REGULATED PRODUCTS HANDBOOK

A GUIDE FOR MANUFACTURERS, IMPORTERS, DISTRIBUTORS, AND RETAILERS ON PROCEDURES RELATING TO THE ENFORCEMENT OF STANDARDS AND REGULATIONS ISSUED UNDER THE CONSUMER PRODUCT SAFETY ACT (CPSA), THE FEDERAL HAZARDOUS SUBSTANCES ACT (FHSA), THE FLAMMABLE FABRICS ACT (FFA), THE POISON PREVENTION PACKAGING ACT (PPPA), AND THE REFRIGERATOR SAFETY ACT (RSA)

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This handbook contains information needed by manufacturers, distributors, importers, and retailers charged with violating a CPSC statute or regulation to ensure appropriate steps are taken to comply with CPSC requirements.

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REGULATED PRODUCTS HANDBOOK

INTRODUCTION

The U.S. Consumer Product Safety Commission (CPSC) is an independent Federal regulatory agency charged with reducing unreasonable risks of injury and death associated with consumer products. The CPSC has jurisdiction over about 15,000 types of consumer products used in the home, in schools, and in recreation. To carry out its mission, CPSC administers five statutes passed by Congress. They are: (1) the Consumer Product Safety Act, 15 U.S.C. §§ 2051-2084 (CPSA), (2) the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1278 (FHSA), (3) the Flammable Fabrics Act, 15 U.S.C. §§ 1191-1204 (FFA), (4) the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-1476 (PPPA), and (5) the Refrigerator Safety Act, 15 U.S.C. §§ 1211-1214 (RSA).

This Handbook has been developed to assist firms in understanding what steps they should take when CPSC informs them or they become aware of a violation of CPSC statutes and regulations. Firms should review this Handbook in conjunction with the Letter of Advice (LOA) CPSC staff sends informing a firm of a violation and the applicable statutes and regulations provided with the LOA. After reviewing the information in the Chapters which follow, please direct any questions to the appropriate CPSC Compliance Officer or the Office of Compliance at 301-504-7913.

HOW CPSC ENFORCES ITS STATUTES

The goal of the Commission's Compliance Program is to ensure that firms comply with the laws, regulations, and standards that protect consumers from hazardous products. To achieve this goal, the agency conducts three main types of compliance activities:

- Informing industries of CPSC requirements for their products and educating them through seminars and information letters, as appropriate;
- Maintaining surveillance over consumer products and following up on reports of products that may not be in compliance with federal standards or may be potentially hazardous products;
- Identifying and obtaining corrections of violations and recalls of hazardous products from the marketplace or consumers, primarily by working cooperatively with industry, but through litigation when necessary.

Specific compliance activities include the following:

- Enforcing existing regulations and laws by (1) conducting both domestic surveillance through inspections of the regulated industry and import surveillance at Ports of Entry in conjunction with the U.S. Bureau of Customs and Border Protection, and (2) following up on injury reports, consumer complaints, trade complaints or other allegations or indications that a firm is manufacturing or distributing a consumer product not in compliance with the law.
- Section 15 of the CPSA requires manufacturers, distributors, and retailers to report to the CPSC, among other things, products that fail to comply with a standard or banning rule issued under the CPSA. If a product violates a mandatory standard under the FHSA, FFA, PPPA or RSA, the firm must determine whether the violation rises to the level of a defect that could create a substantial product hazard or creates an unreasonable risk of serious injury or death*. If so, the firm must report. Section 37 of the CPSA requires manufacturers to report to the Commission products which are the subject of at least three civil actions within a 24-month period that result in a judgment or final settlement in favor of the plaintiff. The Commission has the authority to remove hazardous products from the marketplace under section 15 of the CPSA and section 15 of the FHSA.

Once the CPSC staff determines a product violates a specific statute or regulation, CPSC Compliance staff generally notifies the responsible firm (the product manufacturer, importer, distributor, or retailer). Notification to the responsible firm is usually in the form of an official letter, referred to in this handbook as a Letter of Advice (LOA).

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^{*} When the Commission issues a product standard, it finds that the standard is necessary to protect against an unreasonable risk of injury. Thus, for reporting purposes, firms must determine whether a violation of a standard under the FHSA, FFA, PPPA, or RSA creates a risk of serious injury or death.

The LOA informs the firm of the specific product and violation involved, requests the firm to take specific corrective actions, and informs the firm of the legal actions available to the Commission in the event the firm does not agree to correct the violations voluntarily.

In addition, the LOA informs the firm that if it disagrees with CPSC staff that a violation has occurred or believes the product is not subject to the Commission's laws, it may question the staff's findings and present evidence to support its position.

CHAPTER 1 - SANCTIONS UNDER CPSC STATUTES

In enacting the various statutes administered by CPSC, Congress provided specific sanctions which may be imposed against firms that violate any provision of the statutes. These sanctions include both civil fines against the responsible firm and individual, up to a maximum of \$1.825 million** (69 Fed. Reg. 68884, November 26, 2004) and criminal fines, and imprisonment of the responsible individual(s) for not more than one year. In addition, firms and individuals may be enjoined from continuing to violate CPSC statutes and regulations, and pursuant to court order, violative products may be seized to prevent distribution in commerce. Following is a discussion of the penalties and other sanctions that may be imposed by CPSC for violations of its statutes.

PENALTIES APPLICABLE TO FIRMS AND INDIVIDUALS

When a product is found to violate a CPSC statute, safety standard or banning regulation, the Compliance staff issues a LOA to the responsible firm and individuals. The LOA informs the firm what regulation or standard has been violated, what statute has been violated and states that a prohibited act has occurred. The prohibited acts are found in section 19 of the CPSA, 15 U.S.C. § 2068; section 4 of the FHSA, 15 U.S.C. § 1263; section 3 of the FFA,15 U.S.C. § 1192; and section 403 of the Federal Food, Drug, and Cosmetics Act (FD&CA), 21 U.S.C. § 343, for violations involving foods, drugs, and cosmetics subject to special packaging standards under the PPPA.

Once a firm and/or individual is informed of the prohibited act(s), the firm and individual can determine the maximum sanctions to which they may be subject. Generally, the LOA will not contain specific details regarding penalties but will refer to this *Handbook* for assistance in determining the applicable penalties. Following is a summary of the penalties available under the CPSA, FHSA, FFA, and PPPA enforced through the FHSA and FD&CA.

PENALTIES AVAILABLE UNDER THE CPSA

Civil Penalties under CPSA - Under section 20 of the CPSA, any person who knowingly violates section 19 of the CPSA shall be subject to a civil penalty not to exceed \$8,000 for each such violation**. With some exceptions, a violation of § 19(a)(1), (2), (4), (5), (6), (7), (8), (9), (10), or (11) shall constitute a separate

** The maximum penalty amounts are adjusted for inflation every five years. The next adjustment will occur in January 2010.

offense with respect to each individual consumer product involved, except that the maximum civil penalty shall not exceed \$1.825 million for any related series of violations (69 Fed. Reg. 68884, November 26, 2004).

