemicals unless there are sufficient toxicological data to demonstrate that the chemicals pose no health risk.

Cathy Jones Interiors, Inc. stated that the use of FR chemicals may have long-term negative effects on humans. They also believe that a single 2-day public hearing on FR toxicity cannot capture all relevant information. In addition, they noted that the U.S. government previously has recognized the potential health and environmental danger of FR chemicals as demonstrated by the U.S. government spending over \$20 million to clean up a Newark, N.J. Superfund site, which contained FR chemicals, among other things.

ATMI commented that some CPSC staff mistakenly considers eight FR chemicals to be "safe" to use on residential upholstered furniture, as per the National Academy of Sciences (NRC) report (NRC, 2000).

Response: The possible health hazards or long-term human health risks from the use of selected FR chemicals on residential upholstered furniture have been examined by the CPSC Directorate for Health Sciences staff (Babich and Thomas, 2001). In addition to information gathered at the public hearings, the staff evaluated scientific literature identified through extensive literature searches, risk assessments performed by the UK and the European Union (EU), and data submitted by industry. The staff performed extensive reviews of the toxicity data for 16 FR chemicals or chemical classes to

determine whether these chemicals would be considered toxic under the Federal Hazardous Substances Act (FHSA).

Although several commenters pointed out the toxicity of various chemicals and requested consideration of these data, it is important to note that a toxic chemical will not present a hazard to consumers if there is no exposure to the chemical. Some chemicals are bound covalently to the fibers and will not dissociate. Others are contained in a polymeric matrix and are not bioavailable. Thus, a chemical may not have a complete data set, but if the exposure assessment shows little or no exposure to the chemical, then there is minimal risk to the consumer. Similarly, a chemical can be considered "toxic" under the FHSA, yet not be considered a hazardous substance if there is no exposure or if exposure through reasonably foreseeable handling or use does not result in an unreasonable risk of injury or death.

Additionally, in its fiscal year 1999 appropriation to CPSC, Congress directed the Agency to contract with the NAS National Research Council (NRC) to perform an independent study of the "toxicological risk" of some FR chemicals. The NRC selected and convened a subcommittee of scientific experts to study the issue. This subcommittee completed its independent risk assessment (NRC, 2000) and its findings were considered by the CPSC staff. The NRC subcommittee (NRC, 2000) found that the use of 8 of the 16 proposed FR chemicals on residential upholstered furniture fabrics would present a minimal risk, even under worst case exposure assumptions. They recommended further exposure studies for the remaining eight chemicals, to determine whether additional toxicity studies need to be conducted.

Generally, exposure data were limited or not available for the 16 chemicals. The NRC subcommittee used very conservative assumptions about how consumers might be exposed to FR chemicals on upholstered furniture in order to be protective of public health. As the NRC acknowledged, this approach tended to overestimate the potential exposure, and therefore the risk, to consumers using FR-treated upholstered furniture. The actual risk to human health is likely to be lower than that estimated by the subcommittee.

CPSC staff did additional studies, such as exposure and migration studies, dermal penetration studies, and performed risk assessments. The risk assessments for FR chemicals likely to be used in upholstered furniture fabrics that were performed by both the CPSC staff and the NRC have concluded that there are certain chemicals that can be used for this purpose without presenting a hazard to consumers.

The CPSC staff has never stated that the textile industry has "safe" FR chemicals to use on upholstered furniture. There is no regulatory guidance for making a determination that a consumer product is "safe" under the FHSA. Rather, the staff has found that certain FR chemicals, proposed by the FRCA as likely candidates for use, do not, under the FHSA criteria, present a hazard under reasonably foreseeable use conditions.

The EPA recognizes that a hazard may exist to both human health and the environment when there is chemical contamination at Superfund sites, either in the presence or absence of FR chemicals. The commenter did not specify which FR chemicals were found at the Superfund site, so it is possible that none of the chemicals under consideration were found at that site. However, even if they were present, the exposure pathways, chemical concentration, forms of FR chemicals present (which might affect the toxicity), and other factors are very different at Superfund sites from household usage conditions affecting upholstered furniture. Thus, the exposures in these two scenarios are vastly different and need to be evaluated independently.

Issue: FR chemicals proposed for use on upholstered furniture may be more or less toxic than other chemicals already applied to upholstered furniture fabrics.

Several submitters remarked on the relative toxicity of other chemicals (dyes, finishes, etc.) applied to fabrics, as compared with FR chemical application. Gary Stevens from the University of Surrey, UK, stated that it is important to put the risks associated with human exposure to flame retardants in context with the risks of new and existing chemicals. The Consumer Safety Unit of the UK DTI has noted that most plastics contain a variety of chemicals, including pigments, stabilizers, and plasticizers, and question why any of these chemicals should be considered any less or more dangerous to children than the repertoire of modern flame retardants. Dr. Stevens commented that FR chemicals should not be considered *a priori* to have hazards or risks higher than those of other substances. Albemarle stated that there are many different chemicals applied to textile fabrics, of which FRs are just one class. UFAC stated that there is a host of dyestuffs and other finishing agents used in the manufacture and finishing of fabrics but that they do not have specific information on these substances.

Response: The Commission staff is committed to developing a small open flame standard for upholstered furniture without creating additional health hazards to consumers or workers or harming the environment. The CPSC staff agrees that there are various other chemicals used in the manufacture and finish of upholstery fabric. However, there is no evidence that the use of certain FR chemicals in upholstered furniture will present a risk to consumers.

II. Toxicity

Issue: The CPSC staff should conduct further evaluation on the toxicity and/or bioavailability and perform risk assessments on these chemicals.

UFAC noted that in the October, 1997 briefing package (Ray, 1997), the CPSC staff reviewed different FR chemicals than did the FRCA. ATMI noted that many of the chemicals in the October, 1997 briefing package were reported as toxic in the CPSC Federal Register notice (March 17, 1998) (63CFR13017).

Data were submitted from many textile, furniture, decorator, and chemical industries and trade groups. Both federal government and international health organizations also submitted data.

Response: The CPSC staff toxicity reviews in the October, 1997 briefing package were considered preliminary. Since that time, additional data have been obtained. All submitted data were carefully reviewed and considered by the CPSC staff in preparing the more comprehensive toxicity reviews, risk assessments, economic evaluations, and staff recommendations for the current briefing package. Updated searches of the scientific peer-reviewed literature were also performed for the current assessment. The CPSC staff has also considered risk assessments on selected FR chemicals that were performed by the UK DTI and the EU European Chemical Bureau. Additionally, CPSC staff conducted exposure and migration studies, and dermal penetration studies on certain FR's, the results of which were considered when the CPSC staff performed its exposure and risk assessments (Babich and Thomas, 2001).

The NRC performed an independent assessment of the toxic risk posed by the use of FR chemicals using the assumption that a residential upholstered furniture standard for small open flames is adopted. The NRC subcommittee found that 8 of the 16 chemicals or chemical classes that they reviewed could be used with minimal risk to consumers. In their report, the NRC considered available toxicity data, bioavailability by the inhalation, oral, and dermal routes of exposure, and other exposure data on the chemicals. When exposure data were not available, the NRC subcommittee used extremely conservative assumptions to overestimate risk. The CPSC staff also considered these data and conclusions.

Thus, the CPSC staff has reviewed all submitted data and testimony as well as other toxicity and exposure information germane to the possible use of FR chemicals on residential upholstered furniture.

Issue: There is a need for additional toxicity data on the FR chemicals proposed for use.

Both the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) and the Environmental Defense Fund (EDF) urged CPSC to require adequate toxicity and carcinogenicity data when evaluating chemical safety and noted that many of these data are not currently available. IARC notes that most chemicals on the list for possible use, including boric acid, HBCD, urea, PIP, ammonium bromide, Proban[®], Pyrovatex[®], ammonium polyphosphates and others have not been evaluated by IARC. The National Cotton Council of America stated that available toxicity data are incomplete and that the approval methodology for FR chemicals by CPSC staff is inconsistent, due to the lack of toxicity data. They also believe that testing should satisfy requirements of the FHSA and TSCA. The National Cotton Council of America and Solutia suggest that the Organization for Economic Development (OECD), Screening Information Data Set (SIDS) or some other set of tests should be conducted on chemicals as a basis for approval under FHSA, in order to

provide confidence that the chemicals used would not present a risk to human health or the environment. They stated that SIDS criteria require that the following tests be performed: acute toxicity, chronic toxicity, developmental/reproductive toxicity, neurotoxicity, mutagenicity, carcinogenicity, ecotoxicity, and environmental fate. ATMI commented that both acute and chronic data are needed to make a full and complete assessment about the potential use of an FR chemical.

Response: The CPSC staff's chemical review has taken into account chemical hazard data and analytical methods from a wide range of sources including CPSC's own laboratory testing. This information helps the agency satisfy its obligations under the Federal Hazardous Substances Act (FHSA), the statute under which the Commission is considering a possible performance standard for small open flame ignition of upholstered furniture. The Commission does not have the authority to "approve" chemicals under the FHSA. Risk assessments are based on all available data. While the OECD and other groups may provide scientific guidance for the way in which sound toxicological tests should be conducted, CPSC functions under its own set of regulations that provide similar guidance.

The Chronic Hazard Guidelines were issued by the Commission in 1992 to assess chronic hazards under the FHSA. They provide a description of principles that staff uses to determine whether a study is well conducted, whether appropriate endpoints are examined, and ultimately, whether sufficient evidence exists for a determination that a substance causes chronic toxicity. The Guidelines themselves establish no mandatory requirements. Manufacturers may use the Guidelines to aid in their determination of whether a product is a hazardous substance due to chronic toxicity and thus would require labeling under the FHSA or would be banned if the product was intended for use by children.

While the CPSC cannot require a specific battery of toxicological tests be performed on FR chemicals in performing its toxicity reviews, the CPSC staff did identify and note toxicity and exposure-related data gaps, as did the NRC in their report (NRC, 2000). Since the October, 1997 briefing package (Ray, 1997) was written, the CPSC staff have conducted additional studies to address exposure/risk issues. These include: migration studies on treated fabric using various media (water, weak acid, and organic solvents); accelerated aging and wear testing studies; soil and cleaning studies; and dermal penetration studies (conducted by EPA/NHEERL). Some of these exposure data were used to calculate human health risk, despite some gaps in the toxicity data. For other chemicals, however, data may be insufficient and the risk could not be calculated.

The FHSA does not require specific toxicological tests, but the CPSC is working to obtain additional data in coordination with U.S. EPA, which can require that chemical manufacturers submit data on chemicals that aren't adequately tested. EPA, under the Toxic Substances Control Act (TSCA), is developing a Significant New Use Rule (SNUR). The SNUR will require that chemical manufacturers provide data to support the contention that their products do not present unreasonable risks before they are

allowed to be used. EPA staff testified to the CPSC that they have been working with the Chemical Manufacturers Association (CMA), recently renamed the American Chemistry Council, to negotiate toxicity testing on a number of brominated flame retardants, including DBDPO and HBCD. EPA staff has also been working with OECD on a base set of testing for many chemicals, several of which are flame retardants. EPA staff testified that there was no standard set of studies required by EPA for every chemical, but rather, studies are required on a case-by-case basis (except where there is an exposure-based finding, which is determined by the production volume of the chemical). For full-production chemicals, EPA staff testified that EPA requires some testing, but if data are not available, then effects of similar chemicals, molecular weight, and exposure potential, etc. are examined.

Issue: There may be a correlation between the use of FR chemicals and sudden infant death syndrome (SIDS).

Trevira, a producer of synthetic chemicals, and Lois Scheel, a consumer, questioned whether there might be a link between the action of microbes on FR chemicals such as antimony in children's mattresses and the incidence of SIDS. The UK Department of Trade and Industry commented that an independent study done at the University of Surrey, UK have published interim findings that do not support the theory that antimony compounds in mattresses contribute to SIDS.

Response: There is no evidence that the use of FR chemicals is related to SIDS. Sudden infant death syndrome (SIDS) is defined as "the death of an infant under one year of age, which remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene, and review of the clinical history" (Willinger, 1991). Although the etiology of SIDS remains unknown, the following have been identified as independent risk factors for SIDS:

- A) Prone sleeping has been recognized as the major risk factor for SIDS. A large number of epidemiological studies throughout the world have identified the prone sleeping position as the most significant risk factor for SIDS with odd ratios ranging between 1.7 and 12.9 (Mitchell et al., 1991; Dwyer et al., 1994; Irgens et al., 1995). Countries that have national campaigns for promoting the supine sleeping position for infants have shown a dramatic drop in SIDS rate. In addition, in countries where caretakers traditionally place infants to sleep in a non-prone position have a lower incidence of SIDS (Davies et al., 1985; Lee, 1989; Kattwinkel, et al., 1992, 2000; Dwyer et al., 1995; Mitchell et al., 1994)
- B) Maternal smoking during the pregnancy (Hoffman et al., 1992; Schoendorf et al., 1992; MacDorman et al., 1997).
- C) Overheating (Fleming et al., 1990; Gilbert, 1992; Haglund and Cnatingius, 1990; Ponsonby et al., 1992).
- D) Lack of prenatal care, young maternal age, premature birth and/or low birth weight (Malloy et al., 1995).

In 1994, a report was published suggesting that poisoning by toxic gases may be a primary cause of SIDS (Richardson et al. 1994). The author suggested that flame retardant chemicals in infant mattresses, including antimony compounds, were capable of being metabolized into toxic gases by the fungus *Scopulariopsis brevicaulis* found in the mattress environment. This report generated much media attention and controversy and led the Department of Health in the United Kingdom to convene a scientific panel to review the scientific evidence. The panel unanimously concluded that the researcher had not provided firm evidence that antimony contributed to SIDS. In the United States, the SIDS Alliance also convened a panel of medical experts to evaluate the study (Krous et al., 1994). This panel also concluded, "...there is no evidence that the level of antimony in crib mattresses is unsafe."

To determine whether a link could be found between SIDS and the presence of such flame retardant materials in mattresses, the Department of Health in the United Kingdom supported a number of studies in various medical centers. Some of those studies included testing mattress material from reported cot death cases. These studies found little evidence of antimony volatilization as a cause of SIDS (Warnock et al., 1995; Gates, et al. 1997; Jenkins et al., 1998; Pearce et al., 1998).

