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United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM **DATE:** September 26, 2001

TO : The Commission
Through : Todd Stevenson, Acting Secretary
Through : Michael S. Solender, General Counsel
Through : Carolyn Croft, Executive Director
Through : Alan H. Schoem, Director, Office of Compliance
Through : Eric L. Stone, Director, Legal Division
FROM : Michael J. Gidding, Attorney

SUBJECT: Response to Comments on the Proposed Amendment to 16 CFR 1115: Reporting Information under 15 U.S.C. § 2064(b) about Potentially Hazardous Products Manufactured or Distributed outside the United States

I. Background

Section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. § 2064(b) requires manufacturers, distributors, and retailers of consumer products to report potential product hazards to the Commission. In 1978, the Commission published an interpretative rule, 16 C.F.R. 1115, that clarified the Commission's understanding of this requirement and that established policies and procedures for filing such reports and proffering remedial actions to the Commission. That rule also discusses generally the types of information a firm should evaluate in considering whether to report, but does not specifically address information about experience with products manufactured or sold outside of the United States. Neither the statute nor the rule, however, excludes such information from being evaluated or reported under section 15(b). The rule simply notes the obligation that firms have to report upon obtaining reportable information. 16 CFR 1115.10. Section 1115.11 imputes to a firm the knowledge that a reasonable firm would have obtained acting in the circumstances in which the firm finds itself.

As we have pointed out in our memorandum of May 3, over the past several years, we have received reports under section 15(b) that included information on experience with products abroad and technical data concerning such products. When appropriate, we have initiated recalls based in whole or in part on that experience. In addition, the Bridgestone/Firestone tire recall of 2000 focused public attention on the possible relevance of information generated abroad to safety issues in the United States. Accordingly, to assure that firms who obtain information generated abroad are aware that they should consider such information in deciding whether there is a need to report under section 15(b), we recommended that the Commission issue a policy statement to this effect.

CPSA 6 (b)(1) Cleared
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Products Identified
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Firms Notified,

NOTE: This document has not been reviewed or accepted by the Commission.
Initial MJG Date 10/4/01

On January 3, 2001, the Commission solicited, in the FEDERAL REGISTER, comments on a proposed policy statement. The statement set forth the Commission's position that information concerning products manufactured or sold outside of the United States that may be relevant to defects and hazards associated with products distributed within the United States should be evaluated and may be reportable under section 15(b). On June 7, 2001after considering the comments, the Commission published a final policy statement (Tab A) memorializing this position. Simultaneously, the Commission voted to propose for comment an amendment to 16 CFR 1115 (Tab B) that would codify this policy guidance as part of the interpretative rule. The proposed amendment notes that the information that firms should study and evaluate under section 15(b) may include information about product experience, performance, design or manufacture outside the United States that is relevant to products sold or distributed in the United States.

The Commission received four comments (Tab C) in response to the proposed amendment. On July 10, we met with one of the commentors, the American Home Appliance Manufacturers Association, and, on July 19, with commentors Michael Brown (Brown and Freeston, PC) and Michael Wiegard (Eckert, Seamans, Cherin, and Mellott, LLC). We requested those meetings to make sure that we adequately understood their concerns and to discuss ways in which to address them. During these meetings, the participants elaborated on their written comments, but raised no additional issues. Our analysis of and response to the comments appears below.

II. Discussion

One of the commentors, the CPSC Coaltion of the National Association of Manufacturers ("NAM"), resubmitted comments that it had presented in response to the Commission's January proposed policy statement. NAM's resubmission contended that the Commission's response to its comments to that proposal did not take the Coalition's concerns into account. However, NAM did not point to any specific inadequacy in the Commission's response, nor did it otherwise elaborate on its contention. We, on the other hand, believe that the Commission's response to the NAM comments in the June 7 FEDERAL REGISTER notice (Tab A, pages 3 and 4) was more than adequate. The NAM comments largely voiced the same hypothetical concerns that commentors on the original 1977 proposed interpretative rule on reporting raised. As the response in the June 7 notice points out, the Commission addressed the substance of those comments in the preamble to and text of the final rule in 1978. 43 FR 34988. We believe, therefore, that the NAM comments require no further response.