Criminal Penalties under CPSA - Under section 21 of the CPSA, any person who knowingly and willfully violates section 19 of the CPSA after having received notice of noncompliance from the Commission shall be fined (as described below) or imprisoned for not more than one year, or both. The Criminal Fine Improvements Act of 1987, Public Law 100-185, increased maximum criminal penalties under the CPSA to \$100,000 for individuals and \$200,000 for organizations unless a death occurred, in which case the maximum fine is \$250,000 for individuals and \$500,000 for organizations.

PENALTIES AVAILABLE UNDER THE FHSA

Civil Penalties under FHSA - The Consumer Product Safety Improvement Act of 1990, Public Law 101-608, amended section 5 of the FHSA by adding a new section 5(c)(1), 15 U.S.C. § 1264, which gives the Commission the authority to seek civil penalties against any person who knowingly violates section 4 of the FHSA. The term "knowingly" is defined in section 5(c)(5) of the FHSA. 15 U.S.C. § 1264(c)(5). The Commission may seek a civil penalty of up to \$8,000** per violative product, up to a maximum of \$1.825 million for any related series of violations (69 Fed. Reg. 68884, November 26, 2004).

Criminal Penalties under FHSA - Under section 5(a) of the FHSA, 15 U.S.C. § 1264(a), any person who violates section 4 of the FHSA shall be guilty of a misdemeanor and shall upon conviction thereof be subject to a fine (described below) or to imprisonment for not more than 90 days (one year for violations committed with intent to defraud or mislead or for second and subsequent offenses), or both. The Criminal Fine Improvements Act of 1987, Public Law 100-185, increased the maximum criminal penalties provided for in section 5(a) of the FHSA to \$5,000 for individuals and \$10,000 for organizations for first violations; \$100,000 for individuals and \$200,000 for organizations for second and subsequent offenses and for offenses committed with intent to defraud or mislead; and \$250,000 for individuals and \$500,000 for organizations for violations resulting in death.

PENALTIES AVAILABLE UNDER THE FFA

Civil Penalties under FFA - The Consumer Product Safety Improvement Act of 1990, Public Law 101-608, amended section 5 of the FFA, by adding a new section 5(e), 15 U.S.C. § 1194 (e), which gives the Commission the authority to seek civil penalties

against any person who knowingly violates a regulation or standard issued under section 4 of the FFA, 15 U.S.C. § 1193. The term "knowingly" is defined in section 5(e)(4) of the FFA, 15 U.S.C. §1194. The Commission may seek a civil penalty of up to \$8,000** per violative product, up to a maximum penalty of \$1.825 million for any related series of violations (69 Fed. Reg. 68884, November 26, 2004).

Criminal Penalties under FFA - Under section 7 of the FFA, 15 U.S.C. § 1196, any person who willfully violates section 3 or 8(b) of the FFA or fails to comply with section 15(c) of the FFA shall be guilty of a misdemeanor, and upon conviction thereof shall be fined (as described below) or imprisoned not more than one year or both. The Criminal Fine Improvements Act of 1987, Public Law 100-185, increased the maximum criminal penalties provided for in section 7 of the FFA to \$100,000 for individuals and \$200,000 for organizations unless a death occurred, in which case the maximum fine is \$250,000 for individuals and \$500,000 for organizations.

PENALTIES AVAILABLE UNDER THE PPPA

In enacting the PPPA, Congress chose to incorporate the penalties available under two existing statutes rather than provide separate penalties for prohibited acts involving products regulated under the PPPA. Depending on the type of product and the specific prohibited act involved, penalties provided for under the FHSA or the FD&CA may be applicable.

Civil Penalties - The failure to comply with a standard under the PPPA results in the product being classified as either a misbranded hazardous substance under the FHSA or a misbranded food, drug, or cosmetic under the FD&CA, as amended. If the product involved is classified as a misbranded hazardous substance, see Civil Penalties under FHSA, above. If the product involved is a misbranded food, drug, or cosmetic, refer to Criminal Penalties below, since no civil penalties are provided for under the FD&CA.

Criminal Penalties - If the product involved is a misbranded hazardous substance, see Criminal Penalties under FHSA, above. If the product involved is a misbranded food, drug, or cosmetic, criminal penalties for violations of the PPPA are spelled out in section 303(a)(1) of the FD&CA, 21 U.S.C. § 333. Under that section, any person who violates a provision of section 301 shall be guilty of a misdemeanor, and upon conviction thereof shall be fined (as described below) or imprisoned for not more than one year (or for subsequent offenses and offenses committed with the intent to defraud or three years). The Criminal Fines mislead. Improvements Act of 1987, Public Law 100-185, increased maximum criminal penalties under the FD&CA for first violations to \$100,000 for individuals and \$200,000 for organizations and for second and

subsequent offenses and for offenses committed with intent to defraud or mislead to \$250,000 for individuals and \$500,000 for organizations.

INJUNCTIVE ACTIONS

Following are the applicable provisions which authorize the Commission to seek to enjoin firms from violations of the CPSC statutes and regulations.

INJUNCTIONS UNDER THE CPSA

Section 22(a) of the CPSA, 15 U.S.C. § 2071, states: "The United States district courts shall have jurisdiction to take the following action:

- 1. Restrain any violation of section 19;
- Restrain any person from manufacturing for sale, offering for sale, distributing in commerce, or importing into the United States a product in violation of an order in effect under section 15(d).:
- Restrain any person from distributing in commerce a product which does not comply with a consumer product safety rule."

INJUNCTIONS UNDER THE FHSA

Section 8(a) of the FHSA, 15 U.S.C §1267, states: "The United States district courts and the United States courts of the territories shall have jurisdiction, for cause shown and subject to the provisions of rule 65 (a) and (b) of the Federal Rules of Civil Procedure, to restrain violations of this Act."

INJUNCTIONS UNDER THE FFA

Section 6(a) of the FFA, 15 U.S.C. §1195, states: "Whenever the Commission has reason to believe that any person is violating or is about to violate section 3. or a rule or regulation prescribed under section 5(c), of this Act, and that it would be in the public interest to enjoin such violation until complaint under the Federal Trade Commission Act is issued and dismissed by the Commission or until an order to cease and desist made thereon by the Commission has become final within the meaning of the Federal Trade Commission Act or is set aside by the court on review, the Commission may bring suit in the district court of the United States. for the district in which such person resides or transacts business ... to enjoin such violation and upon proper showing a temporary injunction or restraining order shall be granted without bond."

