CONSUMER PRODUCT SAFETY COMMISSION

Conditions Under Which the Staff Will Refrain From Making Preliminary Hazard Determinations

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Act requires manufacturers, distributors, and retailers of consumer products distributed in commerce to notify the Commission of certain defects, unreasonable risks, or non-compliance with voluntary or mandatory standards. The Commission has made permanent its “No PD” program: The staff refrains from making a preliminary hazard determination when firms report and, within 20 working days, implement an acceptable corrective action.

DATES: The Commission’s revised procedures became permanent on March 27, 1997.

FOR FURTHER INFORMATION CONTACT: Marc J. Schoem, Office of Compliance, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814 (mailing address: Washington, DC 20207); telephone 301-504-0608, extension 1365; e-mail address sect15@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Under section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2064(b), manufacturers, distributors, and retailers of consumer products must report certain potential product hazards to the Commission. They must report immediately if they obtain information which reasonably supports the conclusion that a product (1) fails to comply with certain mandatory or voluntary standards, (2) contains a defect which could create a substantial product hazard, or (3) creates an unreasonable risk of serious injury or death, 15 U.S.C. 2064(b).

If the Commission believes that a product presents a substantial product hazard under the CPSA, 15 U.S.C. § 2064 (c) and (d), or contains a defect which creates a substantial risk of injury to children under the Federal Hazardous Substances Act, 15 U.S.C. § 1274(a), (b) and (c), it may pursue corrective action.

After receiving a report, the Commission staff evaluates the hazard. If the available facts justify pursuing corrective action for the product, the staff generally makes a preliminary determination (“PD”) of “substantial product hazard” or “substantial risk of injury to children.” See 16 CFR 1115.12(a).

B. Initiation of “No PD” Pilot Program

On August 17, 1995, the Commission initiated a six-month pilot program in which, under certain conditions, the Office of Compliance staff would not make a preliminary determination. See 60 Fed. Reg. 42848 (Aug. 17, 1995). Later, the Commission extended the pilot program through March 1997.

The Commission initiated the pilot program to use staff resources more efficiently and to promote quicker recalls. In addition, the Commission hoped to reduce any disincentive to companies that want to report and undertake corrective action, but fear the consequences of a staff preliminary determination.

When the staff preliminarily determines that a product presents a substantial product hazard or creates a substantial risk of injury to children, it requests that the reporting company take corrective action. If a company acts promptly to correct a defective product, staff resources can be devoted to helping the company recall the product instead of investigating the defect and making the preliminary determination.

The Commission designed the pilot program to “reward” companies that acted quickly on a corrective action. The staff made no preliminary determination concerning the products of those companies.

C. Results of Pilot Program

The pilot program was successful. During its first six months, companies participating in the program initiated 57 corrective action plans that affected approximately 3.5 million products. By the end of the pilot program’s extension, companies had initiated 140 recalls of approximately 12.9 million products.

On average, companies in the pilot program took 14 working days to initiate corrective action plans. The staff sometimes granted an extension of time for issuance of a joint news release or final staff approval of an alternative notice program. In most of those cases, however, the firm’s corrective action plan was underway within 20 working days.

During the pilot program, companies undertook corrective actions for a variety of products. They included children’s articles with small parts that presented choking hazards, products that collapsed and presented impact hazards, bicycles and recreational vehicles that could cause falls or loss of control, products that presented the risk of carbon monoxide poisoning, electrical products that presented shock and fire risks, and power tools that could cause serious lacerations.

Industry response to the pilot program was positive. During the program, more than one-third of the companies making section 15 reports initiated corrective actions under the “no preliminary determination” approach.

D. Permanent Program

After reviewing the results of the pilot program, the Commission revised its procedures on a permanent basis effective March 24, 1997. The permanent program is governed by the following requirements and procedures:

1. If a company reports and implements within 20 working days after filing an initial report a corrective action that the staff believes will be effective, the staff will generally refrain from making a preliminary determination. “Implement” means issuance of a news release or other form of public notice approved by the staff commencing a consumer-level corrective action.

If the Commission believes that more than 20 working days is necessary, the Director of the Division of Corrective Actions may extend the time period for any reasonable reason, including that: (a) technically complex issues must be resolved to assure the staff that the company’s action is adequate (for example, laboratory testing is necessary); (b) retailers and distributors must be notified in advance so that the plan will be effective; or (c) the news release must be scheduled for optimum coverage (for example, a video news release is necessary).