In 1998, the report of a three and half year study conducted in the UK concluded, "...there is no evidence to suggest that antimony or phosphorus containing compounds used as fire retardant in PVC and other cot mattress materials are a cause of Sudden Infant Death Syndrome. Parents can be reassured that the toxic gas hypothesis and the claims put forward in the Cook Report do not stand up to scientific scrutiny." (Cullen et al., 1998).

Another study aimed at comparing the concentration of antimony in the serum of infants dying from SIDS and a control group of infants who died from other causes (Cullen et al., 2000). It was found that there were similar concentrations levels among the two groups and again, there was no evidence that antimony plays a role in SIDS.

In the absence of peer reviewed studies that provide scientific evidence showing a causative relationship between antimony and SIDS and in light of the numerous published reports that found no relationship between them, CPSC staff concurs with the assessment that antimony compounds in mattresses are not a factor in the etiology of SIDS.

Issue: Some commenters noted parallels between the use of FR chemicals for upholstered furniture and the past use of the FR chemical tris(2,3-dibromopropyl)phosphate (TRIS) in children's sleepwear.

Several textile manufacturers and IARC, an international scientific organization, questioned whether the Commission had considered the parallels between the approval of the FR chemical tris(2,3-dibromopropyl)phosphate (TRIS) for use in children's

sleepwear in the 1970's and the use of FR chemicals in residential upholstered furniture. They believe that the chemicals should be adequately studied before the proposed standard is enacted. There was also concern expressed about the ramifications of a toxicity finding once such treated products are on the market and have been sold.

Trevira, a producer of synthetic textiles, expressed concern about how furniture or fabric recalls could be handled realistically if these chemicals were later found to present a hazard like TRIS. Trevira also noted that poor individuals would be those most likely to be affected if there were such a recall, which would result in an "environmentally unjust" situation. The Environmental Defense Fund and UFAC stated that CPSC should be very careful to examine the safety of these chemicals, given the previous experience with TRIS. UFAC noted that TRIS was used although nothing was known about its toxicity, and it was found later to have some chronic toxicity.

Response: TRIS was originally introduced to make children's sleepwear to comply with the flammability requirements of the 1972 children's sleepwear standards enacted by the FTC under the Flammable Fabrics Act (FFA). In 1973, the Consumer Product Safety Act (CPSA) transferred the enforcement of that act and its implementing regulations to the newly formed Consumer Product Safety Commission.

After it became known that TRIS was carcinogenic in animals, the CPSC moved quickly and in 1977 took the position that TRIS, when used as a flame retardant in children's sleepwear, was a banned hazardous substance. It is unlikely that a similar situation would ever occur with the use of FR chemicals in upholstered furniture for the following reasons:

- a) Today, it is less likely that the carcinogenic potential of existing chemicals will be unknown. During the 1970's, health and safety experts were still learning how to identify carcinogens in a systematic way. New carcinogens were being reported on a regular basis. Currently, scientists are better able to identify problem chemicals and assess risks before they are used in products. There are a number of government programs (that the CPSC staff actively participates in) that either test chemicals for carcinogenicity or evaluate carcinogenicity data on chemicals. Therefore, CPSC staff obtains carcinogenicity information as soon as the studies are completed.
- b) Before the Commission requires that furniture manufacturers meet a small open flame standard, all existing data will be carefully assessed by the CPSC staff to ensure that there will be no unreasonable risk to consumers associated with FR's that may be used to achieve compliance. In 1999-2000, the NRC conducted an independent study of the risks of using FR chemicals on residential upholstered furniture. Both the CPSC staff and the National Academy of Sciences concluded that certain FR chemicals could be used in upholstered furniture without presenting a hazard to consumers (Babich and Thomas, 2001; NRC, 2000).

- c) EPA now has a number of procedures in place, designed to prevent the new use of potentially hazardous chemicals. The new chemical program under the Toxic Substances Control Act (TSCA) was not in place when TRIS was introduced. If EPA was concerned about a chemical's toxicity, human exposure, or the availability of toxicity or exposure data, EPA could use TSCA to restrict the chemical's use, pending additional testing. EPA also requires that a manufacturer file a Premanufacture Notice (PMN) for a new chemical's use before the chemical is put on the market. Finally, in the case of FR chemicals, EPA is expected to issue a SNUR that would require an FR chemical to undergo a more rigorous review before it is put to a new use.
- d) The application of flame retardant chemicals on upholstered furniture fabric as is currently being considered is very different from that of TRIS flame retardant in infant sleepwear. Some sleepwear was surface-treated with TRIS so that the TRIS was not tightly bound. In contrast to TRIS-treated infant sleepwear, upholstered furniture fabric will be treated in ways that will minimize exposure. For example, many flame retardants will be applied as a backcoating or will be bound chemically within the fibers of the upholstery fabric. In addition, there is a requirement in the draft proposed standard that the FR treatment remains in the fabric when it is wet.

Issue: The way in which CPSC defines the terms "toxic", "hazardous substance", "hazard", and/or "risk" may or may not agree with definitions of these terms by other groups or regulators. Federal, state, and international programs might exist for evaluating new and existing FR chemicals. Some programs limit the introduction of new hazardous FR chemicals that would be used in upholstered furniture.

Comments were submitted by textile and furniture trade associations and environmental groups suggesting that CPSC require a comprehensive battery of toxicological tests before a standard is enacted. The ATMI commented that the toxicity testing of FR chemicals should satisfy the requirements of all applicable laws, including the FHSA and TSCA, workplace, and environmental regulations. The Environmental Defense Fund and Steve Hart, a consumer, stated that CPSC should establish a stringent set of review criteria before approving any chemicals.

UFAC stated that there is an inconsistency in the way chemicals were "approved" for the October 1997 briefing package and the way in which staff accepted information from other reports. UFAC reported that sometimes some toxicological data were missing but that the data sets were deemed acceptable. They asserted that if there were limited data or limited evidence of an effect, then the chemical was deemed "non-toxic" by the CPSC staff. UFAC suggested expanding definitions so that if there is limited evidence, then other studies should be performed to further clarify whether the limited information is erroneous or if a problem exists. UFAC suggested the expansion of CPSC's regulatory definitions to include requirement of a complete data set, including

neurotoxic, developmental, reproductive, carcinogenic, and other chronic endpoints and the allowance of limited evidence of carcinogenicity.

Response: The CPSC administers the FHSA, the relevant statute for this issue, and its implementing regulations, 16 CFR 1500. The toxicity of the FR chemicals was evaluated using the criteria found in this statute. This statute was promulgated by Congress and cannot be changed by the Commission or its staff. The FHSA defines a "hazardous substance" as a substance that satisfies both parts of a two-part test. To be a hazardous substance, a product must first present one or more of the hazards enumerated in the statute, that is, it must be toxic, corrosive, flammable, an irritant, or a strong sensitizer, or generate pressure through decomposition, heat, or other means. Second, the product must have the potential to cause substantial personal injury or *substantial illness during or as a result of any reasonably foreseeable handling or use*, including reasonably foreseeable ingestion by children. That is, whether a given substance presents a hazard depends not only on its toxicity, but also on the potential exposure to it. The FHSA does not require manufacturers to perform any specific battery of toxicological tests to assess the potential for chronic hazards though the Commission's Chronic Hazard Guidelines do provide guidance in that area. Thus, CPSC risk assessments are based on all available data. The FHSA does not provide for premarket registration or approval. This places responsibility on the manufacturer to ensure either that their products are not hazardous substances under the FHSA or that they are labeled as required by the FHSA. Hazardous children's products are by definition banned hazardous substances.

The commenter incorrectly interpreted the CPSC staff's assessment of chemicals with limited or insufficient evidence. In evaluating the potential hazards presented by flame retardant chemicals, the CPSC staff follows the definitions for toxicity (both acute and chronic), irritancy, and sensitization in the FHSA. The Chronic Hazard Guidelines, described previously, explain the principles used by the Commission staff for assessing chronic toxicity under the FHSA, including carcinogenicity, neurotoxicity, *reproductive/developmental toxicity*. The Guidelines provide a description of principles that staff uses to determine whether a study is well conducted, whether appropriate endpoints are examined, and ultimately, whether sufficient evidence exists for determination that a substance causes chronic toxicity. They are also sufficiently flexible to incorporate the latest scientific information, and to allow for the determination of risk on a case-by-case basis. Thus, deviation from default procedures is permissible, if the procedures used are scientifically defensible and supported by appropriate data. The quality of the data reviewed is always considered.

After evaluation of the data using the principles outlined in the Chronic Hazard Guidelines, a substance may be determined to be a "possible", "probable", or "known" human toxicant. Possible human toxicants are not considered "toxic" under the FHSA. However, frequently this determination is based on limited or insufficient evidence in animals. This does not mean that this chemical is "safe", only that there are not sufficient data to satisfy the regulatory definition of toxic. If a substance is determined to be a "probable" or "known" human toxicant, however, it is considered "toxic" under the

FHSA. In this case, the Agency staff must perform a quantitative assessment of exposure and risk to decide whether the substance may present a hazard to consumers. A determination would then be made as to whether the product would be considered a "hazardous" substance under the FHSA. This determination would be made if the exposure during "reasonably foreseeable handling and use" were to exceed the acceptable daily intake. Although the FHSA defines "toxic" and "hazardous substance", it does not define "non-toxic", "nonhazardous", or "safe."

In addition to the statutory requirements of CPSC under the FHSA, EPA has some jurisdiction in this area. The EPA SNUR process for existing chemicals has previously been discussed. EPA has the statutory authority to look at the full extent that a chemical can pose a risk, i.e., manufacture through disposal, including use by consumers. The Toxic Substances Control Act (TSCA), which is administered by EPA, is a gatekeeper for new chemicals before they go to marketplace; EPA has very strong authority in this area. EPA does not approve these chemicals, but it has the authority to review and restrict or deny access or use in the marketplace. Under Section 5 of TSCA, EPA must show that a chemical may present an unreasonable risk to restrict or deny access to the marketplace. The assessment of risk includes exposures and risks to workers, consumers, and the general population, as well as effects on the environment. A submitter or importer must provide all existing health and environmental data. If the data are lacking, a structure activity relationship (SAR) approach is used by EPA to decide whether there is unreasonable risk. New chemicals frequently are submitted with little or no test data, so that when EPA regulates them, it is done to restrict the chemical until necessary data are provided.

Issue: The Chronic Hazard Guidelines used by the CPSC staff were improperly applied in evaluating consumer risk.

The Environmental Defense Fund (EDF) and Steve Hart, a consumer, believe that the Commission should approve no chemical unless there are sufficient toxicological data to demonstrate that the chemicals pose no health risk. If there were insufficient toxicological data, then no chemical should be approved for use as a flame retardant. UFAC stated that the Chronic Hazard Guidelines stipulate that the default value of 100% should be used for bioavailability when no data are available that would lead to an alternate approach.

Response: If a chemical is determined to be toxic under the FHSA, then a quantitative assessment of exposure and risk must be performed. Under the FHSA, chemicals are not pre-approved for use. Rather, chemicals are required to be labeled appropriately if they present a "hazard" to consumers under reasonably foreseeable handling and use, including ingestion by children. Such "hazardous substances" are banned if they are in a product intended for use by children.

The Commission's 1992 Chronic Hazard Guidelines for assessing chronic hazards under the FHSA explain the principles used by the Commission staff for assessing chronic toxicity under the FHSA. They provide a description of principles that

staff uses to determine whether a study is well conducted, whether appropriate endpoints are examined, and ultimately, whether sufficient evidence exists for a determination that a substance causes chronic toxicity. The Guidelines themselves establish no mandatory requirements. Manufacturers may use the Guidelines to aid in their determination of whether a product is a hazardous substance due to chronic toxicity and thus would require labeling under the FHSA or would be banned if the product was intended for use by children.

There may be deviation from the guidelines if there is a valid reason. Under the Chronic Hazard Guidelines, the implied assumption for the bioavailability for oral exposures is that it is the same in humans as it is in the animals. For the dermal route of exposure, experimental data are used if available, but in their absence, reasonable estimates are made based on the physico-chemical characteristics of the substance. For inhalation exposure, the bioavailability is generally assumed to be 100%. In both the NRC and the CPSC staff risk assessments for inhalation exposure, 100% bioavailability was assumed.

The CPSC 1997 toxicity reviews (Mishra, 1997) originally assessed by UFAC were preliminary. CPSC staff did more complete toxicity reviews in 1999. Data from EPA's TSCATS database and unpublished studies have been added to the data analyzed by staff. Studies on ingestion of FR chemicals from treated fabrics and dermal absorption of FR chemicals have also been performed. The CPSC and the NRC in their risk assessments (Babich and Thomas, 2001; NRC, 2000) also reviewed the bioavailability of the FR chemicals. In neither of these reports was the bioavailability considered to be zero. Thus, the CPSC staff appropriately followed the Chronic Hazard Guidelines, which allow deviations when there is a valid scientific reason. Both the NRC and the CPSC risk assessments on FR chemicals found that a number of FR chemicals would not present a hazard to consumers.

Issue: DBDPO is not toxic under the FHSA, but has been characterized as such by the CPSC.

Albemarle, a chemical company that produces DBDPO and HBCD, disagreed with the conclusions of the CPSC staff that DBDPO is toxic and is a "possible" developmental toxicant under the FHSA (Bittner, 1999a). Albemarle stated that CPSC's conclusions were largely based on a study that tested a substance that was only 77% DBDPO, which does not reflect the purity of the product currently sold by Albemarle ($\geq 97\%$ DBDPO). In addition, while Albemarle agrees with the CPSC staff assessment that HBCD is not toxic under the FHSA, they disagree with CPSC staff's conclusion that HBCD is a possible reproductive toxicant and possible neurotoxicant (Hattelid, 1999).

Response: When making a determination of chronic toxicity under the FHSA, the CPSC staff examines several endpoints: systemic, neurological, reproductive, developmental, and carcinogenic. If there are sufficient data to warrant a finding of "probable" or "known" toxicity in any one of these categories, then the substance is a chronic toxicant or "toxic" under the FHSA. If, however, there are data showing adverse

effects on an endpoint, but the data are not sufficient, as defined under the FHSA, to make a determination of "probable", then the substance may be considered a "possible" toxicant. The finding of "possible" toxicity is not sufficient to make a finding of chronic toxicity under the FHSA.