INJUNCTIONS UNDER THE PPPA

For violations of the PPPA which result in a product being classified as a misbranded hazardous substance, see Injunctions Under The FHSA, above. For PPPA violations which result in the product being classified a misbranded food, drug, or cosmetic, the injunctive provisions of the FD&CA apply. Section 302(a) of the FD&CA, 21 U.S.C. § 332, states: "The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j)."

SEIZURE OF VIOLATIVE PRODUCTS

Products which are in violation of an applicable standard or regulation are subject to seizure and condemnation proceedings under the various statutes.

SEIZURE UNDER THE CPSA

Section 22(b) of the CPSA, 15 U.SC.§ 2071(b), states "Any consumer product

- 1. which fails to conform with an applicable consumer product safety rule, or
- the manufacture for sale, offering for sale, distribution in commerce or the importation into the United States of which has been prohibited by an order in effect under section 15(d),

when introduced into or while in commerce or while held for sale after shipment in commerce shall be liable to be proceeded against on libel of information and condemned in any district court of the United States within the jurisdiction of which such consumer product is found...."

SEIZURE UNDER THE FHSA

Section 6(a) of the FHSA, 15 U.S.C. §1265(a), states "Any misbranded hazardous substance or banned hazardous substance when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 4(f), be introduced into interstate commerce, or which has been manufactured in violation of section

4(g), shall be liable to be proceeded against while in interstate commerce or at any time thereafter, on libel of information and condemned in any district court in the United States within the jurisdiction of which the hazardous substance is found: *Provided*, That this section shall not apply to a hazardous substance intended for export to any foreign country if it (1) is in a package branded in accordance with the specifications of the foreign purchaser, (2) is labeled in accordance with the laws of the foreign country, and (3) is labeled on the outside of the shipping package to show that it is intended for export, and (4) is so exported."

SEIZURE UNDER THE FFA

Section 6(b) of the FFA, 15 U.S.C. §1195(b), states "Whenever the Commission has reason to believe that any product has been manufactured or introduced into commerce or any fabric or related material has been introduced into commerce in violation of section 3 of this Act, it may institute proceedings by process of libel for the seizure and confiscation of such product, fabric, or related material in any district court of the United States within the jurisdiction of which such product, fabric, or related material is found...."

SEIZURE UNDER THE FD&CA (FOR CERTAIN PRODUCTS REGULATED UNDER THE PPPA)

Section 304(a) of the FD&CA, 21 U.S.C. § 334, states "Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found...."

CHAPTER 2 - PRESENTING EVIDENCE THAT A PRODUCT IS NOT VIOLATIVE

This Chapter contains the procedures to be followed if a firm disagrees with the Commission staff determination that a product is in violation of a regulation or standard administered by CPSC.

RESPONDING TO CPSC NOTIFICATION OF VIOLATIVE PRODUCT STATUS

When the CPSC Compliance Officer notifies you in a LOA that a product you manufacture, import, or distribute fails to comply with a CPSC statute, standard or regulation, you may disagree with the staff's determination.

The LOA will state that the firm may present evidence that a violation does not exist or that a product is not covered by the applicable statute or regulation. In response to the LOA, you may submit to the Compliance Officer evidence and arguments that support why you believe the product is not violative, not covered by a specific regulation, or should not be refused admission into the U.S. (if the violation involves an import sample).

A firm may respond to a Letter of Advice in writing and/or the firm may request an informal hearing to meet personally with the Office of Compliance staff to orally present views and evidence.

Such evidence may consist of:

- results of tests indicating the product complies with the applicable regulation;
- marketing data indicating the product is not intended for the population group protected by the regulation;
- any other type of information.

CPSC RESPONSE TO INFORMATION SUBMITTED BY FIRM

Any additional evidence or arguments that a firm presents are reviewed by the appropriate CPSC Compliance staff, including appropriate technical staff. If the information you present does not, in the staff's opinion, refute the staff's claim that the product is violative or covered by a specific regulation, the Commission staff generally will notify you in writing why it believes the information submitted is insufficient before pursuing any enforcement action against the products or your firm.

If a firm continues to disagree with the staff and declines to take corrective action, the staff may request the Commission to approve appropriate legal proceedings including issuance of an administrative complaint, injunctive action, seizure action, or such other action as may be appropriate.

CHAPTER 3 - HOW A FIRM UNDERTAKES A PRODUCT RECALL

This Chapter provides information on initiating a product recall when the CPSC staff determines that the hazard associated with a product warrants such action.

PREPARING FOR A PRODUCT RECALL

Once the CPSC staff determines that a product is in violation of a Commission statute or regulation, it will notify you in the LOA that corrective action to address the violation is warranted. The LOA generally will also include specific corrective actions the CPSC staff believes are appropriate to address the violation. Where appropriate, based on the nature of the hazard and the likelihood of injury associated with the noncomplying product, the Compliance staff will request that the firm recall the product from the marketplace, including consumers who already own the product. This corrective action plan, after being reviewed by the CPSC staff for adequacy, forms the basis for any action you take to resolve the problem.

It is unlikely that any two recall programs will ever be identical. Therefore, companies should be prepared to address issues that invariably arise. For instance:

- How did the product fail to comply with government safety regulations?
- Where are the unsafe products located? How many are there?
- Has the firm discontinued production and shipments of these products to distributors and retailers?
- Has the firm notified distributors and retailers to stop selling the product and asked them to help identify consumers who own the product?
- Has the firm started reviewing existing databases to identify potential product owners, e.g., product registration and customer service records?
- Has the firm drafted a press release announcing the recall? What other forms of public notice are needed?
- Has the firm set-up a toll-free telephone service that will be able to handle the number of calls expected after the recall is announced?

- Is the firm prepared to deploy people and/or fund an effort to provide replacement parts for defective products or to exchange them for new products that do not have the problem?
- Has the firm developed a plan to ship replacement parts or new units to distributors and/or retailers involved in the product recall, or otherwise repair the units in their inventory?
- Is the firm prepared to monitor the product recall and provide timely reports to the Commission on the progress of the recall?
- Has the firm developed a plan to dispose of recalled units?
- How is the firm upgrading its quality control or risk analysis procedures to prevent a similar product recall in the future?

This list addresses administrative and operational functions of a firm involved in a product recall. Even if a product recall is merely potential, a firm should be prepared to respond to the questions listed above.

ELEMENTS OF A RECALL

A firm that undertakes a recall should develop a comprehensive plan that reaches throughout the entire distribution chain and to consumers who have the product. The firm must design each communication to motivate people to respond to the recall and take the action requested by the firm.

