U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

MINUTES OF COMMISSION MEETING

December 14, 1983

Third Floor Hearing Room
1111 - 18th Street, N.W.
Washington, D.C.

The December 14, 1983, meeting of the U.S. Consumer Product Safety Commission was convened in open session by Chairman Nancy Harvey Steorts. Commissioners Terrence Scanlon, Stuart M. Statler, and Sam Zagoria were present.

Ballot Vote Decisions. Chairman Steorts read into the record the following decisions made by ballot vote of the Commissioners.

NOTE: Decisions on Items 1 through 4 were made prior to Commissioner Sloan leaving the Commission.

1. Consent Agreement: Janex Corporation, CPSC Docket No. 83-3

The Commission voted unanimously (5-0) to accept a consent agreement and to issue a Commission Order in the matter of Janex Corporation, CPSC Docket 83-3.

2. Issuance of Subpoenas: Honeywell, Inc., CPSC Docket No. 83-2

The Commission voted unanimously (5-0) to grant complaint counsel's application for issuance of subpoenas in the matter of Honeywell, Inc., CPSC Docket No. 83-2.

3. Comment Period for Proposed Amendments to Guaranty Testing Rules

The Commission voted 3-1 to approve a Federal Register notice reopening the comment period, for an additional 60 days, on proposed amendments to regulations which prescribe requirements for testing and recordkeeping to support initial guaranties of items subject to the Standard for Flammability of Clothing Textiles (16 CFR Part 1610). Commissioner Scanlon voted not to approve the Federal Register notice and filed a statement with the Office of the Secretary. Commissioner Sloan did not vote on this matter.

4. Appeal of Denial of Consumer Complaint Reports, S-306262

The Commission voted 4-0 to affirm the decision of the Freedom of information Officer to withhold specified information. Commissioner Statler has filed a brief statement with the Office of the Secretary explaining his vote. Commissioner Sloan did not vote on this matter.

5. Proposed Revocation of Regulatory Definition of Strong Sensitizers

The Commission voted 4-0-1 to approve a proposed revocation of 16 CFR Part 1500.3(c)(5), a regulation that supplements the stautory definition of "strong sensitizer" contained in the Federal Hazardous Substances Act at 15 U.S.C. Part 1261(f)(1)(vi). Commissioner Armstrong abstained.

6. Privacy Act Notice - Credit Reporting Agencies

The Commission voted 4-0-1 to approve a Federal Register notice adding a disclosure notice to three of the Commission's Privacy Act systems of records in accordance with the Debt Collection Act of 1982. Commissioner Armstrong abstained.

Agenda Matters.

1. Section 6(b), CPSA: Final Rule

The Commission considered a draft final interpretive rule containing the Commission's policy and procedure under Section 6(b) of the Consumer Product Safety Act (CPSA) for disclosing to the public information from which the identity of the manufacturer or private labeler can be readily ascertained. The rule explains how the Commission will carry out its Section 6(b) responsibilities to give notice and opportunity for comment to manufacturers and private labelers of proposed disclosures of such product-specific information, and to take reasonable steps to assure the accuracy and fairness of the information to be disclosed and that disclosure is reasonably related to effectuating the purposes of the acts the Commission administers. The Commission was briefed on the draft final rule at the November 16, 1983, Commission meeting. At today's meeting, the Commission considered a number of suggested revisions to the draft rule made by individual Commissioners and the Office of the General Counsel.

Following discussion, the Commission voted unanimously (4-0) to incorporate in the final rule or in the preamble to the rule the clarifying changes suggested by the Office of the General Counsel, and clarifications relating to the following specific concerns:

(1) on a case by case basis, CPSC will follow Section 6(b) procedures, although not legally obligated to do so, in processing information that might be in its files pertaining to a product outside CPSC jurisdiction; (2) the agency will use and emphasize the terms staff and preliminary on all staff preliminary hazard determination reports; (3) the Commission and its staff will follow the provisions of the 6(b) rule although it is interpretive; and (4) another agency to which CPSC forwards information on matters not in CPSC jurisdiction is not required to itself follow Section 6(b) requirements prior to its own disclosure of the information. On a separate motion, the Commission decided by a vote of 3-1, with Chairman Steorts, Commissioner Statler and Commissioner Zagoria constituting the majority and Commissioner Scanlon dissenting, that it was unnecessary to add to the rule a specific provision about the qualifications of CPSC staff who evaluate information proposed to be disclosed or the methods of analysis used by staff. A motion to add to staff preliminary hazard determination reports explanatory language regarding no formal action having been taken by the Commission failed for lack of a second.