Available data support the finding that DBDPO is toxic under the FHSA, based upon systemic toxicity (liver effects) in animals. These effects were observed in rodents in an NTP (1986) bioassay, in which animals were fed ~97% DBDPO in the diet (Bittner, 2000). Thus, while Albemarle suggests that the effects were due to the presence of lesser-brominated compounds in the DBDPO formulation in some studies, the effects were also observed in a 2-year study in which the purity of the test compound was much higher (NTP, 1986). Support for the CPSC finding that the liver effects observed in the NTP bioassay were related to administration of the test compound can be found in the NRC (2000) risk assessment for DBDPO.

CPSC staff maintains the classification of DBDPO as a "possible" developmental toxicant under the FHSA. While the staff acknowledge that the developmental effects observed in rats in the Norris et al. (1974) study were observed after administration of the less pure (77.4%) DBDPO, these data can be used in the absence of other data using a more pure formulation. The NRC examined these same data and also noted the developmental effects (NRC, 2000).

Thus, although the classification as a "possible" developmental toxicant is not sufficient to classify DBDPO as "toxic" under the FHSA, the overall categorization of "toxic" was determined by using data on liver effects in the NTP (1986) study, in which the more pure form of the compound was used.

CPSC staff considers HBCD to be a "possible" reproductive and neurological toxicant under the FHSA based on limited data in experimental animals. As described in both the CPSC toxicity review (Hattelid, 1999) and the NRC (2000) report, effects observed in rats after oral administration of high doses of HBCD included inhibited oogenesis (reproductive) and unsteady gait (neurological) (Zeller and Kirsch, 1969).

Although HBCD is a possible reproductive and neurological toxicant, based on one study using high doses in animals, it does not meet the definition of toxic under the FHSA, which requires a finding of "probable" or "known" toxicity for at least one endpoint (systemic, neurological, reproductive, developmental, carcinogenic).

Issue: The toxic effects of smoke arising from fires involving FR-treated furniture products may or may not be more deleterious than smoke from non-treated upholstered furniture fires.

Several groups stated or implied that the toxicity of smoke from FR-treated furniture is no more toxic than that from treated furniture. The Polyurethane Foam Association noted that carbon monoxide (CO) is the primary constituent of smoke that causes the most deaths and that the use of FR chemicals reduces the overall amount of

CO by lowering the burn rate and material mass loss. American Flamecoat of Southern New Jersey commented that burning non-treated fabrics release more harmful materials into the air than treated fabrics and the smoke toxicity from FR treated fabrics should not be any more dangerous than for other fabrics.

Other commenters believe that smoke from FR-treated furniture is more toxic than smoke from non-treated furniture. The Environmental Defense Fund and Steve Hart recommended that the products of combustion be identified and tested. They also commented that no studies have been conducted on the human health risks due to exposure to the products of combustion of FR chemicals and that such data are needed.

Response: As proposed for use in upholstered furniture, FR chemicals will reduce the potential for ignition and thus, decrease injuries that occur as a result of ignition.

No evidence was submitted that indicated that the smoke from fires involving FR-treated fabrics is significantly more toxic than that of non-FR treated fabrics. The staff agrees that the primary threat to human health from fires is the production of CO. The possible smoke toxicity of flame retardant chemicals is important because more fire-related fatalities result from smoke inhalation than from burns (Hall, 2000). Smoke can cause health effects, including eye and respiratory tract irritation. In some cases, the presence of FR chemicals may slow the production of CO.

Since FR chemicals reduce the total amount of material that is burned and decrease a material's burning rate, the overall amount of CO released into a room is expected to be reduced (NIST, 1991; CMA, 1997).

Both FR and non-FR treated upholstered furniture will, when burned, produce potentially harmful combustion by-products, depending upon the chemical composition of the burning material. However, the overall contribution of these combustion by-products to deaths in fires is considered minimal compared to the toxic effects of CO.

Hydrogen cyanide (HCN), which is a rapidly acting chemical asphyxiant and carbon dioxide (CO₂), which at high concentrations will suppress breathing, can also be produced in some fires and exacerbate the overall narcotic effects of CO.

When materials containing brominated FR chemicals (BFR's) chemicals are burned, they may produce combustion by-products such as hydrogen bromide (HBr), which may be eye or respiratory irritants. Eye irritants may impair egress from the home because the victim may be unable to see clearly and respiratory irritants may impair the ability of the victim to escape due to labored breathing. In comparison to the more deleterious effects of the narcotic gases such as CO and HCN, the irritation potential of HBr is a lesser concern. Further, the total amount of BFR that is applied to upholstered furniture is relatively small. Typically, BFR's that are applied to the furniture fabric comprise a relatively small fraction of the fabric weight. When the total amount of

flammable material in a piece of furniture is considered, the fraction of the weight comprised of BFR is minuscule.

Issue: Dioxins and/or furans may or may not be found in FR chemicals as impurities and may or may not be formed in a fire situation.

Several submitters commented on dioxins and/or furans being formed in a fire scenario or being present as impurities in FR chemical products. Gary Stevens, University of Surrey, UK testified to the Commission that dioxins are formed from most chlorine and bromide containing compounds during a fire. The National Cotton Council of America discussed the European Union Ecolabeling Initiative for textiles, which is intended to limit the impact of products that may contain impurities such as dioxins and furans.

Response: Dioxins and furans are products of incomplete combustion, which are produced by virtually any combustion process, including residential fires. Commenters did not provide any evidence that more dioxins would be produced when FR chemicals are present. The presence of FR chemicals reduces the potential for fire growth, which reduce the production of these chemicals.

In a residential fire, the acute or short-term effects of smoke and heat, which include death, are considerably more immediately hazardous than are the chronic effects. The primary concern is to prevent immediate injury to the occupants due to smoke and heat, thus, mechanisms that prevent the ignition or spread of fire are desirable.

As stated previously, dioxins can be found in any fire, whether FR chemicals are present or not. Commenters did not submit any data nor are we aware of such data that show FR treated fabric produce more dioxins and furans in a fire situation than do non-treated fabrics.

At the May, 1998 public hearing, Marcia Hardy, a toxicologist for Albemarle, testified that there have been no health effects observed in workers from plastics industries using DBDPO that could be associated with exposure to dioxins/furans. They have tested soot and char found neither to be acutely toxic nor chloracnegenic, which are characteristic of dioxins and furans.

Issue: CPSC should review the draft European Union (EU) risk assessments on decabromodiphenyl oxide and hexabromocyclododecane.

UFAC submitted a review of the EU draft risk assessments on DBDPO (EU, 1999a, 2000) and HBCD (EU, 1999b) by Toxicology Consulting Services. The review noted that the draft risk assessments expressed concern about the formation of dibenzofurans and brominated dibenzo-p-dioxins from combustion/pyrolysis products of DBDPO; environmental effects of both DBDPO and HBCD; and changes in chemical

composition over time and from fires. The review also noted the conclusion of the EU assessment that HBCD should not be used in consumer products.

Response: The CPSC staff had previously reviewed the draft EU risk assessments that were provided by UFAC (Bittner, 2001). The CPSC staff has considered all of the issues and concerns raised in these draft documents. The CPSC staff has performed its own risk assessment on these chemicals. The CPSC staff risk assessment on HBCD concluded that its use in upholstered furniture will not present a hazard to consumers by the most likely routes of exposure (Babich and Thomas, 2001). The issues of dioxin formation, smoke toxicity, and aging have been previously discussed in this document. With regard to the EU conclusion that HBCD should not be used in consumer products, both the NRC report (NRC, 2000) and the CPSC staff (Babich and Thomas, 2001) performed quantitative risk assessments and concluded that there would be a minimal risk to consumers with the use of HBCD on residential upholstered furniture.

III. Exposure and Bioavailability

Issue: Lack of data on exposure and availability of FR chemicals.

In their comments and testimony, representatives of AFMA and UFAC argued that there is a general lack of data on exposure and bioavailability for the FR chemicals proposed for use in upholstered furniture. They argued further that the potential for exposure is high. In contrast, representatives of FR chemical producers argued that bioavailability and the potential for exposure are generally low (AOIA, Albemarle, Ciba, and FRCA). Alan Mann, on behalf of the U.K. Department of Trade and Industry, testified that it is very important to consider bioavailability in assessing risk, and that exposure to antimony trioxide (AT) from upholstery fabric is low compared to background exposure. Mr. Mann added that additional data on the bioavailability of FR chemicals in general are needed.

Response: Under the FHSA, exposure and bioavailability must be considered in the determination of whether a substance is hazardous. In order for a substance to be considered hazardous under the FHSA, it must not only have the potential to be toxic, but it must be demonstrated that (a) the substance may come into contact with the body, (b) the substance can be absorbed by the body, and (c) there is a significant risk of an adverse effect associated with these events. These events represent exposure, bioavailability, and risk (CPSC, 1992, p. 46644). Some authors, as well as some respondents, use the term bioavailability to include exposure, that is, both (a) and (b) above. By either definition, both exposure and bioavailability must be considered in determining whether a substance is hazardous under the FHSA.

FR chemical manufacturers and applicators as well as fabric manufacturers and finishers are responsible for ensuring that their products do not present a hazard to consumers, or if they do, that they are properly labeled. Manufacturers, applicators, and/or finishers should conduct appropriate migration and emission tests and perform

quantitative risk assessments to determine whether their products are hazardous under the FHSA.

As part of the CPSC staff risk assessment, the staff performed migration tests on five different FR chemicals to assess the potential for dermal and oral exposure. The staff also contracted with the EPA National Health and Environmental Effects Research Laboratory (NHEERL) to test the dermal bioavailability (that is, dermal absorption) of three FR chemicals (DBDPO, HBCD, and TDCP). In these studies, TDCP was rapidly absorbed through the skin, while DBDPO and HBCD were absorbed more slowly. These data, as well as all available data on bioavailability of the chemicals considered, were included in the CPSC staff risk assessment (Babich and Thomas, 2001).

Issue: General comments on exposure and bioavailability.

Representatives of FR chemical manufacturers (Albemarle, Akzo Nobel, Ciba, and FRCA) testified that the potential for exposure to FR chemicals is likely to be low, because the FR's are physically or chemically bound to the fabrics. In contrast, representatives of the upholstered furniture industry expressed concern regarding potential consumer exposure to FR chemicals in upholstered furniture (Coalition of Converters of Decorative Fabrics, Decorative Fabrics Association, BIFMA, and UFAC). Specifically, furniture industry representatives noted that there are little or no data to support the claims made by FR manufacturers that exposure is, in fact, negligible (UFAC). They specifically noted that exposure by all possible routes—dermal, inhalation, oral—should be considered, and that migration studies with FR-treated fabrics should be conducted. Data on bioavailability are also needed.

Response: The CPSC staff agrees that all potential routes of exposure—dermal, inhalation, and oral—should be considered. Certain methods used to apply FR chemicals, such as back-coating, and the use of reactive chemicals are expected to reduce the potential for exposure. While back-coatings may reduce exposure to FR chemicals, it cannot be assumed that exposure to all FR chemicals applied in back-coatings will be at negligible levels. Exposure and risk depend on the properties of the particular FR chemical and back-coating used. Reactive FR chemicals either polymerize within fabric fibers or else react chemically with them. However, there is a potential for exposure to unreacted FR chemicals, reaction by-products, or decomposition products. Therefore, when a given FR chemical or its by-products is considered "toxic" as defined under the FHSA, then manufacturers, applicators, and/or finishers should conduct appropriate migration and emission tests and perform quantitative risk assessments to ensure that their products are not hazardous under the FHSA or, if they are hazardous, that they are labeled in accordance with the FHSA. In some cases, additional bioavailability data such as percutaneous absorption studies may be needed. Manufacturers should then perform quantitative risk assessments to determine whether their products are hazardous, as defined by the FHSA. 15 USC 1261 (f)(1)(A).

The CPSC staff conducted migration studies on fabrics treated with five different FR chemicals (Bhooshan and Cobb, 2000) and performed a quantitative risk assessment for a total of eight FR's (Babich and Thomas, 2001). The CPSC staff concluded that four of these—cyclic phosphonate esters (CPE); decabromodiphenyl oxide (DBDPO); hexabromocyclododecane (HBCD); and phosphonic acid, (3-[[hydroxymethyl]amino]-3-oxopropyl-, dimethyl ester (PA) would clearly not be considered hazardous to consumers under the FHSA when exposure from all three exposure routes (dermal, oral, and inhalation) are combined. PA did not meet the FHSA definition of "toxic". A fifth chemical, 2-ethylhexyl diphenyl phosphate (EDHP), would probably also not be hazardous to consumers, although it could present a hazard of systemic (non-cancer) effects from dermal exposure only if the treated fabric were cleaned with a solvent based dry cleaning fluid. However, migration data would be needed to confirm this conclusion.

The staff cautioned, however, that these conclusions are specific to the fabric samples that the CPSC staff tested, and would not necessarily apply to all fabrics treated with these chemicals. Thus, manufacturers are responsible for determining whether their own products may be hazardous. The staff also concluded that additional data are needed to assess the potential risks from the remaining three FR treatments considered—antimony trioxide (AT); tetrakis (hydroxymethyl) phosphonium chloride (THPC), and tris(1,3-dichloropropyl-2) phosphate (TDCP).

FR chemical manufacturers and applicators may conduct their own risk assessments. Suggested methods for conducting migration studies and risk assessments are described in the CPSC staff reports on the migration studies (Bhooshan and Cobb, 2000) and the risk assessment (Babich and Thomas, 2001), respectively. Manufacturers may also consult the CPSC chronic hazard guidelines, which describe the methods that the CPSC staff uses to determine whether products are hazardous (CPSC, 1992). Manufacturers are free to develop their own methods for assessing exposure and risk, provided that they are scientifically defensible and supported by appropriate data.

Issue: Bioavailability of FR chemicals applied in backcoatings.