Once the CPSC Compliance staff and a firm agree on a remedy to correct a violative product, the CPSC Compliance staff works with the firm to put together an effective plan for public notification and implementation of the recall. The Commission will publicize the terms of the plan to inform the public of the nature of the noncomplying product hazard and the actions being undertaken to correct that hazard.

The objectives of a recall are:

- 1. To locate all noncomplying products as quickly as possible;
- To remove noncomplying products from the distribution chain and from the possession of consumers; and
- To communicate accurate and understandable information in a timely manner to the public about the noncomplying product, the hazard,

and the corrective action. Companies should design all informational material to motivate retailers and media to get the word out and consumers to act on the recall.

In determining what forms of notice to use, companies should consider where and how the product was marketed, its user population, the estimated useful life of the product, and how the product is most likely to be maintained and repaired.

A firm conducting a recall must take particular care to coordinate the notice portion of the recall so that all participating parties, including retailers, have sufficient advance notice so that they can carry out the actions agreed upon. Notice also needs to be balanced — the purpose of some elements, such as news releases, press conferences, and video news releases — is to get the media to publicize information about the recall widely. Other elements, such as advertisements and posters, assure that the information is available to the public throughout the course of the recall and is to be designed to reach consumers who did not hear the original announcement.

COMMUNICATING RECALL INFORMATION

The Commission encourages companies to be creative in developing ways to reach owners of recalled products and to motivate them to respond. The following are examples of types of notice that may be appropriate. This list is meant as a guide only, and is by no means all-inclusive. As new or innovative methods of notice and means of communication become available, such as use of the Internet, the staff encourages their use.

- A joint news release from CPSC and the firm;
- Targeted distribution of the news release;
- A dedicated toll-free number and/or fax number for consumers to call to respond to the recall notice;
- Information on recalling firm's world wide web sites and ability to register for recall remedy on-line;
- A video news release to complement the written news release;
- A national news conference and/or television or radio announcements:
- Direct notice to consumers known to have the product -- identified through registration cards, credit cards, sales records, catalog orders, or other means:

- Notices to distributors, dealers, sales representatives, retailers, service personnel, installers, and other persons who may have handled or been involved with the product;
- Purchase of mailing lists of populations likely to use the product;
- Paid notices via television and/or radio;
- Paid notices in national newspapers and/or magazines to reach targeted users of the product;
- Paid notices through local or regional media;
- Incentives such as money, gifts, premiums, or coupons to encourage consumers to return the product;
- Point-of-purchase posters;
- Notices in product catalogs, newsletters, and other marketing materials;
- Posters for display at locations where users are likely to visit, such as stores, medical clinics, pediatricians' offices, day care centers, repair shops, equipment rental locations, etc.;
- Notices to repair/parts shops;
- Service bulletins;
- Notices included with product replacement parts/accessories;
- Notices to day care centers;
- Notices to second hand stores.

The Compliance staff must review and agree upon each communication that a firm intends to use in a product recall before publication or dissemination. It is, therefore, imperative that companies give the Compliance staff advance drafts of all notices or other communications to media, customers, and consumers. Following are some specific suggestions for communicating recall information:

NEWS RELEASES

Unless a firm can identify all purchasers of a product being recalled and notify them directly, the Commission typically issues a news release jointly with the firm. The Compliance staff develops the wording of the release with the recalling firm and in conjunction with the Commission's Office of Information and Public Affairs. The agreed-upon language for the news release provides the foundation for preparing other notice documents. The Commission discourages unilateral releases issued by companies because they create confusion among the media and public, particularly if CPSC is also issuing a release on the same subject.

The CPSC's Office of Information and Public Affairs sends the news releases to national wire services, major metropolitan daily newspapers, television and radio networks, and periodicals on the agency's news contact mailing list. News releases from the Commission receive wide media attention and generate a good response rate from consumers.

Each recall news release should use the word "recall" in the heading and should begin, "In cooperation with the U.S. Consumer Product Safety Commission (CPSC)...."

Recall news releases must include the following:

- The name and location of the recalling firm
- The name of the product
- The number of products involved
- A description of the hazard
- The number of deaths, injuries, and incidents involving the product
- Detailed description of the product, including model numbers, colors, sizes, and labeling
- A line drawing or photograph of the product
- Major retailers and where and when the product was sold and retail cost
- Complete instructions for consumers on how to participate in the recall

CPSC posts recall news releases on its Internet web site (available via: www.recalls.gov) and requests companies to provide color photographs of recalled products for the web site.

RECALL ALERTS

When a recalling firm has the ability to reach all owners of a recalled product through direct notification (for example, by registration cards, membership or loyalty cards, catalog sales, credit card purchases, extended warranty sales, etc.), the staff will prepare a recall alert in the form and style of a press release. It will be posted on the CPSC website (available via: www.cpsc.gov or www.recalls.gov) so consumers can confirm and verify the Commission is involved in the

recall. Summaries of recall alerts are also provided to national wire services.

VIDEO NEWS RELEASES

A video news release (VNR) is a video version of the written news release that describes the recall in audiovisual terms. Distributed via satellite to television stations nationwide, it is an effective method to enhance a recall announcement. A VNR increases the chances that television news media will air information about a recall because it effectively provides news of the recall to television news producers in the form that they need.

Commission staff works with firms to produce VNRs announcing recalls. Like news releases, VNRs need to communicate basic information clearly and concisely. VNRs should incorporate the same information as the news release, as well as video images of the product. They often also include brief statements of firm officials and/or the Chairman of the Commission. When writing a VNR script, remember that, if this information is to reach consumers, television networks or local stations must pick it up -- which means that the script must be written for television producers.

A brief guide describing how to produce a VNR is available from the Office of Compliance upon request or at: http://www.cpsc.gov/BUSINFO/vnrprod.html.

POSTERS

Posters are an effective means of providing continuing notice of recalls to consumers at points of purchase or other locations that they visit. Guidelines for posters and counter cards are as follows:

- Keep them BRIEF and eye-catching; in general, a poster requires far fewer words than a news release.
- Describe the hazard and tell consumers what to do.
- Use color to make the poster stand out.
- Use a print font, size, and color that provides a strong contrast to the background color of the poster.
- Include the terms "safety" and "recall" in the heading.
- Use a good quality line drawing or photograph of the product with call outs identifying product information, such as model numbers and date codes.

- The firm's toll-free telephone number should be in large size type at the bottom of the poster.
- The poster should include "Post until [date at least 120 days from recall announcement]."
- Consider tear-off sheets with each poster with information on the recall for consumers to take home.

When a firm produces a point of purchase poster announcing a recall, it must contact its retailers or other entities that the firm wants to display the posters before the recall is announced. The firm must explain the reason for the recall and the contribution to public safety that the posters provide. The firm must also:

- Advise retailers or other firms to place the posters in several conspicuous locations in their stores or offices where customers will see them, <u>e.g.</u>, the area where the product was originally displayed for sale, store entrances, waiting rooms in pediatric clinics, service counters at repair shops.
- Provide sufficient numbers of posters for retailers or others to display them in more than one place in each store or location, and provide a contact for ordering additional posters.