The Commission then voted 3-1, with Chairman Steorts, Commissioner Statler and Commissioner Zagoria constituting the majority and Commissioner Scanlon dissenting, to approve the final interpretive 6(b) rule as revised at today's meeting. Each of the Commissioners filed a statement concerning his or her vote, and these are attached. Commissioner Armstrong was not present for the discussions on this matter and did not participate in the vote.

2. Formaldehyde in Products

The staff briefed the Commission on its investigation of products to determine which consumer products could be potential major contributors to consumer formaldehyde exposure. The staff reported its conclusion that fibrous glass insulation and ceiling tiles would have little impact on in-home formaldehyde levels, while pressed wood products were identified as having the potential to contribute significant amounts of formaldehyde to the indoor air. Investigation of pressed wood is a continuing CPSC project in the Household Structures program. The staff also noted its continuing investigation of formaldehyde-resin treatment of textiles, which will be the subject of a separate briefing.

3. Chronic Hazard Advisory Panel on Formaldehyde

The Commission discussed the letter sent to the National Academy of Sciences concerning the formation of a Chronic Hazard Advisory Panel (CHAP) on formaldehyde as to whether the letter should be revised to include reference to specific consumer products the CHAP would be asked to examine. The Commission agreed that the letter would stand as transmitted and that further specificity could be incorporated in the Federal Register notice inviting nominations for the formaldehyde CHAP.

4. Chronic Hazard Advisory Panel on DEHP

The Commission considered a draft Federal Register notice inviting recommendations for expert scientists to serve as members of a Chronic Hazard Advisory Panel (CHAP) on di(2-ethylexyl) phthalate (DEHP) in various children's products. The Commission had voted on September 15, 1983, to convene this CHAP on DEHP.

Following a brief discussion, the Commission voted unanimously (4-0) to issue the Federal Register notice as drafted. Commissioner Armstrong was not present for discussion of this matter and did not participate in the vote.

5. Nitrosamines in Pacifiers

Meeting then in closed session, the Commission considered a draft Statement of Enforcement Policy that would advise manufacturers and importers of rubber pacifiers that the Commission may bring individual enforcement actions against pacifiers containing more than 60 parts per billion of nitrosamines as banned hazardous substances under the Federal Hazardous Substances Act (FHSA). Publication of a CPSC policy statement, applicable to pacifiers introduced into interstate commerce after December 31, 1983, would be coordinated with a similar notice by the Food and Drug Administration concerning nitrosamines in rubber baby bottle nipples. The staff had briefed the Commission in a closed session on November 14, 1983, on this approach for addressing the potential risk of chronic illness presented by nitrosamines in pacifiers.

Following discussion, the Commission voted 3-1 to approve the draft Federal Register notice of enforcement policy with regard to rubber pacifiers containing nitrosamines with the addition of language to advise consumers that CPSC is testing pacifiers for nitrosamine content and upon completion and evaluation of the testing will provide guidance to consumers to assist them in evaluating the comparative safety of rubber pacifiers. A joint statement by Chairman Steorts, Commissioner Statler and Commissioner Zagoria on the views of the majority and a statement of dissent by Commissioner Scanlon were filed, copies of which are attached. Commissioner Armstrong was not present for discussion of this matter and did not participate in the vote.

There being no further business, Chairman Steorts adjourned the meeting.

For the Commission:

Sadye E. Dunn

Sadye E. Dunn
Secretary

Attachments

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

The Chairman

STATEMENT
Nancy Harvey Steorts, Chairman
Consumer Product Safety Commission

Commission Meeting Final Rule on Section 6(b)
Wednesday, December 14, 1983

In my view, the final draft section 6(b) rule which the Commission voted on and approved today is well reasoned and balanced. It carries out both the letter and the spirit of section 6(b).

More importantly, as it now stands, this rule reflects a consensus. Incorporated into this interpretation are a number of changes based on comments submitted by members of industry and consumer groups. I believe these changes have helped to clarify a number of the provisions in the proposed rule. This is as it should be in the spirit of cooperation.