Some FR chemical companies (Albemarle, Akzo Nobel, FRCA) commented that back-coatings would effectively encapsulate FR chemicals, specifically DBDPO, HBCD, and organophosphates, and that this would lead to negligible exposure or bioavailability by either the dermal, inhalation, or oral routes. They also claimed that cleaning solvents would not extract DBDPO. In contrast, representatives of furniture industry groups commented that it has not been demonstrated that backcoatings would adequately encapsulate FR chemicals (Coalition of Converters of Decorative Fabrics, Decorative Fabrics Association, BIFMA, and UFAC). At the public hearing, Mr. Joseph Ziolkowski, representing AFMA and UFAC, demonstrated that the backcoating may be partially exposed to the top surface of the finished fabric. Mr. Ziolkowski also displayed a sample of back-coated fabric with a sweetener added to the backcoating and stated that the backcoating tasted sweet, demonstrating that the sugar can migrate from the backcoating into saliva.

Response: The extent to which FR chemicals can migrate from backcoatings can be tested by performing appropriate migration (leaching) experiments. The CPSC staff conducted migration studies with backcoated fabrics containing AT in combination with either DBDPO or HBCD (Bhooshan and Cobb, 2000; see also Levenson, 2000). The staff used two different test methods intended to estimate dermal and oral exposure, respectively. To estimate dermal exposure, a piece of filter paper was placed on top of a fabric sample, and the fabric and filter paper were then saturated with an appropriate solvent. The extent of migration of FR chemical into the filter paper was measured. The staff tested a variety of solvents including saline, citric acid solution, a water-based upholstery cleaner, and a dry cleaning solvent (methyl chloroform). The extent of migration depended on the solvent and FR chemical. For example, migration of DBDPO and HBCD was non-detectable with saline, citric acid, and the water-based upholstery cleaner. However, the level of migration was greater with methyl chloroform. Migration of AT was low with saline and upholstery cleaners, but increased with citric acid.

The CPSC staff used the "head-over heels" method to estimate oral exposure (Bhooshan and Cobb, 2000). In the head-over-heels method, both sides of a fabric sample are exposed to a simulated saliva solution while the sample and solution tumble at 60 rpm in a screw cap bottle. The amount of FR chemical in the simulated saliva is determined at 30-minute intervals and the migration rate is calculated. The migration rate was detectable in all cases, although generally low.

The CPSC staff used these migration data to estimate dermal and oral exposure to FR chemicals during reasonably foreseeable handling and use (Babich and Thomas, 2001). The staff also used mathematical models to estimate inhalation exposure to particles and vapors. Based on these estimates, the staff concluded that the estimated exposure from DBDPO, and HBCD would be well below the negligible risk levels for these compounds. Furthermore, HBCD does not satisfy the definition of "toxic" under the FHSA. Therefore, the staff concluded that DBDPO, and HBCD would not present a hazard to consumers.

Fabric samples treated with organophosphates were not available for testing. However, the staff performed a preliminary exposure and risk assessment for the organophosphate TDCP by using a surrogate compound with similar physico-chemical properties (HBCD) to predict dermal and oral exposure and mathematical models to predict inhalation exposure. By this methodology, the staff preliminarily concluded that exposure to TDCP by the dermal, oral, and inhalation routes would be sufficiently high to present a hazard to consumers. Migration data and data on the emission of TDCP from treated fabrics are needed to confirm these preliminary conclusions.

The sweetener that Mr. Ziolkowski added to the back-coating was probably water-soluble, which would tend to increase its migration into saliva. In contrast, AT, DBDPO, and HBCD have limited water solubility and migrate into saliva simulant at a low rate (Bhooshan and Cobb, 2000). Thus, the sweetener does not behave as AT, DBDPO, and HBCD when present in a back-coating.

The CPSC staff concludes that, while back-coatings may reduce exposure to FR chemicals, it cannot be assumed that exposure to all FR chemicals applied in back-coatings will be at negligible levels under all conditions. Exposure and risk depend on the properties of the particular FR chemical and backcoating used. Each combination of FR chemical, backcoating and fabric should be considered separately to determine whether they may present a hazard under the FHSA.

Issue: Exposure to light, including ultraviolet and infrared, might affect human exposure to FR treatments by affecting the upholstery fabric.

Several representatives of the furniture industry commented that the effects of age and wear could increase the potential for exposure to FR chemicals (Amoco, Decorative Fabrics Association, BIFMA, and UFAC). For example, back-coatings could erode over time and there is no test that can replicate this process. One fiber manufacturer reported that some FR treatments reduce the UV stability of their products (Amoco). FR chemical manufacturers responded that their products are durable and resist the effects of age and wear (Bostik, Ciba, and FRCA). FR-treated fabrics have been subjected to various tests designed to simulate age and wear. FR treatments remain durable after exposure to repeated laundering (Ciba, FRCA), UV exposure (FRCA), and mechanical wear (Bostik).

Response: The CPSC staff agrees that age and wear might increase the potential for exposure to FR chemicals. In its risk assessment (Babich and Thomas, 2001), the CPSC staff considered the potential effects of age and wear on dermal, oral, and inhalation exposure. Fabric samples were subjected to an accelerated aging protocol, which involved exposure to ultraviolet radiation and elevated temperatures (Bhooshan and Cobb, 2000). The conditions simulate approximately 5000 hours of exposure to ultraviolet light such as may be found indoors. Fabric samples were also subjected to an accelerated wear protocol. The migration tests performed with new fabrics were repeated following the accelerated age or wear treatments. On average, migration rates were two-fold greater with the aged or worn fabrics. The staff also considered the erosion of airborne particles from upholstered furniture due to wear and tear (Babich and Thomas, 2001). All of the information on the effects of wear and age was included in the CPSC staff risk assessment (Babich and Thomas, 2001). Even after allowing for the effects of age and wear, the staff concluded that CPE, DBDPO, HBCD, and PA would not present a hazard to consumers. Furthermore, EDHP would also probably not be hazardous to consumers, although it could present a hazard of systemic (non-cancer) effects from dermal exposure only if the treated fabric were cleaned with a solvent based dry cleaning fluid. However, migration data would be needed to confirm this conclusion.

Issue: Oral exposure to FR chemicals can occur when children suck or chew on upholstered furniture fabric, such as the arm caps.

Representatives of AFMA and UFAC commented that oral exposure to infants is reasonably foreseeable and that migration data are needed (UFAC). Mr. Ziolkowski,

representing AFMA and UFAC, added that arm covers are removable and, therefore, the back-coating is exposed.

Response: The CPSC staff agrees that mouthing of upholstered furniture by infants is reasonably foreseeable, but that it will be relatively infrequent and of limited duration, as compared to teething and toys (Smith, 2000). Nonetheless, mouthing was considered in the CPSC staff risk assessment of upholstered furniture. The staff performed migration studies with FR-treated upholstery fabrics to assess the potential for oral exposure. Fabric samples treated with AT, DBDPO, HBCD, PA, and THPC were tested by the "head-over-heels" method to estimate oral exposure (Bhooshan and Cobb, 2000). In the head-over-heels method, both sides of a fabric sample are exposed to a simulated saliva solution while the sample and solution tumble at 60 rpm using a screw cap bottle. *The results of these tests contributed to the CPSC staff risk assessment.* The staff concluded that oral exposure contributed relatively little to the total exposure, as compared to dermal exposure. The staff further concluded that CPE, DBDPO, HBCD, and PA would not present a hazard to consumers when exposure from all three exposure routes (dermal, oral, and inhalation) are combined. EDHP would also probably not be hazardous to consumers, although it could present a hazard of systemic (non-cancer) effects from dermal exposure only if the treated fabric were cleaned with a solvent based dry cleaning fluid. However, migration data would be needed to confirm this conclusion.

Issue: Using FR chemicals on upholstered furniture might have a deleterious effect on indoor air quality.

BIFMA International and Haworth, Inc. stated that the addition of FR chemicals would appear to be in direct conflict with efforts to improve indoor air quality in the workplace as well as in the home. They stated that EPA is currently working to improve indoor air quality by reducing emissions from furniture and other office products. Use of FR's is in opposition to the EPA/BIFMA initiative because loading a high-wear part of the furniture with chemicals will cause them to powder off with wear and age and make them likely to re-dissolve or otherwise transfer to skin and clothing. Haworth has observed numerous health concerns including contact dermatitis, allergic reaction, respirable dust, and transfer to clothing.

Response: The commenters presented no evidence to support their claims that use of FR chemicals on upholstered furniture would adversely affect residential indoor air quality. The Haworth spokesman testified that he doesn't know whether there are emissions or odors from fabrics. He testified that he knows of no studies that demonstrate that there would be particulate emissions in high-wear situations.

Inhalation exposure to vapors or particles released from fabrics is one of three potential routes of exposure to FR chemicals. It is appropriate to consider inhalation exposure in determining whether a given FR treatment may be hazardous. Exposure to both vapors and particles was considered in the NRC risk assessment (NRC, 2000) and in the CPSC staff risk assessment (Babich and Thomas, 2001). For the most part, the

FR chemicals proposed for use in upholstered furniture have low volatility, which reduces the potential for exposure to vapors.

In the CPSC staff risk assessment, dermal exposure was the primary route of exposure to the FR chemicals that the staff considered. Combining all three routes of exposure, the staff concluded that CPE, DBDPO, HBCD, and PA would not present a hazard to consumers. EDHP would also probably not be hazardous to consumers, although it could present a hazard of systemic (non-cancer) effects from dermal exposure only if the treated fabric were cleaned with a solvent based dry cleaning fluid. However, migration data would be needed to confirm this conclusion. The staff preliminarily concluded that exposure to TDCP vapors would contribute significantly to the overall exposure. While TDCP is more volatile than some FR's (for example, DBDPO and HBCD), the significance of inhalation exposure is primarily due to its toxicity. Migration data and data on the emission of TDCP from treated fabrics are needed to confirm these preliminary conclusions.

Inhalation exposure is not likely to present a hazard for CPE, DBDPO, EHDP, HBCD, PA, or THPC (Babich and Thomas, 2001). FR chemical manufacturers and applicators as well as fabric manufacturers and finishers are responsible for ensuring that their products do not present a hazard to consumers, or if they do, that they are properly labeled. The potential for inhalation of vapors or particles should be considered in any risk assessment to determine whether particular FR treatments are hazardous. Data on the emission of FR chemicals from treated fabrics may be needed for some FR chemicals.

Issue: CPSC chronic hazard guidelines—guidelines for assessing bioavailability.

Representatives of the furniture industry (UFAC) stated that the CPSC chronic hazard guidelines require a default value of 100 percent bioavailability (absorption). The CPSC memorandum (Mishra, 1997) did not assume 100 percent bioavailability as a default.

Response: The CPSC staff and other regulatory scientists generally define “exposure” as the amount of a substance that comes into contact with the body over time, and “bioavailability” as the extent to which a substance in contact with the body is absorbed (CPSC, 1992, p. 46648) (see above). Some authors use the term bioavailability in a broader sense to include both exposure and absorption.

The 1997 CPSC memorandum (Mishra, 1997) was a preliminary review of the toxicology of several FR chemicals considered likely candidates for use in upholstered furniture. The memorandum generally characterized exposure or bioavailability only in qualitative terms.

The CPSC chronic hazard guidelines state that 100 percent bioavailability (not exposure) is the default assumption. That is, that 100 percent absorption is to be assumed in the absence of data to the contrary (CPSC, 1992, p. 46649). However, the

available toxicity data on the FR chemicals are mainly from animal studies. Therefore, the relative absorption in animals and humans, or among exposure routes, is generally more relevant to assessing risk than an absolute measure of absorption (CPSC, 1992, p. 46650). Whether 100 percent or 10 percent of the substance is absorbed is not critical, provided that the extent of absorption is about equal in animals and humans. Many risk assessments, including the CPSC risk assessment on FR chemicals, assume that absorption is equal in humans and animals.

The CPSC staff risk assessment assumed 100 percent bioavailability for oral and inhalation exposure, except in cases where actual data or reliable estimates were available (Babich and Thomas, 2001, Tables II-4a and II-4b). No data on inhalation absorption were available for any of the 8 chemicals included in the risk assessment, while data on oral absorption were available for 2 of 8 chemicals. Data on dermal absorption were available for 4 of 8 chemicals.

When dermal absorption data were not available, the CPSC staff estimated dermal absorption values from the physico-chemical properties of the chemicals. Dermal absorption is known to correlate with physico-chemical properties such as molecular weight and octanol: water partition coefficient (K_{ow}) (EPA, 1992). The NRC estimated dermal permeability coefficients (K_p values) from the physico-chemical properties (NRC, 2000, pp. 39-40).

Furthermore, the CPSC staff applied a route-to-route correction for dermal absorption to account for differences in absorption between the oral and dermal route (Babich and Thomas, 2001, pp. 19-20). The correction was applied, because the dose response studies were generally by the oral route. Applying this correction increases the estimated risk from dermal exposure. The NRC did not apply such a route-to-route correction. The CPSC staff did not apply a route-to-route correction to inhalation exposure, because of the lack of data on, or a means to estimate, the inhalation bioavailability. Therefore, the contribution of inhalation exposure to the total risk may be overestimated.

Issue: Bioavailability of hydrophobic compounds.

At the public hearing, Dr. Vincent Piccirillo, representing FRCA, discussed the toxicology of the FR chemicals that are candidates for use in upholstered furniture. Dr. Piccirillo stated that the bioavailability of hydrophobic compounds such as DBDPO is expected to be low.

Response: The CPSC staff agrees that the physico-chemical properties of chemical substances, such as the molecular weight, solubility, and octanol: water partition coefficient (a measure of hydrophobicity) influence bioavailability, that is, the ability to be absorbed by the body. However, the fact that a chemical is hydrophobic does not necessarily mean that it has negligible bioavailability. For example, the hydrophobic FR chemical TDCP was found to be readily absorbed through the skin *in vitro* (Hughes, 2000). The hydrophobic FR's DBDPO and HBCD were also absorbed by the skin,

although to a lesser extent. In assessing the potential risks from FR chemicals, it is preferable to obtain actual data on exposure and bioavailability and to perform quantitative risk assessments.

Issue: Bioavailability of antimony trioxide (AT), decabromodiphenyl oxide (DBDPO), and hexabromocyclododecane (HBCD).