a. Imputing Knowledge

Comment The three commentors other than NAM expressed concern that the proposed amendment treated information generated abroad in the same manner as domestically obtained data. In the commentors's view, the amendment should have, but did not, take into account differences in data-gathering capabilities abroad from those within the United States, as well as perceptions of the significance of data that becomes available. The commentors requested that

the final rule or its preamble recognize these differences. These commentors also noted that U.S. subsidiaries of foreign companies are often not in a position to require corporate parents to collect and/or forward safety related information to the subsidiary. They further indicated that U.S. subsidiaries will not necessarily be aware of or be able to obtain information that other independent subsidiaries of a common foreign parent acquire. Again, the commentors suggested that the Commission recognize in the final rule or its preamble these possible impediments to the acquisition of information.

Response The issue of obtaining and evaluating information from abroad is pertinent to two aspects of reporting – timely reporting and corrective action. With respect to the first aspect –failing to report in a timely manner or not at all, we believe that the commentors may have misconstrued the intent and scope of the proposed amendment. We recognize and agree with the commentors that a number of factors may affect the ability of a firm located in the United States to obtain information from abroad, including limitations on the availability of and access to information. We understand that training, experience, and corporate position, and differences in product design, use and operating environment from standard practices in the United States may also affect the ability of recipients abroad to appreciate the significance of information that may relate to products sold in the United States. Similarly, we appreciate that the nature of corporate business relationships and affiliations may also impact the ability of a firm located in the United States to obtain such information.

As commentors acknowledged in their written comments and in discussions with the staff, an evaluation of compliance with the reporting obligations requires a case-by-case assessment of relevant facts, including those relating to the considerations identified above. The Consumer Product Safety Act provides the standard for this evaluation. Section 20, 15 U.S.C. §2069, only permits the assessment of civil penalties against a party who "knowingly" commits a prohibited act. Section 20(d) of the act defines "knowingly" as "... (2) the presumed having of knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations."

The existing interpretative rule also provides guidance, consistent with section 20, on how the Commission will analyze the facts of each case. In its discussion of the imputation of knowledge to a firm, 16 C.F.R. 1115.11 notes that "the Commission will deem a subject firm to know what a reasonable person acting in the circumstances in which the firm finds itself would know." The section goes on to explain that this imputation extends to knowledge that a firm could have obtained, had it exercised due care to ascertain the truth of complaints or other representations or conducted a reasonably expeditious investigation into the reportability of a death, grievous bodily injury, or other information. Under section 115.11, the "reasonable person" standard applies to a firm's accountability for failure to obtain or evaluate information that exists abroad. Considerations, such as those described above that may have affected the firm's ability to obtain or appreciate the significance of such information are certainly relevant to whether a firm acted reasonably in the circumstances. In view of the strictures in the statute and the existing interpretative regulation, we believe that the commentors' fears that the Commission would not take such factors into account when assessing a firm's compliance with the reporting obligations are unfounded.

With respect to the second aspect of reporting – corrective action, as the June 7, 2001 final policy statement points out, such information may be relevant to the core issue of whether some form of remedial action is necessary to protect American consumers from defective products that present a substantial risk of death or injury. We would hope that all of the commentors to the proposed amendment, including NAM, accept that, in evaluating potential hazards, firms should obtain all reasonably available information, including that from abroad, in a timely manner to assure that they can reach reasoned decisions. Indeed, one of the three commentors expressly stated its agreement with this proposition. We believe that this perspective is appropriate, since the welfare of their domestic customers should be of paramount concern to U.S. companies.