I believe indeed that enough time has passed. Enough opportunities have been presented for comment. Enough changes have been made. Quite simply, enough is enough.

In my mind the restrictions that 6(b) has placed on this Commission are far too limiting. Although I respect industry's concerns, I do not agree with the general opinion that release of information, especially information that is reasonably accurate, is unfair.

As was discussed, I feel that preliminary hazard determinations should be reviewed on a case by case basis and should be released under appropriate circumstances. However, any documents released must be clearly marked as preliminary staff views.

I am concerned, however, about the lack of manufacturers response to consumer complaints. I hope that in the very near future that all the complaints sent to them from CPSC will be expeditiously handled and that the manufacturers will let us know of their actions. I challenge the manufacturers to use this mechanism so that we may again form a partnership that will be meaningful and informative. Complaints constitute an "early warning signal" that there may be a product safety problem and it will be in everyone's interest if these complaints are addressed immediately.

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

STATEMENT OF
COMMISSIONER STUART M. STATLER
CONCERNING COMMISSION APPROVAL OF RULE FOR
DISCLOSURE OF PRODUCT HAZARDS

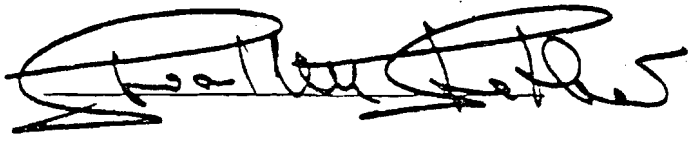
The Commission today approved an operating rule for disclosing information to the public under Section 6(b) of the Consumer Product Safety Act. Of all federal health and safety agencies, the CPSC is shackled by an oppressive statute that severely limits what consumers can be told about specific brands of products that may cause serious injury or death.

Because of limitations imposed by Congress and the courts, the Commission must adhere to a higher degree of caution in releasing hazard information than prosecutors or police do when they air names of persons arrested in criminal investigations. Product names get greater protection than the law affords to private citizens. By statute, protecting a firm's reputation has been accorded more protection than preserving human lives.

Today we made do with what little discretion we have in this matter. We took steps to ensure that accuracy, and fairness to manufacturers and retailers, would be the paramount considerations in any agency disclosure, by permitting hazard information to be cleared, in advance, by the companies named. What we didn't do, and couldn't do was to alter the policy which Congress itself imposed that often gags us, and frustrates our mission to avert human tragedy from unsafe products.

The ball is now back in Congress' court. A better balance must be struck between the public's right to know about product risks as soon as possible and a company's legitimate concern about unfair or misleading publicity. Mistakes can be made. And admittedly, a firm's name, product or profits can be affected. The remedy for that is to stress caution in disclosing information -- not to prevent disclosure -- and to provide for redress against the government in the event of a damaging error.

The Commission needs the same degree of discretion for prompt action to avert injury and death as other health-and-safety agencies have. Without it, we are hardly the watchdog that the public expects and is entitled to.



December 14, 1983

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

STATEMENT

BY

COMMISSIONER SAM ZAGORIA

In adopting today the interpretive rules on Secton 6(b), the Commission has attempted to carry out its statutory obligation to "collect, investigate, analyze, and disseminate injury data and information, relating to the causes and prevention of death, injury and illness associated with consumer products."

While some representatives of industry offered suggestions, some of which were adopted, the Commission wisely voted down proposals which would have hampered the staff and the Commission from doing its duty. Information gathered by competent, trained personnel should not be withheld from the public in order to protect individual firms whose products have been the subject of investigation. Industry is entitled to consideration--and it has been accorded--but so are the consumers, for they are the innocent victims in the heavy toll of deaths and injuries associated with individuals consumer products.

December 14, 1983

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

STATEMENT OF

TERRENCE M. SCANLON, VICE CHAIRMAN

CONSUMER PRODUCT SAFETY COMMISSION

ON

PASSAGE OF FINAL 6(b) RULE UNDER THE CONSUMER PRODUCT SAFETY ACT

December 14, 1983

I reluctantly dissented in approving the final rules implementing the 1981 amendments to Section 6(b) of the Consumer Product Safety Act. I did so because the Commission failed to address the unfairness raised with regard to disclosure of Preliminary Hazard Determinations (PHDs). To disclose these documents without Commission action is unfair to all concerned.