Some manufacturers of FR chemicals claimed that their products are poorly absorbed. Manufacturers of AT (AOIA) and DBDPO (Albemarle) pointed out that these compounds were poorly absorbed in oral studies. Manufacturers predicted that DBDPO would be poorly absorbed by the lungs and through the skin, and that HBCD would be poorly absorbed through the skin.

Response: The CPSC staff is aware of reports that AT and DBDPO were poorly absorbed from the digestive tract of animals; this is likely to be true in humans as well (as cited in Babich and Thomas, 2001, Table II-4a). However, since the acceptable daily intake (ADI) values¹ are based on applied doses, the relative absorption of these compounds in animals and humans, or among different exposure routes, is more relevant in quantitative risk assessment than the absolute absorption (CPSC, 1992, p. 46650). In its risk assessment, the CPSC staff assumed that the oral bioavailability of AT and DBDPO was similar in both animals and humans (Babich and Thomas, 2001). Therefore, because the ADI's were generally based on oral studies, there was no need to adjust for bioavailability when estimating the risk from oral exposure.

One respondent predicted that DBDPO and HBCD would be poorly absorbed through the skin (Albemarle). The CPSC staff obtained data on the dermal absorption of these compounds *in vitro* (Hughes, 2000). In these studies, from 3 to 6 percent of HBCD and from 2 to 20 percent of DBDPO was absorbed. These values include both FR chemical penetrating through the skin, as well as that found within the skin that could not be removed by washing. The CPSC staff concludes that DBDPO and HBCD are absorbed at low, but measurable, rates.

Issue: Bioavailability of phosphonic acid, (3-[[hydroxymethyl]amino]-3-oxopropyl-, dimethyl ester (Pyrovatex) (PA).

At the public hearing, Mr. Carl D'Ruiz, representing Ciba Specialty Chemicals, testified that the FR chemical Pyrovatex (PA) has "low exposure potential" because it is chemically bound to cotton fibers. He also described a study by Ciba showing that sweat and saliva extracts of PA-treated fabrics did not penetrate the skin.

Response: Because PA is chemically bound to cotton fibers, the potential for exposure is expected to be low. However, there is a potential for exposure to unreacted PA or reaction by-products. The CPSC staff reviewed the study by Ciba involving sweat and saliva extracts of PA-treated fabrics (reviewed in Bittner, 1999b). Ciba extracted PA-

¹ The acceptable daily intake (ADI) is the exposure level at which the risk of adverse health effects is considered negligible.

treated fabrics with simulated sweat or saliva, but apparently did not determine whether any PA or PA by-products were present in the extracts. The unanalyzed extracts were applied to skin (porcine ear) *in vitro*. PA was not detected in the receptor fluid (that is, did not penetrate through the skin) at times up to 24 hours. However, the analytical detection limit was not reported. Apparently, Ciba did not test for other organophosphorus compounds such as reaction by-products of the PA process, and no positive controls were tested. The CPSC staff concludes that this study does not establish that the dermal dose would be zero, nor does it establish an upper bound on the dermal dose (see also NRC, 2000, p. 294).

The CPSC staff extracted PA-treated fabrics with saline and other aqueous solutions. The staff found that about 3 percent of the total phosphorus in the fabric migrated into the solutions (Bhooshan and Cobb, 2000). The extracts contained unidentified organophosphorus compounds and some inorganic phosphate. Dermal absorption of PA has not been studied. Based on its physico-chemical properties, PA would likely be absorbed at a relatively low rate (EPA, 1992).

It should be noted that PA does not satisfy the FHSA definition of "toxic" and, therefore, is not considered "hazardous" under the FHSA. However, this conclusion is based on limited toxicity data.

APPENDIX A
Commenters-- Written Submissions

Comment #	Date	Submitter (interest)
1	4/13/98	Westex, Inc. (producer of specialty and flame retardant fabrics)
2	4/16/98	Pan American Health Organization/World Health Organization (WHO)
3	4/20/98	International Agency for Research on Cancer (IARC)/World Health Organization (WHO)
4	4/28/98	U.S. Small Business Administration
5	4/98	Trevira, Germany (producer of synthetic textiles)
6	4/20/98	Albemarle Corporation (FR chemical producer)
7	4/28/98	Amoco Fabrics and Fibers Corporation (producer of polypropylene fibers and yarns for fabrics)
8	5/1/98	National Cotton Council of America (producers, ginner, manufacturers, etc.)
9	5/28/98	Wolf Corporation Mattresses, Box Springs, and Fiber Products
10	6/2/98	Akzo Nobel Chemicals, Inc. (FR chemical producer)
11	6/16/98	National Association of State Fire Marshals (NASFM)
12	6/18/98	US Department of Health and Human Services (DHHS) National Institute for Occupational Safety and Health (NIOSH)
13	6/25/98	American Society of Interior Designers
14	7/15/98	Lois Scheel, Grants Pass, OR (consumer)
15	7/15/98	Ciba Specialty Chemicals Corporation (FR chemical producer)
16	7/21/98	Everfast, Inc. (owner/operator of fabric and home furnishing store chain)
17	7/30/98	The Coalition of Converters of Decorative Fabrics (creates or acquires proprietary rights to designs and has them converted into fabrics) Golenbock, Eiseman, Assor, and Bell, Attys on behalf of...
18	7/30/98	The Decorative Fabrics Association Golenbock, Eiseman, Assor, and Bell, Attys on behalf of...
19	8/3/98	Business and Institutional Furniture Manufacturers Association (BIFMA International)
20	8/3/98	Upholstered Furniture Action Council (UFAC)
21	8/3/98	National Cotton Batting Institute (NCBI)
22	8/3/98	American Textile Manufacturers Institute (ATMI)
23	7/15/98	Fire Retardant Chemicals Association (FRCA)

Comment #	Date	Submitter (interest)
24	7/20/98	Polyurethane Foam Association
25	7/10/98	National Cotton Council of America
26	7/16/98	The Society of Plastics Industry, Inc.
27	7/17/98	Antimony Oxide Industry Association (Latham and Watkins, Attys on behalf of...)
28	9/28/98	American Flamecoat of Southern New Jersey, Inc.
29	10/2/98	International Fire Control Systems, Inc.
30	10/6/98	Environmental Defense Fund (EDF)
31	10/28/98	Steve Hart, Hart (consumer)
32	1/24/99	Wallace Forman (consumer)
33	8/12/98	Cathy Jones Interiors (interior decorator)
34	9/4/98	Institute of Natural Fibers, Poland
35	5/18/98	Chemical Manufacturers Association (CMA) (trade association)
36	6/19/98	Chemical Manufacturers Association (CMA) (trade association)
37	7/17/98	Antimony Oxide Industry Association (Latham and Watkins, Attys on behalf of...)
38	11/17/98	Rohm and Haas (FR chemical producer)
39	Undated	Brominated Flame Retardant Industry Panel of the Chemical Manufacturers Association (BFRIP/CMA)
40	9/10/99	Albemarle Corporation (FR chemical producer)
41	8/3/99	Albemarle Corporation (FR chemical producer)
42	11/4/99	Albright and Wilson (FR chemical producer)
43	8/23/00	American Textile Manufacturers Institute (ATMI)
44	8/28/00	American Chemistry Council (ACC) (formerly CMA)
45	7/99	Albright and Wilson (FR chemical producer)
46	10/30/00	Upholstered Furniture Action Council (UFAC) (upholstered furniture trade association)

Commenters from CPSC Public Hearing, May 17-18, 1998

Fire Retardant Chemicals Association (FRCA)
National Association of State Fire Marshals (NASFM)
Bostik LTD, UK
U.S. Environmental Protection Agency (EPA)
Haworth Incorporated and Business and Institutional Furniture Manufacturers Association (BIFMA)
United Kingdom Department of Trade and Industry (UK DTI)
Ciba Specialty Chemicals Corporation
Albright and Wilson Americas, Incorporated
Upholstered Furniture Action Council (UFAC)

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

CPSC Staff Statement on the
National Research Council Report,
"Toxicological Risks of Selected Flame-Retardant Chemicals"
July, 2000

The report entitled, "Toxicological Risks of Selected Flame Retardant Chemicals," presents the findings of a study prepared by the National Research Council (NRC) of the National Academy of Sciences (NAS) for the U.S. Consumer Product Safety Commission (CPSC or the Commission). NRC performed this study, at the direction of Congress, to independently assess potential health risks associated with flame retardant (FR) chemicals that may be used on upholstered furniture to meet a possible CPSC flammability performance standard. The report concludes that, based on available data, a variety of FR chemicals may be used on upholstered furniture fabrics without presenting health hazards to consumers.

In response to a 1993 petition from the National Association of State Fire Marshals, CPSC is considering a possible flammability standard for upholstered furniture to reduce the risk of fire. Fires involving ignition of upholstered furniture are a leading cause of product-related residential fire deaths. The Commission's proceeding addresses furniture fires ignited by small open flame sources such as matches, cigarette lighters, and candles; since 1990, these small open flame-ignited fires caused an estimated annual average of approximately 90 deaths, 440 injuries, and \$50 million in property loss.

Upholstered furniture flammability standards are already in place in the UK and in California. The standard being considered by CPSC for residential upholstered furniture would specify small open flame performance requirements; it would not, however, stipulate how to meet the requirements. Manufacturers have reported that the most likely way for them to meet

the standard drafted by CPSC staff would be to treat residential upholstery fabrics with flame retardant (FR) chemicals.

The Fire Retardant Chemicals Association identified 16 principal candidate FR treatments for possible use in residential upholstered furniture fabrics. A subcommittee of experts selected by NRC reviewed available toxicological and exposure data on these 16 FR chemicals or chemical classes. Generally, exposure data were limited or not available for the 16 chemicals. Thus, the NRC subcommittee used very conservative assumptions about how consumers might be exposed to FR chemicals on upholstered furniture. As the NRC acknowledges, this approach tended to overestimate the potential exposure--and therefore the risk--to consumers using FR-treated upholstered furniture. The actual risk to human health is likely to be lower than that estimated by the subcommittee.

The NRC report concludes that 8 of the 16 FR chemicals reviewed by the subcommittee would present a minimal risk, even under extreme conditions of exposure. These chemicals are: decabromodiphenyl oxide, hexabromocyclododecane, phosphonic acid (3-(hydroxymethyl)amino)-3-oxopropyl dimethyl ester, tetrakis hydroxymethylphosphonium salts, zinc borate, alumina trihydrate, magnesium hydroxide, and ammonium polyphosphates. Additional exposure studies were recommended by the subcommittee for the remaining eight chemicals: antimony trioxide, tris(2-chloropropyl)phosphate, tris(1,3-dichloropropyl-2)phosphate, calcium and zinc molybdates, antimonates, chlorinated paraffins, aromatic phosphate plasticizers, and organic phosphonates.

CPSC staff is currently developing data on exposure, bioavailability, and dose-response, to be used in conjunction with chemical toxicity data to support the staff's own forthcoming assessment of the risk to consumers from the use of FR chemicals in furniture fabrics. The Commission will consider this and other information in deciding whether to issue a flammability standard for upholstered furniture.



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: April 4, 2001

TO: File

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences *maD*

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences *W*

FROM: Patricia M. Bittner, M.S., Toxicologist, Division of Health Sciences *PMB*

SUBJECT: Update on the Flame Retardant (FR) Chemicals Toxicity Reviews

I. OVERVIEW

The staff of the Consumer Product Safety Commission (CPSC) is currently developing a performance standard to address the fire hazards associated with small open flame ignitions of residential upholstered furniture. If the CPSC mandates a performance standard for residential upholstered furniture to address the risk of injuries and deaths associated with small open flame ignitions, the industry reports that they are likely to use flame retardant (FR) chemicals to comply with the standard. In 1999, the CPSC Health Sciences staff reviewed the toxicity data on 16 FR chemicals or chemical classes.

Since the time these reviews were written, additional data have been submitted to, and reviewed by, the CPSC staff. Updated searches of the peer-reviewed literature were also performed. In addition, the Committee on Toxicology (COT) of the National Academy of Sciences (NAS) National Research Council (NRC) recently completed an independent risk assessment (NRC, 2000) on these chemicals and their findings were also considered by the CPSC staff. This memorandum provides a review of the additional data and amends the conclusions of the original toxicity reviews, as needed.

This memorandum is an amendment to the CPSC staff toxicity reviews written in 1999. After careful review of these additional materials, the staff's conclusions regarding the overall toxicity of these 16 chemicals or chemical classes remain unchanged.

BACKGROUND

The CPSC Upholstered Furniture Project

The Commission staff is developing a performance standard to address the fire hazards associated with small open flame ignitions of residential upholstered furniture. Although the standard being considered would specify requirements for small open flame performance, it would not stipulate the method of compliance. Thus, treatment of upholstery fabric with FR chemicals would not be required. However, manufacturers have reported that most residential upholstery fabrics would be treated with such chemicals to comply with the performance requirements under consideration.

The CPSC staff presented a briefing package (Ray, 1997) to the Commission in October, 1997. This briefing package contained preliminary toxicity reviews on several FR chemicals. In view of the staff's recommendation and concerns about the toxicity of some of these chemicals, and the lack of exposure data, the Commission voted to defer action. The Commission held a public hearing in May, 1998, to gather information on chemical toxicity. Comments were received from fire professionals, furniture and chemical industry representatives, government agencies, consumers, environmentalists, and other interested parties.

CPSC scientists have extensively reviewed the available toxicity data on the 16 FR chemicals or chemical classes that the Fire Retardant Chemicals Association (FRCA) identified as primary candidates for use on residential upholstered furniture. Toxicity data on the following chemicals were reviewed by the CPSC staff: decabromodiphenyl oxide; antimony trioxide; hexabromocyclododecane; tris(2-chloropropyl)phosphate; tris(1,3-dichloropropyl-2)phosphate; phosphonic acid, (3-[hydroxymethyl]amino)-3-oxopropyl dimethyl ester; tetrakis hydroxymethylhydronium salts (precondensate w/urea) and polymer; calcium and zinc molybdates; antimonates; zinc borate; halogenated olefins and paraffins; alumina trihydrate; magnesium hydroxide; aromatic phosphate plasticizers; ammonium polyphosphates and blends; and organic phosphonates.