To assure that the commentors' concerns are addressed in the final rule, we have included the discussion above in the preamble of the draft final amendment for the Commission's consideration.

b. "Obtaining" Information

Comment The proposed amendment noted that information that a firm should study and evaluate in order to determine whether it is obligated to report information under section 15(b) "may include information about product experience, performance, design, or manufacture outside of the United States that is relevant to products sold or distributed in the United States." Two commentors believed that the proposed amendment differed materially from the final policy statement because, unlike the policy statement, the amendment did not expressly note that firms had to have first obtained information from abroad for the obligation to evaluate the information to arise. The commentors feared that the omission signaled a possibility that, in evaluating a firm's compliance with the reporting requirements, the Commission might hold a firm responsible for not exercising due diligence to search for and obtain information that was available abroad, but that had not come to the firm's attention. The commentors therefore requested that the final amendment expressly state that a firm only needs to review information that it obtains.

Response We believe that the proposed amendment implicitly recognized that, in order to have an obligation to study and evaluate information, a firm must first receive the information, or be reasonably expected to have obtained it because, for example, of the firm's relationship with or access to a firm or individual who possesses it. However, to alleviate the apparent confusion, we have included in the draft revised amendment an express statement that the information that should be evaluated includes information that a firm "has obtained or reasonably should have obtained in accordance with section 1115.11" relating to product experience, etc.

We do not, however, recommend that the Commission limit the revision to cover only information that a firm has "actually" obtained, as one commentor requested. As we discussed infra, both the CPSA and the interpretative rule recognize that a firm need not have actually obtained information for obligations under section 15(b) to arise, if a reasonable person acting in the circumstances in which the firm finds itself would have obtained the information.

Accordingly, we believe that these provisions that address the imputation of knowledge to a firm dictate against further limiting the revision to the amendment. Adopting the restriction suggested by the commentor, on the other hand, could encourage firms to avoid seeking reasonably available information from abroad about their products that could ultimately support the need for those firms to take corrective action.

c. Recipients of Information

Comment One commentor stated that the rule should reflect that a firm "obtains" information only when an employee of the firm capable of appreciating its significance actually receives it.

Response Section 1115.11 of the interpretative rule already states that "the Commission will deem a firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information." Because this provision adequately addresses the commentor's request, no additional revision is necessary.

d. Importers, Distributors, and Retailers

One commentor suggested that the Commission include, in the preamble to the amendment, a reminder to importers, distributors, and retailers of their obligations under section 15(b). We believe that this suggestion has merit and have included such a statement in the preamble to the draft final rule.

III. Conclusion

We have revised both the preamble and the text of the draft final amendment (Tab D) to address the commentors' concerns. We, therefore, recommend that the Commission issue the final amendment with those revisions.

TAB A

TAB A

[Federal Register: June 7, 2001 (Volume 66, Number 110)]
[Notices]
[Page 30715-30717]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr07jn01-26]

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CONSUMER PRODUCT SAFETY COMMISSION

Issuance of Policy Statement

AGENCY: **Consumer Product Safety Commission.**

ACTION: Final policy statement.

SUMMARY: Section 15(b) of the **Consumer Product Safety** Act, 15 U.S.C. 2064(b), requires manufacturers, distributors, and retailers of **consumer** products to report potential **product** hazards to the **Commission**. After receiving public comments, the **Commission** issues a final policy statement that information concerning products manufactured or sold outside of the United States that may be relevant to evaluating defects and hazards associated with products distributed within the United States should be evaluated and may be reportable under section 15(b).

DATES: This policy becomes effective June 7, 2001.

FOR FURTHER INFORMATION CONTACT: Marc Schoem, Director, Division of Recalls and Compliance, **Consumer Product Safety Commission**, Washington, DC 20207, telephone--(301) 504-0608, ext. 1365, fax.--(301) 504-0359, E-mail address--mschoem@cpsc.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 15(b) of the **Consumer Product Safety** Act (CPSA), 15 U.S.C. 2064(b) requires manufacturers, distributors, and retailers of **consumer** products to report potential **product** hazards to the **Commission**. In 1978, the **Commission** published an interpretative rule, 16 CFR 1115, that clarified the **Commission**'s understanding of this requirement and that established policies and procedures for filing such reports and proffering remedial actions to the **Commission**. That rule talks generally about the types of information a firm should evaluate in considering whether to report, but does not specifically address information about experience with products manufactured or sold outside of the United States. Neither the statute, nor the rule itself, excludes such information from being evaluated or reported under section 15(b).