PHDs made by staff are released according to our Office of the General Counsel following either (1) a determination that there was no concern with regard to a particular product, or (2) that a voluntary corrective action plan with notice to the consumers has been agreed upon with the manufacturer. To disclose PHDs in such instances is fundamentally unfair to the manufacturer and consumers because the Commission itself has made no final determination with regard to the consumer product in question.

Also, the failure to address the PHD disclosure question is not in the spirit, I believe, of the 1981 Congressional amendments to 6(b).

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Statement of
Nancy Harvey Steorts, Chairman
Stuart M. Statler, Commissioner
Sam Zagoria, Commissioner
on
Nitrosamines in Pacifiers
December 23, 1983

Last year the CPSC was made aware of the fact that rubber pacifiers made for children contained nitrosamines. These chemicals have been shown to be carcinogenic in a large number of laboratory tests in different animal species. As a result, early last year, the Commission voted to designate this issue as a priority project for FY 1983. During this year the staff has worked with the Food and Drug Administration and the National Center for Toxicological Research to identify the specific nitrosamines present in rubber pacifiers and to determine the amounts of these substances that can be released under simulated conditions of use. During this same period the FDA has been investigating these same questions with regard to rubber baby bottle nipples.

We notified the rubber pacifier industry of our results as soon as they became available. In discussions with members of this industry we have emphasized the need to reduce the levels of nitrosamines to the lowest level possible in these products, and have started efforts to achieve these reductions through cooperative efforts that may lead to a voluntary standard.

Most rubber pacifiers sold in this country are imported, coming from many countries in Europe and Asia. This makes the process of achieving consensus more difficult than if the pacifiers were all manufactured in this country. Nevertheless, and in spite of the difficulties, we are very hopeful that a voluntary standard that results in further reductions in nitrosamine levels can be achieved. We understand that significant reductions in nitrosamine levels have already occured.

Because of our concern, and in order to avoid unnecessary exposure of infants and young children to nitrosamines, we decided to vote in support of the staff recommended enforcement policy. This policy states that the Consumer Product Safety Commission will consider taking legal action in those instances where the nitrosamine levels in pacifiers exceed 60 parts per billion. This policy has been closely coordinated with the FDA who has published a compliance policy guide which establishes 60 parts per billion of nitrosamines in rubber nipples as a basis for regulatory action. We are extremely pleased with this example of how government agencies can work together to achieve a common policy and goal.

We have voted to publish this policy not as a substitute for the voluntary standard process, but rather to notify the industry and the public of our intent to ensure that pacifiers with excessive levels of nitrosamines are not introduced into commerce. It is our belief that this combination of efforts will provide the greatest benefit to the consumer.

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

STATEMENT OF

TERRENCE M. SCANLON, VICE CHAIRMAN

CONSUMER PRODUCT SAFETY COMMISSION

ON

NITROSAMINE ENFORCEMENT POLICY

December 23, 1984

I declined to support an enforcement policy toward children's rubber pacifiers containing nitrosamines voted by the Commission. Rather, I would cast my vote for public disclosure of available information on nitrosamine levels found in pacifiers. Such a statement could list known standards on nitrosamines in children's products and the levels that would be allowed in the voluntary standard proposed by industry before this policy was imposed. The voluntary standard paralleled the German Standard and had been accepted by all members of the Toy Manufacturers of America. If possible, and in accordance with the fairness procedures outlined in our statute, we could list manufacturers who will comply with these standards. This approach is fair to consumers because during the pendency of the regulatory proceeding they will be given accurate and precise information that would otherwise not be available. It is, at the same time, fair to manufacturers because it assures that any mandatory action will be in accordance with appropriate rulemaking procedures established by the 1981 amendments.

Congress clearly intended that carcinogens be addressed by a Chronic Hazard Advisory Panel (CHAP). Bypassing that directive now may prove a net detriment to consumers in the long-run. I cannot support such a policy.

* * *

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1610

Standard for Flammability of Clothing Textiles; Reopening of Comment Period on Proposed Amendment of Rules Establishing Requirements for Testing and Recordkeeping To Support Guaranties

AGENCY: Consumer Product Safety Commission.

ACTION: Reopening of comment period.