CPSC recommends that posters be 11 x 17 inches, but in no case smaller than 8.5 x 11 inches. These two sizes are easiest to mail in bulk quantities. Larger sizes may be appropriate for repair and service shops. Also, many retailers, particularly large chains, have specific requirements for posters, including size and some product identification information. To avoid delays and having to reprint, a firm producing a recall poster must contact retailers in advance to see if they have any such requirements.

OTHER FORMS OF NOTICE

Like news releases and posters, letters, advertisements, bulletins, newsletters, and other communications about a recall need to provide sufficient information and motivation for the reader or listener to identify the product and to take the action you are requesting. They should be written in language targeted to the intended audience.

- Letters or other communications should be specific and concise.
- The words "Important Safety Notice" or "Safety Recall" must appear at the top of each notice and cover letter or in the subject line of

- an email notification and must also be on the lower left corner of any mailing envelope.
- Notices to retailers and distributors must explain the reason for the recall, including the hazard, and include all the instructions needed to tell them how to handle their product inventory, as well as instructions for displaying posters or notices, providing information to consumers, and disposing of returned products.
- All letters and other notices to consumers must explain clearly the reason for the recall, including injury or potential injury information, and provide complete instructions.

TOLL-FREE NUMBERS

A firm conducting a recall must provide a toll-free (800/888/877/866) telephone number for consumers to respond to the recall announcement. Generally, this number should be dedicated only to the recall. Historically, the Commission staff has found that most firm's systems for handling consumer relations or for ordering products, repairs, or accessories are unable to respond effectively to callers about recall announcements, particularly during the first few weeks after the initial announcement.

When establishing a telephone system to handle a recall, be over-generous in estimating consumer response, especially during the first several days/weeks. It is easier to cut back than it is to add more capacity once a recall is announced, and consumers who are unable to get through may get upset.

Whether you use an automated system or live operators to answer the calls, prepare scripts and instructions for responding to questions. Operators or taped messages should begin by identifying the firm and product and explaining the reason for the recall. Most consumers who hear about a recall by radio, television, or word of mouth will not remember all the information they initially heard. Again, at its beginning, the message should reinforce the need for listeners to act, particularly if the message is lengthy.

CPSC Compliance staff must review all scripts before the recall is announced. All automated systems should provide a number for consumers to contact the firm for special problems, <u>e.g.</u>, problems completing repairs or installing parts.

WEBSITE INFORMATION

Companies should post and make available a notice of the recall in a conspicuous location on their own website. The recall information should be segregated from other company information with a

distinct icon or heading designating this safety information. Firms should provide historical recall information since not all products are returned during the designated recall period. Companies should provide an opportunity for owners of recalled products to register for the recall remedy on-line.

DEVELOPING A FIRM POLICY AND PLAN TO IDENTIFY DEFECTIVE PRODUCTS AND TO UNDERTAKE A PRODUCT RECALL

Companies whose products come under the jurisdiction of the CPSC should develop an organizational policy and plan of action before a product recall or similar action becomes necessary. This policy and any related plans should focus on the early detection of product safety problems and prompt response.

DESIGNATING A RECALL COORDINATOR

Designating a firm official or employee to serve as a "recall coordinator" is a significant step that a firm can take to meet its product safety and defect reporting responsibilities. Ideally, this coordinator has full authority to take the steps necessary (including reporting to the Commission) to initiate and implement all recalls, with the approval and support of the firm's chief executive officer.

RESPONSIBILITIES OF A RECALL COORDINATOR

We suggest the recall coordinator have the following qualifications and duties:

- Knowledge of the statutory authority and recall procedures of the Consumer Product Safety Commission;
- Ability and authority to function as the central coordinator within the firm for receiving and processing all information regarding the safety of the firm's products. Such information includes, <u>e.g.</u>, quality control records, engineering analyses, test results, consumer complaints, warranty returns or claims, lawsuits, and insurance claims;
- Responsibility for keeping the firm's chief executive officer informed about reporting requirements and all safety problems or potential problems that could lead to product recalls;
- Responsibility for making decisions about initiating product recalls;

- Authority to involve appropriate departments and offices of the firm in implementing a product recall;
- Responsibility for serving as the firm's primary liaison with CPSC.

ROLE OF THE RECALL COORDINATOR

At the outset, the recall coordinator should fully review the firm's product line to verify regulatory conformance of each product.

The firm should institute a product identification system if one is not now in use. Model designations and dateof-manufacture codes should be used on all products, whether they carry the firm's name or are privately labeled for other firms. If a product recall is necessary, this practice allows the firm to identify easily all affected products without undertaking a costly recall of the entire production. Similarly, once a specific product has been recalled and corrected, a new model number or other means of identification used on new corrected products allows distributors, retailers, and consumers to distinguish products subject to recall from the new items. Until a production change can be made to incorporate a new model number or date code, some companies have used sticker labels to differentiate products that have been checked and corrected from recalled products.

RECORDS MAINTENANCE

The goal of any product recall is to retrieve, repair, or replace those products already in consumers' hands as well as those in the distribution chain. Maintaining accurate records about the design, production, distribution, and marketing of each product for the duration of its expected life is essential for a firm to conduct an effective, economical product recall. Generally, the following records are key both to identifying noncomplying products and conducting recalls:

- Records of complaints, warranty returns, insurance claims, and lawsuits. These types of information often highlight or provide early notice of safety problems that may become widespread in the future.
- Production records. Accurate data should be kept on all production runs -- the lot numbers and product codes associated with each run, the volume of units manufactured, component parts or substitutes use, and other pertinent information which will help the firm identify defective products or components quickly.
- 3. **Distribution records.** Data should be maintained as to the location of each product by product line, production run, quantity

- shipped or sold, dates of delivery, and destinations.
- 4. Quality control records. Documenting the results of quality control testing and evaluation associated with each production run often helps companies identify possible flaws in the design or production of the product. It also aids the firm in charting and sometimes limiting the scope of a corrective action plan.
- 5. Product registration cards. registration cards for purchasers of products to fill out and return can help to identify owners of recalled products. The easier it is for consumers to fill out and return these cards, the greater the likelihood the cards will be returned to the manufacturer. For example, some firms provide pre-addressed, postagepaid registration cards that already have product identification information, e.g., model number, style number, special features, printed on the card. Providing an incentive can also increase the return rate. Incentives can be coupons towards the purchase of other products sold by the firm, free accessory products, or entry in a periodic drawing for a product give away. The information from the cards then needs to be maintained in a readily retrievable database for use if recall becomes necessary.
- 6. **Membership/Bonus/Loyalty cards.** Many stores, whether membership or available to all

- consumers, offer bonus or loyalty value cards which may be useful in identifying purchasers of recalled products. Availability and storage of these records should be considered in the event of a recall.
- 7. Credit card purchases. An increasing number of firms are utilizing records from credit card purchases of recalled products as a way of identifying and notifying owners of recalled products. Through the cooperation of issuing banks or through the firms own branded credit cards, many owners of recalled products have been directly notified of the recall, often avoiding other more traditional means of generic notification.