Over the past several years, the **Commission** has received section 15(b) reports that have included information on experience with products abroad. When appropriate, the agency has initiated recalls based in whole or in part on that experience. In addition, the Bridgestone/Firestone tire recall of 2000 focused public attention on the possible relevance of information generated abroad to **safety** issues in the United States. Accordingly, to assure that firms who obtain

information generated abroad are aware that they should consider such information in deciding whether there is a need to report under section 15(b), the staff recommended that the **Commission** issue a policy statement. On January 3, 2001 (66 FR 351), the **Commission** solicited comments on a proposed policy statement stating the **Commission's** position that information concerning products sold outside of the United States that may be relevant to defects and hazards associated with products distributed within the United States should be evaluated and may be reportable under section 15(b).

Discussion

The **Commission** received seven comments in response to the proposed statement. Two supported the policy

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statement. One of these commentors recommended that the **Commission** codify the policy as a substantive rule with specific provisions to prevent firms from circumventing the reporting obligation. A total of five commentors opposed issuing the statement as drafted. Two of these joined with the CPSC Coalition of the National Association of Manufacturers (``NAM'') in requesting that the **Commission** withdraw the policy statement. They also requested that, concurrent with the withdrawal, the **Commission** issue a clarification that no new obligations or modifications to existing rules are established, or, in the alternative, that the **Commission** engage in a public dialogue to review the issues and objectives raised by the policy statement. One commentor supported withdrawing the statement because it contended that the **Commission** had not demonstrated the need for it. The last supported the underlying rationale for the policy, but proposed limiting the policy to requiring the reporting of foreign **product safety** issues only when reporting would be required under the **Consumer Product Safety** Act. A summary of the comments and our responses appear below.

a. Interpretative Rule

In its 1978 Federal Register notice, the **Commission** specifically addressed whether the reporting regulations should be substantive or interpretative. The significance of this distinction is that, once a substantive rule goes into effect, it has the force and effect of law, and its provisions cannot be challenged in a subsequent proceeding, for example, an action to assess civil penalties. An interpretative rule, on the other hand, simply offers guidance as to what the **Commission** believes the law means or requires. A firm that disagrees with one or more of the provisions of an interpretative rule can, in an enforcement proceeding, challenge the reasonableness of the **Commission's** interpretation(s), and can prevail in the proceeding if its contention is upheld. In 1978, after seeking public comment, the **Commission** elected to publish the reporting rule as an interpretative rule.

NAM contends that, in issuing the proposed policy statement, the **Commission** is, in effect, promulgating a substantive rule, and has failed to comply with the formal rulemaking procedures of the Administrative Procedure Act , 5 U.S.C. 553. Thus, NAM claims that the policy would be invalid, if issued.

The **Commission** issued the policy statement because it considered it only fair that firms who might be unfamiliar with the reporting requirements be put on notice of the agency's view that information concerning foreign experience relevant to a **product** in the U.S. should be evaluated and may be reportable if it otherwise meets the criteria of section 15(b) and 16 CFR 1115. As the policy statement expressly

acknowledges, this is a straight-forward interpretation of the requirements of section 15(b), and is consistent with the interpretative reporting regulation which, on its face, does not limit reporting to information derived solely from experience with products sold in the United States. Given the history of the interpretative regulation and the express acknowledgment in the policy statement that it too is interpretative, the NAM's attempt to characterize the statement as a substantive rule is misplaced.