SUMMARY: The Commission announces that it is reopening the period for receipt of written comments on proposed amendments to regulations which prescribe requirements for testing and recordkeeping to support guaranties of products, fabrics, and related materials subject to the Standard for the Flammability of Clothing Textiles. The Commission proposed the amendments because it believed that the requirements for testing and recordkeeping to support guaranties of items subject to the standard could be made less burdensome to the regulated industry without diminishing the level of safety afforded to the public. The Commission is reopening the period for receipt of written comments on the proposal in order to ensure that all interested parties, including consumers, consumer groups, small businesses, and organizations representing small businesses, have opportunity to comment on the proposal. The Commission staff will meet with any parties who desire an explanation of the purpose and provisions of the proposed amendments.

DATES: Interested parties are invited to submit written comments on the proposed amendments on or before February 13, 1984.

ADDRESS: Comments and any accompanying materials should be submitted to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, and filed "Clothing Textiles Standard, Proposed Amendments of Regulations Prescribing Requirements for Testing and Recordkeeping to Support Guaranties."

FOR FURTHER INFORMATION CONTACT: L. James Sharman, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 492-6554.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 12, 1982 (47 FR 35006), the Commission proposed amendment of certain administrative and enforcement rules implementing the Standard for the Flammability of Clothing Textiles (16 CFR Part 1610). That standard and the Flammable Fabrics Act (FFA, 15 U.S.C. 1191 *et seq.*) require that articles of wearing apparel and fabrics used or intended for use as clothing textiles must not exhibit "rapid and intense burning" when tested in accordance with the standard.

The FFA authorizes the Commission to enforce flammability standards by issuing administrative orders and by initiating litigation, including criminal prosecutions in the case of any "willful" violation of such a standard.

Section 8(a) of the FFA (15 U.S.C. 1197(a)) provides that no person shall be subject to criminal prosecution for a violation of the FFA if that person establishes a guaranty received in good faith which meets all requirements of section 8 of the FFA. (A guaranty does not provide a defense to any administrative action or to any civil litigation initiated under the FFA.)

Requirements for Guaranties

Section 8 of the FFA provides for two types of guaranties. The first is an initial guaranty which must be based on "reasonable and representative tests" made in accordance with an applicable standard issued under the FFA. The second is a guaranty based on a guaranty, received in good faith, to the effect that reasonable and representative tests made in accordance with an applicable flammability standard demonstrate conformance with that standard.

Neither the FFA nor the clothing textiles standard require any person or firm to issue guaranties of items subject to that standard. However, the Commission has information to the effect that approximately 1,000 firms conduct testing each year to support initial guaranties of items subject to the clothing textiles standard. That information also indicates that on the average, each of these firms conducts approximately 100 tests, for an industry total of 100,000 tests each year.

Regulations codified at 16 CFR 1610.37 set forth requirements for the types and amounts of testing deemed to be "reasonable and representative" for purposes of supporting initial guaranties of items subject to the clothing textiles standard. Recordkeeping requirements for persons and firms issuing guaranties are set forth at 16 CFR 1610.38.

Review of Standard

In 1982, the Commission reviewed the clothing textiles standard and implementing rules to determine if any burden which they may impose on the textiles industry could be eliminated or

reduced without decreasing the level of safety available to consumers. In this review, the Commission considered the requirements of the standard and implementing rules; a memorandum from the Commission staff with attached background documents; and an informational briefing. The Commission decided that revision of the requirements for the frequency of testing to support guaranties set forth in § 1610.37 may be possible to eliminate any unnecessary burden which may be imposed on the regulated industry without diminishing the level of safety currently afforded to the public by the standard. The Commission also decided to propose reduction of the period required by § 1610.38 for maintenance of records of testing to support guaranties from three years to one year.[1]

The proposal for amendment of the guaranty testing rules was published in the Federal Register of August 12, 1983 (47 FR 35006). That notice proposed revision of existing § 1610.37, which now prescribes the kinds and frequency of tests to support initial guaranties, with a requirement that each person or firm issuing an initial guaranty of a product, fabric, or related material which is subject to the standard shall support that guaranty with a "program of reasonable and representative tests."

The proposed amendment would leave the number and frequency of tests to the discretion of the person or firm issuing the initial guaranty.