These toxicity reviews were performed using criteria found in the relevant statute administered by the Agency, the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261-1278), and its implementing regulations. For a product to be regulated under the FHSA, the Commission must find that the product is a hazardous substance as defined in section 2(f) of the FHSA 15 U.S.C. 1261(f). The FHSA defines a "hazardous substance" as a substance that satisfies both parts of a two-part test. To be a hazardous substance, a product must first present one or more of the hazards enumerated in the statute, that is, it must be toxic, corrosive, flammable, an irritant, or a strong sensitizer, or generate pressure through decomposition, heat, or other means. Second, the product must have the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. The Commission has issued guidelines that specify the conditions under which a substance subject to the FHSA would be considered a carcinogen, neurotoxin, or developmental or reproductive toxicant (Chronic Hazard Guidelines: 16 CFR Section 1500.135). The guidelines also explain certain principles that are used by the CPSC staff to evaluate the risk from exposure.

Reliance on these guidelines is not mandatory; however, they are used by the CPSC staff to determine whether a consumer product would be considered a hazardous substance under the FHSA and thus, subject to regulatory action.

In its fiscal year 1999 appropriations to CPSC, Congress directed the agency to contract with the NAS's NRC to perform a study of the "toxicological risk" of FR chemicals. The NRC selected and convened a subcommittee of experts to study the issue. The study was completed in April, 2000, and the final report was submitted to CPSC and Congress in July, 2000. The CPSC staff reviewed the document and any salient data that might affect the toxicity determinations under the FHSA are discussed in this memorandum.

II. DISCUSSION

This section provides a review of additional toxicity data on the previously reviewed FR chemicals. It also includes a brief discussion of data found in the risk assessments performed by NRC, the European Union (EU), and the United Kingdom (UK).

A. Chemical-Specific Issues

Ammonium Polyphosphates and Blends

Additional data on the ammonium polyphosphates did not alter the conclusions reached in the CPSC toxicity review (Ferrante 1999a) that ammonium polyphosphates are not toxic under the FHSA. At the request of the NRC, Albright & Wilson Americas, Inc. submitted additional data on September 29, 1999, concerning Antiblaze® LR2, Antiblaze® LR3 and Antiblaze® LR4 (Albright and Wilson, 1993).

The new data supported the acute toxicity findings that were reported in the original toxicity review by Ferrante (1999a). In the new study, ten Sprague-Dawley rats (5 male/5 females) were exposed to a mean atmospheric concentration of 5.09 ± 0.35 mg/l Amgard MC(M)* for 4 hours. Rats were observed at hourly intervals during the exposure, immediately after removal from the chamber, at one-hour post exposure, and once daily for 14 days. All of the rats survived the study, but various treatment-related effects were observed during or immediately after the exposure. These included wet fur (9/10), reduced respiratory rate (4/10), hunched posture (10/10), ptosis (eyelid droop) (1/10), piloerection, red/brown staining of the snout (2/10), red/brown staining around the eyes (1/10), lethargy (1/10) and tiptoe gait (1/10). At one hour post-exposure, all of the rats had a hunched posture and piloerection and two rats continued to have a decreased respiratory rate. One day post-exposure, five rats continued to show symptoms (hunched posture, piloerection, & decreased respiratory rate). Two days post-exposure, nine rats had no abnormal clinical signs and one female had a hunched posture. By day three, all the rats appeared normal. No abnormalities were found at necropsy.

Antimony Trioxide, Antimony Pentoxide, and Sodium Antimonate

* Amgard MC(M), now called Antiblaze MC(M), is 100% solid ammonium polyphosphate.

Antimony trioxide is toxic under the FHSA, based on its chronic toxicity. Systemic effects were observed and it is a probable human carcinogen. Antimony pentoxide and sodium antimonate are not toxic under the FHSA, based on limited data. No new data was available for review, but the staff recalculated the ADI. This recalculation does not alter the staff's conclusion regarding the toxicity of antimony trioxide, antimony pentoxide, and sodium antimonate (Hatlelid, 1999a,b).

The ADI for the inhalation route of exposure that was originally calculated in the toxicity review performed by the CPSC staff (Hatlelid, 1999a) has been revised to reflect the use of a more standard value for the respiratory rate of an adult man (EPA, 1997). Using the revised value (i.e., 15 m³/day) for respiratory rate, the ADI is 0.002 µg/kg/day rather than 0.003 µg/kg/day as originally reported in the CPSC staff toxicity review (Hatlelid, 1999a).

This revised calculation is based on the LOEL (adjusted for intermittent exposure) of 0.009 mg/m³ for alveolar/intraalveolar macrophage proliferation resulting from chronic inhalation exposure in rats (Newton et al., 1994). The estimate of the ADI for exposure through inhalation relies on the use of an uncertainty factor of 1,000 (10 to extrapolate from animals to humans, 10 for use of the LOEL rather than the NOEL, and 10 to account for sensitive subpopulations). Dividing the LOEL by 1,000 yields 0.009 µg/m³ (0.009 mg/m³/1000). To convert this concentration to an ADI, the assumptions of standard respiration are applied. Thus, from the LOEL-derived concentration (0.009 µg/m³), the ADI for a 70-kg adult male breathing 15 m³/day is 0.002 µg/kg/day.

Additionally, staff reports a change in the dose calculations in the original toxicity review. This change has no effect on the conclusions reached on the toxicity of the antimony compounds. In the introduction of the CPSC toxicity reviews for the antimony compounds (Hatlelid, 1999a,b), it is stated that the doses for each compound refer to the antimony content of the compound and not the compound itself. The doses of antimony in the Kuroda et al. (1991) study that was reviewed do not represent the content of the antimony. The doses reported for this study in the review refer to doses of the antimony compound rather than the doses of elemental antimony. Thus, each dose for the Kuroda et al. (1991) study in the original toxicity review should be multiplied by 0.84 to yield a consistent dose in mg antimony/kg body weight.

Aromatic Phosphate Plasticizers

The plasticizer TCP is toxic under the FHSA, based on its probable systemic, neurological, and reproductive effects in animals. This assessment has not been changed. The CPSC staff toxicity review for the aromatic phosphate plasticizers (Ferrante, 1999b) reported the results of a 13-week oral study in which reproductive effects were observed in rodents (NTP, 1994). These data were discussed in Table 2 (p. 34) of the CPSC review. Male and female rats (55 and 65 mg/kg/day, respectively) and male and female mice (110 and 65 mg/kg/day, respectively) exhibited cytoplasmic vacuolization of the adrenal cortex when fed TCP in the diet; these were the lowest doses tested. Hypertrophy/hyperplasia were observed in ovarian interstitial cells in all exposure groups of female rats exposed to TCP in the feed; the LOEL was 65 mg/kg/day and a NOEL was not established. This lesion was not observed in mice exposed to TCP in the feed. However, it was also observed in all groups of rats and mice treated by gavage;

the LOEL was 50 mg/kg. Cytoplasmic vacuolization of ovarian interstitial cells was also observed in mice in the feed study at the two highest doses (530 and 1,050 mg/kg/day). Aspermatogenesis and seminiferous tubule atrophy were observed in rats treated with 400 and 800 mg/kg/day TCP by gavage and 430 and 750 mg/kg/day TCP in the diet. The NOELs in these two studies were 200 and 220 mg/kg/day, respectively (NTP, 1994).

Although these effects were discussed in Section 2 ("LD₅₀s and Systemic Effects") of the CPSC review, the study and its results were not specifically discussed in Section 5 ("Reproductive and Developmental Effects") of the review. In addition, the "Discussion" section of the review states that there is sufficient evidence of reproductive toxicity of TCP in male rats and mice and the LOEL for male reproductive effects is 100 mg/kg/day in rats. It further states that TCP may be regarded as probably toxic to the male reproductive system in humans. Although this is correct, this section of the review should also state that TCP has caused reproductive toxicity in female rats and mice. The LOEL for ovarian toxicity in animals was 50 mg/kg. Since oral administration of TCP caused ovarian effects in 2 rodent species, TCP is also a probable female reproductive toxicant in humans based on sufficient evidence in animals. As TCP has already been classified as "toxic" under the FHSA based on chronic organ toxicity and neurotoxicity in animals, this new assessment does not alter its overall classification under the FHSA, but provides additional evidence in support of its conclusion.

Additionally, staff notes an editing error. The correct ADI for the plasticizer 2-ethylhexyl diphenyl phosphate (EHDP) is 1 mg/kg-day, not 0.001 mg/kg as listed in the original toxicity review (Ferrante 1999b). Since Santicizer®-141 (S-141) is composed of 91-93% EHDP, the revised ADI for EHDP should be considered when evaluating the toxicity of S-141.

Chlorinated Paraffins (CP's)

The staff has re-evaluated the developmental effects of the CP's and concludes that CP's are "probable" developmental toxicants, not "possible" developmental toxicants. This does not alter the overall assessment of CP's since they already have been classified as toxic under the FHSA based on systemic toxicity.

The previous toxicity review for chlorinated paraffins (Hattelid, 1999c) stated that in general, the toxicity in both rat dams and rabbit does was similar to the acute toxicity in males and nulliparous females observed in other studies. In rabbits, the short-chain CP's (C₁₀₋₁₃, 58% Cl) caused dose-related whole litter resorptions above 10 mg/kg/day, and 5 g/kg/day of the long-chain CP's (C₂₀₋₃₀, 43% Cl) caused postimplantation loss and decreased numbers of viable fetuses (Serrone et al., 1987).

In rats, no effects were observed with the medium- or long-chain CP's, but C₁₀₋₁₃, 58%Cl caused both maternal and developmental toxicity (Serrone et al., 1987). Dams showed decreased body weight gain and mortality at doses of C₁₀₋₁₃, 58%Cl above 100 mg/kg/day. The highest dose (2,000 mg/kg/day) caused postimplantation loss, decreased numbers of viable fetuses, and missing or shortened digits.

In a reproductive study, these investigators administered the medium-chain CP's to rats in the feed at concentrations of 100, 1000, and 6250 ppm, equivalent to 5, 50, and 312 mg/kg/day (Serrone et al., 1987). Male and female animals were fed C₁₄₋₁₇, 52%Cl for 28 days prior to mating. Females continued to consume the CP's until postnatal day 21. This treatment had no effects on the parents, but the toxicity was evident in the pups. Survival was decreased in high-dose pups by day 10 and in mid-dose pups by day 21. Bruising, bleeding, decreased activity and labored breathing were observed in the pups and necropsy showed multiple organ system effects. The study authors concluded that these effects were due to exposure to the compound through the milk of the dam and not *in utero* exposure. Nonetheless, these effects would still indicate developmental toxicity.

Thus, based upon re-evaluation of the data, staff determined that there is adequate evidence of developmental toxicity. Although the toxicity may depend on the carbon chain length and the degree of chlorination, as observed for other toxic endpoints, there is sufficient evidence for developmental toxicity for several different chlorinated paraffin products. They should be considered "probable" developmental toxicants in humans, rather than "possible" as stated in the CPSC staff toxicity review. However, this change does not alter the overall assessment because there were other chronic effects that met the criteria for classifying CP's as toxic under the FHSA.

Cyclic Phosphonate Esters (CPE's)

In the toxicity review by Hatlelid (1999d), CPE's met the definition for chronic toxicity under the FHSA based on evidence of systemic toxicity in animals and this assessment is unchanged.

In the 1999 review, the ADI of 0.3 mg/kg/day for oral exposure was based upon a LOEL of 300 mg/kg/day for rib defects and delayed ossification in rabbits (Beliles, 1979), using an uncertainty factor of 1,000. No developmental toxicity was observed in other studies, however. Thus, there is limited evidence for developmental toxicity for the cyclic phosphonate esters and these chemicals were judged "possible" developmental toxicants (Hatlelid, 1999d). Since a finding of "possible" toxicity does not render a substance "toxic" under the FHSA, and ADI's are only calculated for chemicals of "known" or "probable" toxicity, the data should not have been used to calculate an ADI. The data that should have been used for this calculation are described below.

There was sufficient evidence of systemic toxicity in subchronic and reproductive/developmental studies. Thus, CPE's are "probable" chronic toxicants under the FHSA. Specifically, there is sufficient evidence for maternal toxicity in the reproductive/developmental study in rabbits by Beliles (1979). The NOEL for maternal toxicity in this study was 1,000 mg/kg/day. Using an uncertainty factor of 100 (10 for interspecies estimates and 10 for sensitive populations), the oral ADI is 10 mg/kg/day (1,000 mg/kg/day/100), rather than the 0.3 mg/kg/day originally calculated. The determination in the 1999 CPSC review that CPE's meet the definition for a chronic toxicant under the FHSA, however, is unchanged.

Decabromodiphenyl oxide

The staff has re-evaluated the existing animal data and has recalculated the ADI. In addition, staff has reviewed new studies indicating the bioavailability of DBDPO. These actions have not changed the staff's conclusion in the 1999 toxicity review that DBDPO is toxic under the FHSA, based on evidence of chronic systemic toxicity (Bittner, 1999a).

The CPSC staff re-evaluated the data on DBDPO and determined that there is sufficient scientific justification for the derivation of a new ADI that can be used to provide a more representative assessment of risk. Although the ADI for DBDPO has been revised, the CPSC staff conclusion that DBDPO is toxic under the FHSA does not change. The staff recalculated the ADI (Bittner, 1999a) because they the original ADI (0.01 mg/kg-day), although conservative, might not provide the best estimate of acceptable daily intake. This is because the treatment levels used in the study upon which the original ADI levels were based, were so low, that no adverse effects were observed.

The original ADI for DBDPO was based on a NOAEL of 1 mg/kg-day, the highest dose tested in a 2-year feeding study in rats (25/sex/dose) (Kociba et al., 1975). The DBDPO tested was composed of 77.4% DBDPO, with the remainder being lower brominated diphenyl ethers. Although the 1999 CPSC toxicity review on DBDPO noted that the doses and numbers of animals used in the Kociba et al. (1975) study might be inadequate to determine its carcinogenic potential, this study was used to derive the ADI because a) the Chronic Hazard Guidelines state that, among well-conducted studies, the lowest NOAEL be used to derive the ADI; b) the NTP (1986) bioassay, while well conducted, did not identify a NOAEL in mice, with liver and thyroid effects were observed at both treatment levels tested; c) EPA based its oral RfD on the Kociba et al. (1975) study (IRIS, 2000); d) supporting data for the Kociba study were reported in a 30-day oral study in rats by Norris et al. (1973, 1975).