CONCLUSION

Consumers no longer view product recalls in a negative light. Many thousands of products have been recalled over the years. Today, consumers believe they enjoy a safer, better product as a result of a recall. How well a firm conducts a timely, reasonable recall of a product it produced can have a strong influence on the consumer's attitude about the firm. Successful product recalls in the past have often rewarded companies with continuing consumer support and demand for the firm's products.

CHAPTER 4 - APPLICATIONS FOR AUTHORIZATION TO RECONDITION VIOLATIVE IMPORTS

This Chapter provides information to firms whose products have been sampled at a Port of Entry on the procedures to be followed in requesting authorization to recondition violative products. This Chapter also includes information on costs chargeable to firms for CPSC monitoring of the reconditioning process.

PROCEDURES FOR OBTAINING AUTHORIZATION TO RECONDITION

When CPSC notifies you in a LOA that a shipment of goods imported by your firm fails to comply with CPSC requirements, you may wish to recondition the goods to bring them into compliance with the applicable requirements. Before undertaking such reconditioning, however, you must request and obtain authorization from CPSC to do so before the goods will be released by U.S. Bureau of Customs and Border Protection.

The CPSC regulations at 16 C.F.R. § 1500.269 covering imported products subject to the Federal Hazardous Substances Act (FHSA) state that application for authorization to relabel or perform other action to bring violative goods into compliance with the FHSA may be filed only by the owner or consignee of the product. This procedure applies to violative imported products subject to all statutes administered by the Commission.

The application for authorization to recondition violative goods held at U.S. Bureau of Customs and Border Protection or released under bond must be submitted in writing to the Director of the Office of Compliance. The application must:

- Contain detailed proposals for bringing the article into compliance with CPSC requirements.
- Specify the time and place where the items will be brought into compliance and the approximate time for their completion. CPSC Form #332 may be used to submit this information to the Commission. A copy of the form generally is provided with the LOA or may be obtained by contacting the Compliance Officer.

If the request for authorization to recondition is granted, the CPSC staff will notify you in writing (or via CPSC Form #332 if the application was submitted using the form), that authorization has been granted. The notice from CPSC will specify:

- 1. The procedure to be followed;
- Who will supervise the reconditioning (normally CPSC or U.S. Bureau of Customs and Border Protection personnel);
- 3. A time limit for completing the operation;
- Such other conditions as are necessary to maintain adequate supervision and control over the article.

If you need an extension of time to complete the reconditioning, you must submit a request for an extension in writing to the Director of the Office of Compliance. The request must contain reasonable grounds for the extension, and the Director may grant additional time for completing the reconditioning as he or she deems appropriate.

Once you submit an application and it is approved, you may amend the application by filing an amended application with the Director of the Office of Compliance, stating reasonable grounds for the amendment. The Director may approve such a request for amendment as deemed appropriate.

If ownership of the goods covered by the authorization to recondition changes before the goods are reconditioned, the original owner will be held responsible, unless the new owner has executed a bond and obtained new authorization.

COSTS CHARGEABLE IN CONNECTION WITH RECONDITIONING VIOLATIVE IMPORTS

The cost of CPSC staff supervising the relabeling or other action necessary to bring the goods seized or detained at a Port of Entry into compliance with CPSC requirements shall be paid by the owner or consignee of the violative goods. The Commission's regulations at 16 C.F.R. § 1500.272, provide for such costs for products seized or detained for violations of the FHSA. The Commission also is authorized to charge for monitoring the reconditioning of products detained under other statutes (see § 17(f) of the CPSA, § 6(d) of the FFA, and § 304(d)(1) of the FD&CA for PPPA violations). The guidelines provided in 16 C.F.R. § 1500.272 are used to determine costs chargeable for monitoring correction of violations under all statutes administered by the Commission. Such costs must be

paid to the Consumer Product Safety Commission. The cost of such supervision shall include, but not be restricted to, the following:

- 1. Travel expenses of the supervising officer.
- 2. Per diem in lieu of subsistence of the supervising officer when away from his home station as provided by law.
- 3. Services of the supervising officer to be calculated at the rate of a GS-11, Step 1 employee.

- 4. Services of the analyst to be calculated at the rate of a GS-12, Step 1 employee (including use of chemical laboratories and equipment).
- 5. The minimum charge for services of supervising officers and of analysts shall be not more than the charge for one hour, and time after the first hour shall be computed in multiples of one hour, disregarding fractional parts less than one-half hour.

CHAPTER 5 - REPORTING REQUIREMENTS

This chapter contains information to familiarize companies with their reporting obligations under the Consumer Product Safety Act (CPSA). Companies that distribute consumer products subject to the provisions of the Federal Hazardous Substances Act (FHSA), Flammable Fabrics Act (FFA), Poison Prevention Packaging Act (PPPA), and Refrigerator Safety Act (RSA) also must comply with these reporting requirements. The information which follows will help you to recognize potentially hazardous consumer products at an early stage, and will assist you in understanding when you are legally obligated to report information about the product to the Commission.

The information contained in this *Handbook* does not replace the Commission statutes or Commission Interpretative Regulations set forth in 16 C.F.R. parts 1115 and 1116.

STATUTORY REQUIREMENTS

REPORTING UNDER SECTION 15 OF THE CPSA

Section 15(b) of the CPSA defines responsibilities of manufacturers, importers, distributors and retailers of consumer products. Each is required to notify the Commission if it obtains information that reasonably supports the conclusion that a product -

- fails to comply with a consumer product safety standard or banning regulation established by the Commission under the CPSA or a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA;
- contains a defect which could create a substantial product hazard described in section 15(a)(2) of the CPSA; or
- creates an unreasonable risk of serious injury or death.