The proposed amendments also contained provisions to exempt certain types of fabric from any requirement for further testing to support grauanties, because experience gained by the industry and the Commission in testing under the standard indicates that these fabrics will always pass the test in the standard. The fabrics which were proposed for exemption from requirements for further testing to support guaranties are:

(1) All plain surface fabrics weighing 2.6 ounces or more per square yard, without regard to fiber content; and

(2) All fabrics made entirely from acrylic, modacrylic, nylon, olefin, or polyester fibers, or entirely from combinations of those fibers, both plain surface and raised-fiber surface, regardless of weight. The proposal also solicited comments about any other types of fabrics which consistently yield acceptable results when tested under the standard, and which should be added to the list of fabrics exemped from requirements for further testing to support guaranties.

The Commission also proposed amendment of § 1610.38 to reduce the period required for retention of records of testing to support guaranties from three years to one year.

A more detailed description of the proposed amendments is contained in the notice of proposal at 47 FR 35008–35009, under the heading "Highlights of Proposal."

Comments on Proposal

In response to the proposed amendments, the Commission received written comments from three manufacturers, seven trade associations, and one consumer group. Those comments, a staff briefing package discussing the comments, and all documents cited in the notice of proposal are available for inspection in the Commission's public reading room, 8th floor, 1111 18the Street, N.W., Washington, D.C., or from the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207; telephone: (301) 492–6800.

At a meeting of September 22, 1983, to consider issuance of final amendments based on the proposal, the Commission expressed concern that consumer groups may not have been aware of or fully understood the proposal for amendment of the guaranty testing rules. Although the notice of proposal contained a certification that the proposed amendments, if issued on a final basis, would not have a significant economic impact on a substantial number of small businesses, the Commission also expressed concern at that meeting that many small businesses and associations representing such firms may have been unaware of the proceeding for amendment of the guaranty testing rules.

The Commission directed the staff to contact individuals and groups representing consumers and small businesses to ensure that they are aware of the proceeding and have an opportunity to comment on the proposal if they desire to do so.

The Commission staff is in the process of calling individuals and groups representing the interests of consumers and small businesses to carry out the direction of the Commission. If requested, the staff may conduct one or more public meetings with such individuals or groups to explain the purpose and provisions of the proposal of August 12, 1982. The time, date, and place of any such meeting will be announced in the Commission's public calendar. Any person or group desiring further information about the proposed amendments should call L. James Sharman, Office of Program Management at (301) 492–6554.

The Commission will consider all comments received through February 13, 1983, in response to this notice, as well as all comments previously submitted in response to the notice of August 12, 1982, before taking any final action in this proceeding.

Dated: December 7, 1983.

Sadye E. Dunn,

Secretary,

Consumer Product Safety Commission.

[FR Doc. 83–33294 Filed 12–13–83; 8:45 am]

BILLING CODE 6355–01–M

[1] Commissioner Edith Barksdale Sloan voted against proposing to reduce the period required for tentention of test records.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Strong Sensitizers

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed revocation.

SUMMARY: The Consumer Product Safety Commission proposes to revoke the definition of "strong sensitizer" given in 16 CFR 1500.3(c)(5). The definition stated in this regulation is narrower than the definition given in the Federal Hazardous Substances Act and does not account for certain current scientific theories about the ways some individuals can become sensitized to certain substances. The supplementary definition in the regulations is being revoked because the statutory definition should be adequate for use in any future regulatory proceeding.

DATES: The proposed effective date is 30 days after the publication of the final notice of revocation in the Federal Register.

Comments must be submitted on or before February 21, 1984.

ADDRESSES: Comments may be mailed to: The Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or hand delivered to the Office of the Secretary, Room 332, 5401 Westbard Avenue, Bethesda, Md.

FOR FURTHER INFORMATION CONTACT: Susan E. Feinman, Ph.D., Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6477.

Harleigh Ewell (Office of the General Counsel), Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6980.

SUPPLEMENTARY INFORMATION: The Federal Hazardous Substances Act (FHSA or "the Act"), 15 U.S.C. 1261-1275, was enacted on July 12, 1960. Included within the Act's definition of "hazardous substance" is "a strong sensitizer." 15 U.S.C. 1261(f)(1)(iv). The FHSA defines "strong sensitizer" as

> a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the [Consumer Product Safety Commission]. Before designating any substance as a strong sensitizer, the [Commission], upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity. 15 U.S.C. 1261(k).

This definition is restated in the regulations under the FHSA published at 16 CFR 1500.3(b)(9).