The new ADI is derived from the NTP (1986) study. This study is being used because a LOAEL was not determined in the Kociba et al. study, which indicates that the dose range was too low. Although the Chronic Hazard Guidelines suggest that the lowest NOAEL be used, it is not the intent of the guidelines to impose an excessively conservative ADI because the doses used in a study were not sufficient to determine a LOAEL. In addition, the compound used in the NTP (1986) bioassay is of higher purity (94-97%) than the compound used in the Kociba et al. (1975) study (77.4%). According to Albemarle Corporation (Albemarle, 1999), a major manufacturer of DBDPO, the more pure compound better reflects the current chemical composition of DBDPO to be used as a flame retardant in upholstered furniture.

The new ADI of 3.2 mg/kg-day is based upon liver effects observed in male mice in the NTP (1986) study that was described above. Although the lowest dose at which effects were observed in either of the 2 species tested was 2,240 mg/kg in the rat, a NOAEL was also established for the rat. For the mouse, the LOAEL was 3,200 mg/kg-day and a NOAEL was not established. The mouse LOAEL of 3,200 mg/kg-day is divided by an uncertainty factor of 1,000 (10 for interspecies variability, 10 for sensitive populations, and 10 for use of a LOAEL instead of a NOAEL) to yield the ADI of 3.2 mg/kg-day.

Albemarle Corporation submitted two dermal irritation/sensitization studies that were conducted in humans and animals; these were not included in the CPSC toxicity review on decabromodiphenyl oxide (DBDPO) (Bittner, 1999a). After evaluating these data, staff determined that neither of these studies change the conclusions in the 1999 toxicity review on DBDPO that this substance does not cause dermal irritation or sensitization. In the first study, men and women showed no treatment-related signs of dermal irritation when dacron fabric was treated with DBDPO and antimony trioxide (1% by weight) and applied to their skin for 6 days (Haskell Lab, 1970a). A challenge test for sensitization also yielded negative results.

In the second study, no dermal irritation was observed after application of a 10%, 25%, or 50% (w/v) suspension of an 8:1 DBDPO/antimony trioxide mixture to intact guinea pig skin (n=10) for 24 hours (Haskell Lab, 1970b). To test for sensitization, 5 guinea pigs received 9 treatments of 25% (w/v) test material on abraded skin and 4 intradermal injections of 1% test material in acetone over a 3-week period. After a 2-week rest period, the animals were challenged with 25% test material on intact and abraded skin and 50% test material on intact skin. Mild erythema was observed in 2/10 or 1/10 animals originally treated with 50% or 25% test material, respectively, on intact skin. No reaction was observed with abraded skin. The study authors did not consider the test compound to be a sensitizer because there was not a 2-step increase in the severity of the reaction over the primary irritation reaction score, which was zero. These effects are equivocal because controls were not used. Therefore, it is not known whether the mild erythema observed was likely to be due to the administration of the test material or to local irritation from the patch.

In addition to the above data, updated literature searches for this chemical yielded new data indicating that DBDPO is bioavailable. In a study by Sjodin et al. (1999), five polybrominated diphenyl ether congeners, including DBDPO, were quantified in blood serum from three categories of Swedish workers in an attempt to determine whether occupational exposure could be related to body burdens. The authors assumed that workers who dismantled electronics equipment were exposed to higher concentrations of DBDPO, since it had been found in ambient air at these plants.

Three groups of workers were tested: two groups of exposed individuals and one group of controls. The first exposed group consisted of 15 men and 4 women who worked at a plant that dismantled personal computers, televisions, and radios. The second exposed group of 20 women worked almost exclusively at computers (clerks). The controls consisted of a group of 20 women who were hospital cleaners. The exposed electronics workers were sampled immediately before beginning their summer vacation; 11 of these workers were also sampled immediately upon return from the 21- to 35-day holiday period, which was considered to be an occupational exposure-free period.

DBDPO was detected in 45/59 blood samples, including 14/20 controls (cleaners), 13/20 clerks, and 17/19 dismantling plant workers before their holiday. The levels of DBDPO in cleaners was above the level of quantification in 7 cleaners and 6 clerks. DBDPO was found in almost all serum samples of all groups of workers, indicating its bioavailability. The median (range) concentrations of DBDPO in the 3 groups were <0.7 (<0.3-3.9) ng/g lipid weight in cleaners (controls), <0.7 (0.3-8.0) ng/g lipid weight in computer clerks, and 4.8 (<0.3-9.9)

ng/g lipid weight in electronics dismantlers ($p < 0.001$). There was no correlation between concentrations and age or fish consumption; fish consumption was presumably tested because there has been concern about this compound accumulating in marine organisms. Serum concentrations decreased 47-100% during the vacation time of some dismantling workers ($n=5$). Thus, it appears that exposure can occur after inhalation of airborne particulates containing DBDPO in workers handling electronics equipment. However, even control workers were observed to have detectable levels in their serum.

Another study performed to quantify DBDPO concentrations in humans was undertaken by Stanley et al. (1991). Adipose tissue samples from the general population collected in FY 1987 through the EPA's National Human Adipose Tissue Survey (NHATS) were analyzed for polyhalogenated dioxins (PHDDs) and furans (PHDFs). The analysis protocol for PHDDs and PHDFs required the simultaneous monitoring of ions characteristic of polybrominated diphenyl ethers (PBDPE) along with ions for the PHDDs and PHDFs. The study performed by Stanley et al. used 12 of the original 48 sample extracts to attempt to confirm the presence of the PHDPEs. The methods used either generated additional mass spectral information using high-resolution gas chromatography/mass spectrometry (HRGC/MS) in full scale mode or used HRGC-HRMS via selected ion monitoring (SIM).

Full-scale HRGC/MS analysis confirmed the presence of a hexabromodiphenyl ether and a nonachlorodiphenyl ether in the selected adipose tissue extracts. DBDPO was detected in three of the 5 extracts, with concentrations of weak detection, 400 pg/g and 700 pg/g (Stanley et al., 1991).

Hexabromocyclododecane (HBCD)

The CPSC 1999 toxicity review on HBCD (Hatlid, 1999c) concluded that it is not acutely toxic by the inhalation, oral, or dermal routes of exposure. It further concluded that HBCD does not meet the definition for chronic toxicity under FHSA, although it is a possible systemic, reproductive, and neurological toxicant.

Several studies were submitted to the CPSC staff since the 1999 toxicity review on HBCD was written. Translations of several studies published in Japanese journals were provided in English. Developmental studies were also submitted. Though these studies do not provide any new data or alter the conclusions on the data previously reported by CPSC staff, they are summarized below to provide updated information.

Additional acute toxicity data in rodents were provided. The LD_{50} s reported in the toxicity review on HBCD (Hatlid, 1999d) were greater than 5-10 g/kg. The new studies evaluated doses up to 40 g/kg; no deaths were observed at these doses. In one of these studies, no toxic symptoms or death were noted after administration of up to 20 g/kg in male and female mice (Tobe et al., undated). In another study, oral administration of 10 or 20 g/kg to male rats caused yellow feces the day after dosing. No other effects or deaths were observed (Ogaswara et al., undated). Male mice dosed with 30-40 g/kg HBCD exhibited slight diarrhea and body weight reduction (Ishizu et al., undated). In addition, swollen livers were observed in all treated

animals, and slightly necrotic foci in some animals. No other toxic symptoms or deaths were observed. No information on the statistical treatment of the data was provided.

Liver effects were observed in two 28-day studies in rats that reported increased absolute and relative liver weights (Chengelis, 1997; Zeller and Kirsch, 1969) and one 90-day study in rats that reported mild fatty changes as well as increased liver weights (Zeller and Kirsch, 1970). They were also observed in one 18-month study in mice that reported more severe lesions, including necrosis, in addition to increased liver weights and fatty changes (Kurokawa et al., undated).

The latter authors reported the results of a terminal 18-month oral carcinogenicity study in mice (Kurokawa et al., undated). Based on the reported doses of 100-10,000 ppm HBCD in the feed, it was estimated that the animals were exposed to approximately 0.01-1 g/kg/day HBCD. The authors reported that liver lesions, including hepatocytic swelling, degeneration, necrosis, vacuole formation and fatty infiltration, were increased in the treated animals compared to controls. Statistical analyses were not provided. No carcinogenicity was reported that related to the administration of the test material.

These data support but do not change the CPSC conclusion that HBCD is a "possible" systemic toxicant. The study was poorly reported and unpublished, and was considered inadequate for use in risk assessment by NAS and EU.

While the three other studies indicate that HBCD administration induces changes in the liver, it is not clear that these changes indicate an adverse effect of the chemical. It is also not clear if the mild fatty changes observed in the subchronic study would progress to unequivocal toxicity if administration were continued in a lifetime study.

Given the uncertainties in the few available studies, HBCD remains "possibly toxic in humans." However, the staff has included HBCD in its exposure and risk assessment of selected flame retardant chemicals by using the NAS hazard assessment.

The CPSC staff toxicity review of HBCD (Hatlelid, 1999d) reported that guinea pigs showed slight positive skin sensitization in two studies (Momma et al., 1993; Nakamura et al., 1994) and concluded that it is a possible mild allergen in humans. A recently submitted study (Wenk, 1996) showed no dermal sensitization in guinea pigs. There does not appear to be an obvious explanation for the conflicting results. These data are not sufficient to alter CPSC's conclusions that HBCD is a possible mild allergen in humans.

CPSC staff reviewed two developmental toxicity studies submitted last year by Chemical Manufacturer's Association (CMA), now known as the American Chemistry Council. While these data are suggestive of an equivocal effect on development, they were not sufficient to classify HBCD as a "possible" developmental toxicant. Stump (1999a) reported on a range finding study using pregnant CD® (SD)IGS BR rats (n=8) dosed by gavage with 0, 125, 250, 500, 750, or 1,000 mg/kg/day HBCD in corn oil from gestation days 6-19. Dams were sacrificed on gestation day (GD) 20. No maternal toxicity was evident from observations of behavior, food consumption, or gross pathology. Significant increases in maternal body weight gain compared

to controls were noted in the 250, 500, 750, and 1,000 mg/kg groups on gestation days 19-20, and corrected net body weight gain was significantly increased in the 2 highest dose groups. All fetuses in this study were sexed, weighed, and examined for external malformations and variations, but were not examined for visceral and skeletal variations and malformations. There were no treatment-related effects on viability noted between treated and control groups. Postimplantation loss, viable litter size, sex ratios and fetal body weights were similar in treated and control groups and any differences did not reflect toxic effects. The only external malformations or variations observed were in one fetus in the 125 mg/kg/day group, which showed mandibular micrognathia (abnormally small jaw at the mandible), unilateral microphthalmia (small eyes) and aglossia (lack of tongue). Although these malformations are rare, they are not believed to be treatment related because they were found only in the low-dose group; no dose response was evident. Based upon the findings in this study, a NOAEL for developmental effects is 1,000 mg/kg/day, although this is tentative as visceral and skeletal examinations were not performed and small numbers of dams were used.

In the full study (Stump 1999b), pregnant CD[®] (SD)IGS BR rats (n=25) were dosed by gavage with 0, 250, 500, or 1,000 mg/kg/day HBCD in corn oil from gestation days (GD) 6-19. Dams were sacrificed on gestation day GD 20. The test article was a composite of HBCD products manufactured by 3 producers. Fetuses were weighed, sexed, and examined for external, soft tissue, and skeletal malformations and variations. One mid-dose female (identified as animal #3620 in the study "Results Summary" on pp. 22 and 31) delivered on GD 20 and was examined at the scheduled laparohysterectomy on that day. The study authors concluded that the early delivery was not treatment-related based on the pup/fetal weights, which they believed indicated an error in the detection of mating, although it was not possible to match this conclusion to the individual data for the reasons discussed in Appendix A. Although there were no early deliveries found in 3,585 pregnant animals in the historical control data provided (study p. 252), it does not appear that the early delivery or increased fetal weights in this one dam (#3658) in the mid-dose group were treatment related.

No clinical signs of maternal toxicity were observed in any treated group. Although mean body weight gain was significantly increased sporadically among mid- and high-dose groups compared to controls, corrected body weight gain was similar between treated and control groups. No treatment-related changes in maternal food consumption or gross pathology were observed. Intrauterine growth and survival parameters, including post-implantation loss, live fetuses, mean fetal body weight, sex ratios, not reflect any toxicity with the test article administration.

The only external fetal malformations were observed in four fetuses in the mid-dose group. Of the 338 fetuses examined in this group, 3 fetuses (3 litters) had bilateral anophthalmia (without eyes). This represented a nonsignificant increase (0.8% [± 2.2] per litter) compared to the control incidence (0% per litter). The incidence (% per litter) fell within the historical control limits (0-1.3% per litter) provided by the performing laboratory for this species. One of these fetuses also had a facial cleft (0.3% [± 1.39] per litter) and exencephaly and another one also had hydrocephalus with a dome-shaped head (0.30% [± 1.30] per litter). A fourth fetus in the mid-dose group was also exencephalic; this fetus belonged to a litter that contained another malformed fetus. The incidence of exencephaly (0.6% [± 1.86] per litter) was greater than that in

the performing laboratory (WIL) historical control data (0-0.5% per litter), although there was no statistically significant increase in the percentage of affected fetuses per litter compared to controls in this study. The WIL historical control incidence of hydrocephaly was 0-0.3% per litter. Facial cleft was not previously reported in the WIL historical control data. Since none of these malformations were observed in the high-dose group, they are not believed to be treatment related. The study authors did not provide statistical analyses for litter effect, i.e., comparison of litters affected in each treated group compared to litters affected in each control group.

The only skeletal malformation observed was in one mid-dose fetus, which consisted of fused lumbar centra. Skeletal variations occurred in all treated and control groups. They primarily consisted of unossified sternbrae, ossified cervical centrum, and other effects; none of these appear to be treatment related.