The Commission's interpretative regulation (16 C.F.R. part 1115) explains the firm's obligations and those of the Commission. A copy of the regulations can be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_00/16cfr 1115_00.html

Firms may report under Section 15 on-line at: https://www.cpsc.gov/sec15.html

REPORTING PRODUCTS INVOLVED IN LAWSUITS

In addition to the reporting requirements at 15 U.S.C. § 2064(b), section 37 of the CPSA, 15 U.S.C. § 2084, requires manufacturers (including importers) of a consumer product to report to the Commission if (1) a particular model of a consumer product is the subject of at least three civil actions that have been filed in Federal or State court, (2) each suit alleges the involvement of that model in death or grievous bodily injury (as defined in section 37(e)(1)), and (3) at least three of the actions result in a final settlement involving the manufacturer or in a judgment for the plaintiff within any one of the two year periods specified in section 37(b). The first two year period began to run on January 1, 1991 and ended on December 31, 1992. Subsequent two year periods started on January 1 in the following years: 1993; 1995; 1997, 1999, 2001, 2003, and so forth. Manufacturers must file a report within 30 days after the settlement or judgment in the third civil action to which the section 37 reporting requirement applies.

REPORTING CERTAIN CHOKING INCIDENTS

Section 102 of the Child Safety Protection Act (CSPA), (Public Law 103-267) requires that manufacturers, distributors, retailers and importers report certain choking incidents to the Commission. The products involved include marbles, balls with a diameter of 1.75" or less ("small ball"); or latex balloon, or a toy or game that contains such a marble, ball, balloon, or other small part. The firm must report information that reasonably supports the conclusion:

- that a child (regardless of age) choked on such a marble, small ball, balloon, or small part; and
- that, as a result of the incident, the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional.

The Commission's interpretive regulation at 16 C.F.R. Part 1117 provides more information on this reporting requirement.

WHY REPORTING IS REQUIRED

The intent of Congress in enacting the reporting requirements was to encourage widespread reporting of potential product hazards. Congress sought not only to have the Commission uncover substantial product hazards, but also to identify risks of injury

which the Commission could attempt to prevent through its own efforts, such as information and education programs, safety labeling, and adoption of product safety standards.

Although CPSC relies on sources other than firm reports to identify substantial product hazards, reporting by companies under the reporting provisions is invaluable because firms often learn of product safety problems long before the Commission. For this reason, any firm involved in the manufacture, importation, distribution or sale of consumer products should develop a system of reviewing and maintaining consumer complaints, inquiries, product liability suits and comments on the products they handle.

If a firm reports to the Commission under section 15 of the CPSA, it does not necessarily mean there is a substantial product hazard. Section 15 simply requires firms to report whenever a product (1) fails to comply with a consumer product safety rule; (2) fails to comply with a voluntary standard upon which the Commission has relied; (3) contains a defect that could create a substantial product hazard; or (4) creates an unreasonable risk of serious injury or death. Thus, a product need not actually create a substantial product hazard to trigger the reporting requirement.

WHEN TO REPORT

It is the Commission's view that a firm should take that all important first step of notifying the Commission when the information available to the firm reasonably indicates that a report is required. It is in the firm's interest to assign the responsibility of reporting to someone in executive authority.

REPORTING PROCEDURES

The Commission considers a firm to have knowledge of product safety information when such information is received by an employee or official of the firm who may reasonably be expected to be capable of appreciating the significance of that information. Under ordinary circumstances, five (5) days is the maximum reasonable time for that information to reach the chief executive officer or other official assigned responsibility

for complying with the reporting requirements. Weekends and holidays are not counted in that timetable. 16 C.F.R. § 1115.14(b).

The Commission will evaluate whether and when a firm should have reported. This evaluation will be based, in part, on what a reasonable person, acting under the circumstances, knows about the hazard posed by the product. Thus, a firm shall be deemed to know what it would have known if it had exercised due care in ascertaining the accuracy of complaints or other representations.

If the firm is uncertain whether the information is reportable, the firm may elect to spend a reasonable time investigating the matter, but no evaluation should exceed ten (10) days unless the firm can demonstrate that a longer timetable for the investigation is reasonable. If a firm elects to conduct an investigation to decide whether it has reportable information, the Commission will deem that, at the end of ten (10) days, the firm has received and considered all information which would have been available to it had a reasonable, expeditious, and diligent investigation been undertaken. 16 C.F.R. § 1115.14(d).

PENALTIES FOR FAILURE TO REPORT

Failure to report in accordance with the above referenced requirement is a prohibited act under section 19(a) of the CPSA, 15 U.S.C. § 2068, which makes it unlawful for any person to fail to furnish information required by section 15(b) or by section 37.

Any person who knowingly commits a prohibited act is subject to civil penalties under section 20 of the CPSA, including fines up to \$1.825 million for a related series of violations, and criminal penalties under section 21 of the CPSA, which includes fines up to \$500,000 or imprisonment not more than one year, or both. Chapter 1 of this *Handbook* provides additional details regarding the penalties.

If a firm is not certain about its reporting obligation, it can contact the Office of Compliance at 301-504-7913.

CHAPTER 6 - EXPORT REQUIREMENTS

This Chapter provides information on the requirement to notify the Consumer Product Safety Commission before exporting products that violate mandatory standards issued by the Commission.

POLICY STATEMENT REGARDING PROHIBITION OF EXPORTATION

When CPSC advises a firm that a product it manufactures, distributes, or imports fails to comply with an applicable CPSC statute or regulation, one option the firm may wish to consider is whether the goods may be exported. CPSC has established specific requirements relating to the exportation of noncomplying products that prohibit or restrict such exportation. Noncomplying foods, drugs, and cosmetics under the PPPA are not covered by the Commission's export notification requirements. Following is a discussion of these limitations.

Products Subject to the FHSA - The Commission's regulation at 16 C.F.R. § 1019.33(b) states that the Commission interprets the provisions of the FHSA to prohibit the export of products that are misbranded hazardous substances or banned hazardous substances if those products have at any time been sold or offered for sale in domestic commerce. Therefore, export of such banned or misbranded hazardous substances can take place only if CPSC exercises its discretion not to prevent their export.

Products Subject to the CPSA - The Commission's regulation at 16 C.F.R. § 1019.33(a) states that the Commission interprets the provisions of the CPSA to prohibit the export of products that fail to comply with an applicable consumer product safety standard or banning rule issued under that Act if those products have at any time been distributed in commerce for use in the United States. Therefore, export of such products can take place only if CPSC exercises its discretion not to prevent their export.

Products Subject to the FFA - In accordance with the Commission's regulation at 16 C.F.R. § 1019.31(b)(6), the Commission's prohibition on the export of noncomplying products that have been distributed in domestic commerce does not include products subject to standards issued under the FFA. Thus, products that violate a flammability standard under the FFA and that have been distributed in domestic commerce may be exported upon proper notification to the Commission.

PROHIBITION ON EXPORTATION

In accordance with § 18(a) of the CPSA, § 5(b)(3) of the FHSA, and § 15(a) of the FFA, the Commission

may prohibit the exportation of any product regulated under these statutes if it determines that the exportation of such products presents an unreasonable risk of injury to consumers within the United States. This authority could be used to prohibit the export of products subject to the FHSA, CPSA, or FFA that have been stopped in import status and products subject to the FFA that have been in domestic commerce.