On August 12, 1961, the Food and Drug Administration (which at that time administered the FHSA) issued regulations under the FHSA which supplemented the statutory definition of strong sensitizer. 26 FR 7334 (§ 191.10(i)). In 1973, the responsibility for the administration of the FHSA was transferred to the Consumer Product Safety Commission, and the supplementary definition of strong sensitizer referred to above is currently published at 16 CFR 1500.3(c)(5). That paragraph states:

> (5) The definition of "strong sensitizer" in section 2(i) of the Act (restated in paragraph (b)(9) of this section) is supplemented by the following: A "strong *allergic* sensitizer is a substance that produces an allergenic sensitization in a substantial number of persons who come in contact with it. An allergic sensitization develops by means of an "antibody mechanism" in contradistinction to a primary irritant reaction which does not arise because of the participation of an "antibody mechanism." An allergic reaction ordinarily does not develop on first contact because of necessity of prior exposure to the substance in question. The sensitized tissue exhibits a greatly increased capacity to react to subsequent exposures of the offending agent. Subsequent exposures may therefore produce severe reactions with little correlation to the amounts of excitant involved. A "*photodynamic* sensitizer" is a substance that causes an alteration in the skin or mucous membrances in general or to the skin or mucous membrances at the site of contact so that when these areas are subsequently exposed to ordinary sunlight (or equivalent radiant energy) an inflammatory reaction will develop. (Emphasis added.)

Since this definition was issued in 1961, there have been many advances in understanding the basic principles involved in allergic hypersensitivity mechanisms. Based on modern concepts of immunology, the definition of "strong sensitizer" in 16 CFR 1500.3(c)(5) is incorrect with regard to the statement that "an allergic sensitization develops by means of an "antibody mechanism" in contrast to a primary irritant reaction."

While certain allergic reactions involve production of antibodies, others, such as allergic contact dermatitis (ACD) do not. ACD is the main type of sensitization reaction caused by the five substances designated as strong sensitizers in 16 CFR 1500.13. The immunological mechanism involved, known as "delayed type hypersensitivity" (DTH) or "cellularmediated immunity," cannot be transferred by serum (that contains antibodies) and has not been shown to be associated with antibodies in any way. (*See*, e.g., Gell, P.G.H., and Coombs, P.R.H., *Clinical Aspects of Immunology*, 2nd ed. (1969) and Patterson, R., *Allergic Diseases: Diagnosis and Management*, 2nd ed. (1980).) This is in contrast to another type of allergy "immediate" or "serum-mediated" hypersensitivity. The definition of "strong sensitizer" stated in the Federal Hazardous Substances Act is broad enough to cover both types of hypersensitivity. It is also broad enough to apply to other current and (probable) future theories about the cause of sensitization reactions from environmental agents.

A second problem with the regulations concerning strong sensitizers lies in the definition of "photodynamic sensitizer" stated in 16 CFR 1500.3(c)(5), which does not conform with current, generally accepted concepts. This definition states that a "photodynamic sensitizer" causes an alteration in the skin or mucous membranes so that, on subsequent exposure to sunlight (or equivalent radiant energy), an inflammatory reaction develops.

However, dermatology, dermatotoxicity, allergy, and contact dermatitis textbooks agree that "photosensitivity" is a term encompassing both allergic (photoallergy) and nonallergic (phototoxic) light-related skin responses, and that photodynamic reactions should be considered as a type of phototoxic reactions.

Photodynamic sensitization is generally viewed as a type of phototoxicity in which oxygen is required for the occurrence of the reaction. (Harber, L.C., Shalita, A.R., and Armstrong, R.B., "Immunologically medicated contact photosensitivity in guinea pigs," *in* Chapt. 16, *Dermatotoxicology*, (Marzulli, F.N. and Maibach, H.I., eds), 2nd ed. (1983); and Pathak, M.A. and M.A. and Epstein, J.H., "Normal and abnormal reactions by man to light," *Dermatology in General Medicine*, Chapt. 17 "Disorders due to physical agents" (1971).) Phototoxic chemicals are thought to act through a mechanism similar to irritation and not to require prior exposure. Thus, the definition of "photodynamic sensitizer" in 16 CFR 1500.3(c)(5) is confusing, if not inaccurate.