Internal examination of the fetuses revealed a visceral variation (retroesophageal right subclavian artery) in one mid-dose (0.3% [± 1.49] per litter) and one high-dose (0.3% [± 1.32] per litter) fetus. It is not known whether these are significant increases compared to control values, since the study authors did not explicitly state that they were "nonsignificant" as they did with other parameters in similar tables. Although there was no increase in response with increased dose, there was a 13% decrease in the numbers of litters examined (14% decrease in fetuses) in the high-dose group compared to the mid-dose group. This may have reduced the power to detect a dose-response. It should be noted, however, that there were 20 litters examined, which meets the generally acceptable minimum requirements for a developmental study.

When the numbers of treated fetuses with this variation were compared to the WIL historical control data included with the study, the incidence (% per litter) was within their historical control limits of the nearest category, major blood vessel variations. Eighteen fetuses (18 litters) of 39,442 fetuses (3,574 litters) reported in historical data had major blood vessel variations (0.0-1.5% per litter). Historical control data compiled by MARTA/MTA (1995) for Crl:CD BR rats reported a much lower incidence of the specific alteration, retroesophageal subclavian artery. Further discussion of these data can be found in Appendix B.

In conclusion, since this is an unusual alteration and the incidence (% per litter) is significantly increased in mid- and high-dose groups compared to concurrent controls, the relationship between this alteration and the test article is equivocal. The evidence is insufficient to label HBCD a possible developmental toxicant. In the view of the CPSC staff, HBCD cannot be classified as toxic under the FHSA.

Organic Phosphonates

Staff re-calculated the ADI's for two members of the class of organic phosphonates, dimethyl phosphonate (DMHP) and dimethyl methyl phosphonate (DMMP), and re-assessed the neurotoxicity associated with DMHP. These actions have not altered the staff's conclusions that under the FHSA, DMHP is both an acute and chronic toxicant and DMMP is a chronic toxicant (Hatlid 1999e). The ADI's for DMHP and DMMP have been adjusted for intermittent exposure (5 days/week). The ADI for DMHP is 0.36 mg/kg-day instead of 0.5 mg/kg-day. The ADI for DMMP has been similarly adjusted to 0.18 mg/kg-day from 0.25 mg/kg-day.

The toxicity review for DMHP (Hattelid, 1999e) reported data demonstrating clinical and histopathological signs of neurotoxicity after DMHP exposure in several studies. Mineralization of the cerebellum was observed in male rats after administration of 200 mg/kg DMHP in a 2-year bioassay (NTP, 1985), while central nervous system vascular lesions, neuromuscular effects, other neurological impairment resulted from the inhalation of 536 mg/m³ DMHP (Ben-Dyke, 1980; Rusch, 1980). Transitory effects such as depression, ataxia, inactivity, and hypoventilation, which generally occurred immediately after dosing, were observed in several studies and also may have been indicative of neurotoxicity.

The 1999 CPSC review stated that these effects may be secondary to serious systemic toxicity, but no conclusions were drawn regarding the neurotoxicity of DMHP under the FHSA. The review should have concluded, "under the FHSA, DMHP may be regarded as "possibly" neurotoxic in humans, based on limited evidence in animals. The conclusion that DMHP is possibly neurotoxic does not, in itself, satisfy the FHSA definition of "toxic." The classification of DMHP as a possible neurotoxicant under the FHSA does not affect the original determination that DMHP is a chronic toxicant under the Act, based upon systemic toxicity.

Tetrakis (hydroxymethyl)phosphonium salts

Both THPS and THPC are considered chronic toxicants under the FHSA (Bittner, 1999b). This determination has not been changed by staff review of additional studies. After re-evaluation of the data, however, staff has determined that THPS may be considered a possible developmental toxicant under the FHSA. Based on new data, both THPC and THPS are considered acute toxicants by the dermal route of exposure under the FHSA. The ADI's for tetrakis (hydroxymethyl)phosphonium chloride (THPC) and tetrakis (hydroxymethyl)-phosphonium sulfate (THPS) have been adjusted for intermittent exposure (5 days/week) during gavage studies. The ADI for THPC has been changed from 0.00375 mg/kg-day to 0.00268 mg/kg-day. The ADI for THPS has been changed from 0.05 mg/kg-day to 0.036 mg/kg-day.

Additional toxicity data were located on the tetrakis (hydroxymethyl)phosphonium salts manufactured by American Cyanamid (American Cyanamid, 1981). The submission included data on the products Pyroset[®] TKC (tetrakis [hydroxymethyl]phosphonium chloride or THPC); Pyroset[®] TKO or TK-115 (tetrakis [hydroxymethyl]phosphonium sulfate or THPS); and Pyroset[®] TKS (tetrakis [hydroxymethyl]phosphonium oxalate), among other salts. The neurological effects observed after dermal application of THPS were similar to effects observed in other studies that have previously been reported in the CPSC review (Bittner, 1999b). The new data did provide dermal LD₅₀s for both THPC and THPS. Based on these new data, both THPC and THPS are considered acute toxicants by the dermal route of exposure under the FHSA because the LD₅₀s are <2,000 mg/kg.

The oral LD₅₀ of Pyroset[®] TK-115 was reported to be 0.292 mL/kg in rats; the dermal LD₅₀ was 0.635 mL/kg in rats. No concentrations were reported so the doses could not be calculated (American Cyanamid 1981). Other acute data for TK-115 that were reported by American Cyanamid (1981) included a dermal LD₅₀ in rats of 1.41 mL/kg and a dermal LD₅₀ in

rabbits of 1.13 mL/kg. Using Pyroset® TKC, the oral LD₅₀ was 0.769 mL/kg and the dermal LD₅₀ was 0.566 mL/kg (American Cyanamid 1981). The oral LD₅₀ of Pyroset® TKC in rats was also reported to be 0.625 mL/kg and the dermal LD₅₀ in rabbits was 0.252 mL/kg (American Cyanamid, 1981). Data were also provided on testing results for the various reaction products of Pyroset® TK-115.

The submitted studies reported both neurological and dermal effects. Pyroset® TKO (THPS) caused ataxia after single dermal applications (doses unspecified), but application of Pyroset® TKC (THPC) did not. Rabbits (n=4) were treated dermally with Pyroset® TK-115 (0.05 or 0.2 mL/kg) once/day, 5 days/week for 2 weeks (American Cyanamid, 1981). Two of four high-dose animals died and low-dose animals lost weight after treatment. No overt signs of neurotoxicity were observed in animals treated with Pyroset® TK-115, but severe irritation and necrosis of the skin developed (American Cyanamid, 1981).

No neurotoxicity was reported after dermal treatment of rats or rabbits with Pyroset® TKO. Rats (n=2/group) treated dermally with 0.2 or 0.5 mL/kg of Pyroset® TKO 5 days/week showed severe dermal reactions, including necrosis, and weight loss. The two high-dose rats died on the ninth and tenth day of dosing. Low-dose animals showed desquamation and necrosis; necropsy revealed abscessed pneumonia and a gas-filled GI tract in one animal (American Cyanamid, 1981). No neurotoxicity was reported in a subacute dermal study in which 4-5 male rabbits/dose received 23 applications of Pyroset® TKO (0.1 or 0.2 mL/kg) over 31 days. The intent of this study had been to induce neurotoxicity in the animals, then administer an antidote. One high-dose animal died after receiving 9 doses although the study stated that this may have occurred from lung infection. Body weights were less than controls at high dose. Although no clinical signs of systemic toxicity were reported, skin reactions among treated animals included marked erythema and edema, necrosis, desquamation, and pustules. After 23 days, the study was terminated due to severe dermal effects; no neurotoxicity had been observed.

Pyroset® TKC and Pyroset® TK-115 were neurotoxic in a cat (n=2/group) study in which 0.2 mL/kg were applied dermally for 15 days (American Cyanamid, 1981). The study was designed specifically to examine the neurotoxicity of the compounds. Equilibrium disturbance, and sensory and motor involvement of the limbs was observed within 5-13 days of the first dose. All animals in each of the treatment groups died within a few days of clinical signs of neurotoxicity. Animals maintained for recovery continued their neurological decline, indicating irreversibility of effects. No significant histological changes were observed in neural tissue that was examined from treated animals. This study was repeated with similar results.

Two studies were performed that examined the toxic effects of feeding pulverized cloth treated with flame retardant chemicals to rats (n=5/sex/group) in the diet (American Cyanamid, 1981). In one study, the treated cloth was fed to the animals for 6 weeks at a concentration of 1% in the diet. A 4-week recovery period then followed. Although the compounds used to treat the cloth were not definitively identified, it appears that they included a 100% cotton sample that had been treated with Pyroset® TKC in an ammonia cure process. No clinical or histopathological findings associated with toxicity were observed that could be related to treatment with Pyroset® TKC. The histopathological examination included very few organs.

The second study examined the effects of feeding two types of unoxidized pulverized cloth samples to rats for 5 weeks, with up to a 7-week recovery time (American Cyanamid, 1981). Since oxidation is the final step in the curing process, this cloth was not completely cured. A polyester/cotton blend that had been treated by a pad/dry/cure process with Pyroset® TKO caused no toxicity when fed to rats (n=5/sex/group) in a dietary concentration of 1%. A cotton sample treated with Pyroset® TKC (ammonia cured) induced neurotoxicity in female rats after 2 weeks of feeding; most died or were sacrificed *in extremis*. One of five male rats also developed neurotoxic signs after 6 weeks of treatment. These symptoms included splaying of the hind legs and instability of the front legs. Body weight loss was also observed sporadically in both treated groups, particularly in the Pyroset® TKC group. Since both of these samples were unoxidized, these effects might not necessarily be observed with the fully cured product.

No dermal irritation was observed in 200 healthy adults when Pyroset® TKC or TK-115 in an ammonia cure process or Pyroset® TK-115/urea in a pad/dry/cure process in cloth were applied moist and under occlusion for one week (American Cyanamid, 1981). Following a 7-day rest period, the moistened material was applied to a fresh site on the subjects for another week and no contact sensitization was reported.

Dermal applications of 1 g/kg/dose (6 hours/day, 9 of 11 days) of Pyroset® TKO or TKC wetted on unoxidized cloth produced no adverse dermal effects or clinical signs in male rabbits (n=4/group) (American Cyanamid, 1981). Since oxidation is the final step in the curing process, this cloth was not completely cured. Loss of body weight was observed in some animals from each group. At necropsy, however, 2/4 rabbits treated with Pyroset® TKO or TKC had pale kidneys and one other rabbit treated with TKC had pale and enlarged kidneys and diaphragmatic congestion.

Additional data on THPS were evaluated. A letter from Technical Assessment Systems, Inc. (TAS, 1990) to US EPA provided interim summary data submitted on behalf of Albright and Wilson on an oral (gavage) teratology study in rabbits using THPS. The letter states that reduced body weights and increased eye and limb malformations were observed in the offspring of does treated with 60 mg/kg/day during gestation days 7-19. This dose also resulted in marked maternal toxicity including weight loss and reduced food intake. The NOEL was 18 mg/kg/day. It is also reported that in a range-finding study in rabbits dosed with THPS by gavage, no adverse effects on fetal "values" or external fetal abnormalities were found at 80 mg/kg/day, the maternally toxic dose.

The CPSC toxicity review (Bittner 1999b) stated that there are insufficient data to fully evaluate the reproductive and developmental effects of THPS. Based upon the preliminary information communicated in this letter, however, THPS may be considered a possible developmental toxicant under the FHSA.

Zinc Borate

Due to the paucity of toxicological data on zinc borate ($3\text{ZnO}\cdot 2\text{B}_2\text{O}_3$), the CPSC staff reviewed toxicity data on zinc oxide (ZnO), boric acid (H_3BO_3), and boric anhydride (B_2O_3) (Hatlelid, 1999f). In this review, H_3BO_3 and B_2O_3 were determined to be acutely toxic by the oral route of exposure. H_3BO_3 met the definition for chronic toxicity as a probable reproductive and developmental toxicant in humans under the FHSA. These conclusions have not been changed after staff review of another study.

Lord's Additives recently submitted data on zinc borate that they had translated from Russian (Silaev, 1981). The oral LD_{50} was reported to be 9.74 g/kg and 10 g/kg in male and female rats, respectively, and 7.2 g/kg in male mice. It was noted that the effects of administration were similar to those of potassium pentaborate reviewed in Hatlelid (1999f), but further details of the study were not provided. The LC_{50} in rats was reported to be 104 mg/m^3 .

The Silaev study also reported that conjunctivitis and keratolucoma were observed when 50 mg of the substance was instilled into the eyes of rabbits. No dermal irritation was found after 20 applications of 50% test article in lanolin ointment to rats and guinea pigs. Thus, although the pure compounds of zinc borate and boric acid cause minor eye and skin irritation in humans, 50% zinc borate in an ointment was not a dermal irritant to animals. Therefore, based on these data, zinc borate is considered a possible skin irritant.

B. General Issues:

UK Risk Assessment

The UK Department of Trade and Industry (DTI) commissioned a risk assessment of FR chemicals that was performed by the Polymer Research Centre, University of Surrey, England (UK Report) (UK, 1999). The report included a toxicity assessment for selected FR chemicals. Toxicity data on four of these chemicals (alumina trihydrate, antimony trioxide, decabromodiphenyl oxide, and tris[chloropropyl]phosphate) were also reviewed by the CPSC staff (Bittner, 1999a,c; Ferrante, 1999c,d; Hatlelid, 1999a; Saltzman and Babich, 1999).

The CPSC staff reviewed the UK risk assessment and compared the toxicity assessment section of the UK document to the CPSC staff toxicity assessments (Bittner and Ferrante, 1999; Bittner et al., 1999). The CPSC staff found that:

a) Generally, both reviews conclude that *aluminum hydroxide (alumina trihydrate)* has low acute oral toxicity and there is no evidence showing that it is mutagenic/carcinogenic or produces reproductive toxicity. Additionally, both agree that chronic use of this chemical in particularly sensitive populations, such as chronic renal failure patients and infants, can produce toxic effects, including encephalopathy and osteomalacia (Bittner et al., 1999).

b) Although the conclusions of the UK Report are similar to those of the CPSC staff with regard to acute toxicity of *antimony trioxide*, the assessments differed with respect to its chronic toxicity (Bittner et al., 1999). The UK Report concluded that there would be no adverse effects