b. Specificity of the Policy Statement

NAM posed a number of hypothetical questions that it claims the policy statement should, but does not address. In doing so, it treats the reporting rule as a substantive rule that firms must follow, even though it acknowledges in a footnote that the rule is interpretative. The short response to the NAM queries is, of course, that, as an interpretative rule, the reporting rule imposes no binding obligation on any firm. Moreover, the concerns that NAM raises--for example, whether a firm is responsible for reporting if an employee has knowledge of a reportable problem, and the extent to which a firm must investigate incidents--are not unique to multi-national business operations. They have equal applicability to domestic operations. In fact, many of those concerns are substantially the same as those that commentors on the proposed interpretative rule on reporting raised in 1977, and that the **Commission** addressed in the preamble to and text of the final rule in 1978. 43 FR 34988. Thus, for example, section J of the preamble discusses imputing knowledge of **safety**-related information to a firm only when an employee capable of appreciating the significance of the information receives it. Section L points out the **Commission**'s views on the need for firms to exercise reasonable diligence in investigating possible **product** defects. It further notes that the **Commission** will take into account the reasonableness of a firm's behavior in the circumstances when it considers the firm's compliance with the reporting regulations. Section 1115.14 of the rule and section J of the preamble acknowledge that the time frames recommended for investigation of possible defects and the imputation of knowledge have flexibility, depending on the circumstances of a particular case.

While there may be a difference in degree in what it is reasonable to expect from reporting firms with respect to the content of and time for collecting foreign, as opposed to domestic, information, the **Commission** believes that the basic principles and procedures embodied in the 1978 rule and discussed in the preamble have always been and continue to be applicable to both domestic and multi-national business operations. Those principles and procedures have withstood almost a quarter of a century of experience--experience that has often involved firms obtaining and analyzing information from foreign sources, especially in cases involving products imported into the U.S. Moreover, over that period, the **Commission** has consistently recognized that what information it is reasonable to expect a firm to provide in a specific case depends on a number of factors. These include the size of the firm, the nature of its business, the method in which it conducts its operations, the age of the **product** involved, and the availability of relevant information. The location from which such information may be obtained and the difficulty in obtaining that information are simply additional factors to take into account.

The **Commission** notes that the process of business globalization and improvements in communication have substantially reduced the impediments to obtaining information from abroad that might have existed twenty years ago. Firms frequently communicate in seconds via the computer, telephone, and fax machine with their overseas customers,

suppliers, and corporate relatives. Thus, the **Commission** sees no sound justification for accepting NAM's implicit premise that obtaining foreign information is so much more difficult than obtaining the same types of information generated domestically that different policies and procedures should apply. In fact, the **Commission**'s experience demonstrates otherwise in that firms that have reported foreign information to the **Commission**, either on their own initiative or upon request of the staff, have been able to obtain the necessary information in a timely manner. Accordingly, for the reasons discussed above, the **Commission** does not believe that the concerns NAM has expressed warrant withdrawing or revising the policy statement.

c. Need for the Policy Statement

The **Consumer** Specialty Products Association (CSPA) suggested that the policy places an undue burden on

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companies to implement monitoring programs abroad, comparable to those in the United States. The Association therefore took the position that the **Commission** must demonstrate the need for such a policy before establishing it.

Section 15(b) contemplates that manufacturers, distributors and retailers must consider all information relevant to the determination of whether a specific **product** contains a defect which could create a substantial **product** hazard or an unreasonable risk of serious injury or death. As the policy statement points out, neither the law nor the interpretative regulation excludes information from evaluation because of its geographic source. Accordingly, to the extent that CSPA implies that the statement imposes a burden on firms that did not previously exist, it is mistaken.

As an example of the need for the policy, the **Commission** recently accepted a substantial penalty to settle allegations that a company failed to report information relating to a defective water distiller in a timely manner. That information included analyses of incidents of **product** failure in Asia which the firm had learned about substantially before it finally reported to the **Commission**. Had the firm reported that information to the **Commission** in a timely manner, it could have expedited the subsequent recall, thus protecting consumers from the risk of fire at a much earlier date. Fires that later occurred in the U.S. could have been prevented. Examples of other cases in which information generated abroad has been relevant include corrective actions involving oil-filled radiators, stacking toys, strollers, and swimming vests, and civil penalty cases involving children's products, burners for boilers, and pacifiers. Moreover, in terms of need for the policy statement, with the volume of imported products entering the United States, information which is only available abroad, such as that related to **product** design, manufacturing changes, and quality assurance is essential to the evaluation of potential defects. The statement helps firms that may be unfamiliar with or unaware of this aspect of reporting to comply with their obligations under the law.