A more detailed discussion of the current scientific theories concerning allergic and photodynamic sensitization, with references to the available scientific literature, is contained in a memorandum from the Commission's Directorate for Health Sciences dated October 19, 1983. Single copies of this memorandum and other materials concerning this proposal may be obtained from the Commission's Office of the Secretary.

For the reasons given above, the Commission concludes that the definition of strong sensitizer given in 16 CFR 1500.3(c)(5) is no longer appropriate. In addition, the Commission believes that the definition of strong sensitizer given in the FHSA at 15 U.S.C. 1261(k) is adequate for any future regulatory determination that a substance is a strong sensitizer. Therefore, the Commission has decided to propose to revoke § 1500.3(c)(5).[1]

Environmental Considerations

The proposed revocation of the supplementary definition of "strong sensitizer" is not intended to affect the status of any product containing a substance that has been declared previously to be a hazardous substance under the FHSA. Accordingly, no product will be directly affected by this proposed action; and future regulatory proceedings to designate a substance as a strong sensitizer will utilize the statutory definition in 15 U.S.C. 1261(k). Therefore, the Commission concludes that the revocation proposed below has little or no potential for affecting the human environment and that neither an environmental assessment nor an environmental impact statement is required. See 16 CFR Part 1021.

Regulatory Flexibility Act Certification

Since for the reasons explained in the preceding paragraph, no products will be directly affected by this proposed action, the Commission certifies that this revocation, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Conclusion

Since the supplement to the definition of strong sensitizer has the deficiencies noted above, and since the statutory definition is adequate for any future regulatory proceedings, the Commission proposes to revoke § 1500.3(c)(5) of Title 16 of Code of Federal Regulations.

Authority. Secs. 2, 10, Pub. L. 86-613, 74 Stat. 372, 378 (15 U.S.C. 2061, 1269).

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous Materials, Imports, Infants and children, Labeling, Law enforcement, Toys.

Dated: December 16, 1983.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR-Doc. 83-33856 Filed 12-21-83; 8:45 am]

BILLING CODE 6355-01-M

[1] Chairman Nancy Harvey Steorts and Commissioners Stuart M. Statler, Sam Zagoria, and Terrence M. Scanlon voted to propose the revocation. Newly appointed Commissioner Saundra Armstrong abstained.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1101

Information Disclosure Under Section 6(b) of the Consumer Product Safety Act; Correction

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule: Correction.

SUMMARY: This document corrects a final interpretive rule containing the Consumer Product Safety Commission's policy and procedure for disclosing to the public information from which the public can readily ascertain the identity of the manufacturer or private labeler of a consumer product. The rule interprets section 6(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2055(b). The rule appeared at pages 57406–57437 in the **Federal Register** of Thursday, December 29, 1983 (48 FR 57406–57437). The action is necessary to correct typographical errors.

FOR FURTHER INFORMATION CONTACT: Michael J. Gidding, Attorney, Office of the General Counsel, (301) 492–6980.

The following corrections are made in the **Federal Register** issue of December 29, 1983:

1. On pages 57407 the 18th line of the first full paragraph in column one under § 1101.11(a), "aristing" is corrected to read "arising."

2. On pages 57426 in the first column at the bottom under § 1101.45, the last four lines reading "docket maintained in 6 (b)(1) through (b)(3). The Commission declines therefore to adopt the commenter's recommendation" should be corrected to read "docket maintained in" and the balance of the lines should be eliminated.

On page 57426 in the second column "Section 1101.45 Adjudicatory Proceeding Exception" and the two paragraphs under it should be eliminated.

On page 57426 in the middle of the second column, the heading "Section 1101.46 Other Administrative or Judicial Exception," the first 12 lines of the first paragraph under that heading and the word "grant" in the beginning of the 13th line, should be eliminated.

On page 57433 near the top of the second column "§ 1101.3 General requirements." Should be corrected to read "§ 1101.31 General requirements."

On page 57435, third column, § 1101.45, the third line of paragraph (c) reading "the adjudication, whether in documents" should be corrected to read "the adjudication, whether in documents filed or".

On page 57435 third column, § 1101.45, the fourth line in paragraph (c) reading "exchanged during discovery filed or in" should be corrected to read "exchanged during discovery, or in".

* * * * *

Dated: March 1, 1984.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 84-6077 Filed 3-6-84; 8:45 am]

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