Before prohibiting the exportation of such products the Commission would have to make a factual determination about the existence of an unreasonable risk. Relevant factors would include the nature and degree of the risk to consumers, the economic effects on business people, the attitude of the foreign country scheduled to receive the products, and the likelihood of the products re-entering the United States if exportation were permitted.

EXPORT NOTIFICATION REQUIREMENTS

The Commission's regulations at 16 C.F.R. part 1019 require that, before a firm may export products that fail to comply with the CPSA, FHSA, and FFA, a firm must notify the Commission at least 30 days in advance of the exportation date. This includes noncomplying goods stopped in import status.

The following information must be provided to the Commission:

- Name, address and telephone number of the U.S. exporter;
- 2. Name and address of each consignee;
- Quantity and description of the goods to be exported to each consignee, including brand or trade names or model or other identifying numbers;
- Identification of the standards, bans, regulations and statutory provision applicable to the goods being exported, and an accurate description of the manner in which the goods fail to comply with applicable requirements; and.
- Anticipated date of shipment and port of destination.

Address the notification of intent to export to:

Assistant Executive Director for Compliance U.S. Consumer Product Safety Commission Washington, D.C. 20207

The following paragraphs reflect the requirements of the various statutes:

FHSA Violations - Export notification is required by section 14(d) of the FHSA, 15 U.S.C. §. 1273. The failure to provide such a notice is a prohibited act under section 4(i) of the FHSA, 15 U.S.C. § 1263(i), and subject to the penalties described in section 5 of the FHSA, 15 U.S.C. § 1264.

CPSA Violations - Export notification is required by section 18(b) of the CPSA, 15 U.S.C. § 2067(b). The

failure to provide such a notice is a prohibited act under section 19(a)(10), 15 U.S.C. § 2068(a)(10), and is subject to the penalties described in sections 20 and 21 of the CPSA,15 U.S.C. §§ 2069 and 2070.

FFA Violations - Export notification is required by section 15(c) of the FFA, 15 U.S.C. § 1202(c). The failure to provide such a notice is subject to the criminal penalties of section 7 of the FFA, 15 U.S.C. § 1196.

CHAPTER 7 - CONFIDENTIAL TREATMENT OF INFORMATION SUBMITTED

This Chapter provides information on the confidential treatment of information submitted to the CPSC in response to a Letter of Advice (LOA) or a report filed with the Commission under sections 15 and 37 of the Consumer Product Safety Act (CPSA), Section 102 of the Child Safety Protection Act, and requests for Exportation of violative products.

CONFIDENTIALITY OF INFORMATION UNDER SECTION 6 OF THE CPSA

Section 6(a) of the CPSA, as amended by the Consumer Product Safety Amendments of 1981, 15 U.S.C. § 2055(a), provides protection for trade secrets or confidential information. Section 6(a)(3), 15 U.S.C. § 2055(a)(3), gives manufacturers an opportunity to mark information as confidential.

If you believe any of the information you submit to the Commission is a trade secret, or privileged or confidential information, you must accompany the submission with a request that the information be considered exempt from disclosure or indicate that a request will be submitted within 10 working days of the submission. The failure to make a request within that time will be considered an acknowledgment that you do not wish to claim exempt status. In accordance with the Commission's regulations at 16 C.F.R. § 1015.18(c), the following information must be included with the request for exemption:

- Specifically identify the exact portion(s) of the document claimed to be confidential;
- State whether the information claimed to be confidential has ever been released in any manner to a person who was not an employee or in a confidential relationship with the firm;
- State whether the information so specified is commonly known within the industry or is readily ascertainable by outside persons with a minimum of time and effort;
- State how release of the information so specified would be likely to cause substantial harm to the firm's competitive position; and
- 5. State whether the submitter is authorized to make claims of confidentiality on behalf of the person or organization concerned.

If the Commission determines that information marked as confidential may be disclosed because it is not

confidential, the Commission must provide written notice that it intends to disclose this information. This notice must be provided not less than 10 working days prior to disclosure. Any person receiving such notice may bring an action in an appropriate district court to prevent disclosure of the information, 15 U.S.C. § 2055(a)(5).

The Commission's regulations under the Freedom of Information Act, 16 C.F.R. 1015, govern confidential treatment of requests for exportation of violative products which have claimed trade secret or confidential commercial or financial information.

In addition, section 6(b) of the CPSA, 15 U.S.C. § 2055(b), also provides limitations on the Commission's disclosure of any information identifying manufacturers or private labelers, and further limits the Commission's disclosure of information received under section 15(b) of the CPSA, 15 U.S.C. § 2055(b)(5).

CONFIDENTIALITY OF REPORTS UNDER SECTION 15(b) OF THE CPSA

The Commission often receives requests for information provided by firms under section 15(b) of the CPSA, 15 U.S.C. § 2064(b). Section 6(b)(5) of the CPSA, 15 U.S.C. § 2055(b)(5), prohibits the release of such information unless a remedial action has been accepted in writing, a complaint has been issued or a firm consents to the release.

Reports under section 102 of the Child Safety Protection Act receive the same confidential treatment as information submitted under Section 15 of the CPSA.

CONFIDENTIALITY OF REPORTS UNDER SECTION 37 OF THE CPSA

Section 6(e) of the CPSA, 15 U.S.C. § 2055(e), protects from disclosure certain information submitted to the Commission by a manufacturer pursuant to section 37 of the CPSA, 15 U.S.C. § 2084. See Chapter 5 of this *Handbook* for information on the Section 37 reporting requirement.

Section 6(e)(1) provides that information furnished under sections 37(c)(1) and (c)(2)(A) may not be publicly disclosed, 15 U.S.C. §§ 2084 (c)(1) and (c)(2)(A). Section 6(e)(2), 15 U.S.C. § 2055(e)(2), provides that any report submitted pursuant to section 37(c)(1) or (c)(2)(a) shall be immune from legal process and shall not be subject to subpoena or other

discovery in any civil action in a State or Federal court or in any administrative proceeding, except in an action against such manufacturer under section 20, 21, or 22 of the CPSA, 15 U.S.C. §§ 2069, 2070, 2071, for failure to furnish information required by section 37.

USE OF INFORMATION BY THE COMMISSION

As part of any recall or other corrective action plan undertaken by your firm, pertinent information relating to the corrective action plan may be included in the recall section of the CPSC web site or in other publicly available materials. The information may include the date the corrective action plan is initiated, the name of the firm involved, the name of the product(s) involved, the geographic area of distribution of the product(s), the hazard identified by the Commission staff, the labeling of the product(s) and the type of corrective action being taken.