2. A company’s reporting obligations remain unchanged. Specifically, companies that have an obligation to notify the Commission under section 15(b) or section 37 of the CPSA, or section 102 of the Child Safety Protection Act, must continue to do so even when they believe the risk does not warrant corrective action.

3. A company must file a full report under 16 CFR 1115.13(d). In particular, the report must include copies of complaints and claims, which is crucial for staff evaluation and which many companies currently omit.

4. A company must advise the staff that it wishes to participate in the program.

5. A company must submit a proposed corrective action plan in sufficient time for the staff to review and analyze it. In addition, the staff must have sufficient time to work out the details of the corrective action with the company. All of this must occur before the company initiates the plan.
within 20 working days of filing its report.

6. A company’s proposed corrective action plan must include:
   (a) A description of the recall action (refund, repair, or replacement) that the company will take to eliminate the identified risk.
   (b) Sufficient product design, incident, and testing information to allow the staff to determine whether the proposed action corrects the identified problem and the problem is limited to the model(s) and production dates identified by the company. Such information should include, but is not limited to: consumer complaints, test data, engineering drawings, material specifications, samples of product, and/or component parts, as needed. If the needed information and documentation is being compiled, but is not yet available, the company must provide the date it expects to forward the information to CPSC. CPSC staff must have sufficient time to review the information and respond within the 20 working day time limit.
   (c) Usually, the company’s proposed plan must include notice of the recall to distributors, retailers, and consumers of the subject product. The notice must describe the product, the hazard, the number and type of injuries that have been reported, the type of injury that can occur, and the action to be taken in plain language understandable to the people to whom the notice is directed. Generally, the plan must include a joint news release with the Commission announcing the recall, letters and instructions to retailers and distributors, point-of-purchase posters, and, depending upon the level of risk, the population at risk, age and number of products involved, additional notice. Supplementary notice may include a video news release, print and/or radio advertisements, incentives or bounties to encourage consumer response, posters for specific audiences, such as for posting in pediatricians’ offices, medical clinics, national parks and campgrounds, and repair shops (see Corrective Action Handbook, available for CPSC Division of Corrective Actions). In those cases where all purchasers can be contacted directly, a news release may not be necessary.
   (d) An agreement that the Commission may publicize the terms of the plan and inform the public of the nature and the extent of the alleged hazard. The consumer notice should be targeted to reach a significant portion of the public likely to have purchased the subject product. (See 16 CFR § 1115.20(a) and CPSC Corrective Action Handbook.)

7. The corrective action plan and notice must be acceptable to the staff. The staff will consider whether the corrective action plan adequately addresses the risk of injury presented by the product and whether the notice and corrective action plan are designed to make the plan as effective as is reasonably possible given the nature of the product and the risk.

8. The staff will provide expedited review of every proposal submitted and work with every interested company to develop an acceptable corrective action plan that can be implemented within 20 working days. However, there may be cases where the staff cannot evaluate and approve implementation of a corrective action plan within 20 working days, even though the company has submitted all the necessary information in a timely manner. Similarly, there may be cases where the staff and firm agree that notice and corrective action should occur after 20 working days have passed (for example, in the case of a seasonal product). So long as delay is not caused by the fault of the company, the staff generally will not make a preliminary hazard determination.

9. If corrective action is implemented within 20 working days, staff will acknowledge in writing that the company has submitted information under section 15(b) of the CPSA and that, based on available information, the proposed corrective action plan is adequate. In addition, the staff will advise the company that it has a continuing obligation to report new or different information that may affect the scope, prevalence or seriousness of the defect or hazard. Once the company implements its corrective action plan, the staff will monitor its progress.

10. If the company does not implement a corrective action acceptable to the staff within 20 working days, the staff will continue its evaluation and will preliminarily determine whether the product contains a defect that creates a substantial risk of injury to children under the FSHA or presents a substantial product hazard under the CPSA. The staff will inform the company.

11. A company should not delay its corrective action plan. In order to prepare a corrective action plan, the staff will not refrain from making a preliminary determination if the information available suggests that a company did so.