d. Additional Comments

One commenter feared that the policy statement would require firms to report products that violate **safety** standards issued by other countries, even if those products were in full compliance with U.S. requirements. The commenter requested that the **Commission** adopt a policy that would require the reporting of foreign **product safety** issues only when reporting would otherwise be required under section

15(b). The **Commission** believes that the commentor may have misconstrued the scope of the policy statement, since the commentor's suggested alternative is in effect what the policy statement contemplates.

Conclusion

The **Commission** does not believe that any of the comments submitted warrant withdrawing or revising the statement. Accordingly, the **Commission** is issuing the policy statement. The **Commission** has, on its own initiative, made one revision to the statement to make it clear that the policy applies to information concerning products manufactured outside of the United States, as well as to information about products distributed abroad. The text of the policy statement is as follows:

Guidance Document on Reporting Information Under 15 U.S.C. 2064(b) about Potentially Hazardous Products Manufactured or Distributed Outside the United States

Section 15(b) of the **Consumer Product Safety** Act (CPSA), 15 U.S.C. 2064(b), imposes specific reporting obligations on manufacturers, importers, distributors and retailers of **consumer** products distributed in commerce. A firm that obtains information that reasonably supports the conclusion that such a **product**:

Fails to comply with an applicable **consumer product safety** rule or with a voluntary **consumer product safety** standard upon which the **Commission** has relied under section 9 of the CPSA,

Contains a defect that could create a substantial **product** hazard as defined in section 15(a)(2) of the CPSA, 15 U.S.C. Sec. 2064(a)(2), or

Creates an unreasonable risk of serious injury or death

must immediately inform the **Commission** unless the firm has actual knowledge that the **Commission** has been adequately informed of the failure to comply, defect, or risk.

The purpose of reporting is to provide the **Commission** with the information it needs to determine whether remedial action is necessary to protect the public. To accomplish this purpose, section 15(b) contemplates that the **Commission** receive, at the earliest time possible, all available information that can assist it in evaluating potential **product** hazards. For example, in deciding whether to report a potential **product** defect, the law does not limit the obligation to report to those cases in which a firm has finally determined that a **product** in fact contains a defect that creates a substantial **product** hazard or has pinpointed the exact cause of such a defect. Rather, a firm must report if it obtains information which reasonably supports the conclusion that a **product** it manufactures and/or distributes contains a defect which could create such a hazard or that the **product** creates an unreasonable risk of serious injury or death. 15 U.S.C. 2064(b)(2) and (3); 16 CFR 1115.4 and 6. Nothing in the reporting requirements of the CPSA or the **Commission**'s interpretive regulation at 16 CFR Part 1115 limits reporting to information derived solely from experience with products sold in the United States. The **Commission**'s interpretative rule enumerates, at 16 CFR 1115.12(f), examples of the different types of information that a firm should consider in determining whether to report. The regulation does not exclude information from evaluation because of its geographic source. The **Commission** interprets the statutory reporting requirements to mean that, if a firm obtains information that meets the criteria for reporting listed above and that is relevant to a **product** it sells or distributes in the U.S., it must report that information to the CPSC, no matter where the information came from. Such information could include incidents or experience with the same or a substantially

similar **product**, or a component thereof, sold in a foreign country.

Over the past several years, the **Commission** has received reports under section 15(b) that have included information on experience with products abroad, and, when appropriate, has initiated recalls based in whole or in part on that experience. Thus, a number of companies already view the statutory language as the **Commission** does. However, with the expanding global market, more firms are obtaining this type of information, but many may be unfamiliar with this aspect of reporting. Therefore, the **Commission** issues this policy statement to assist those firms in complying with the requirements of section 15(b) of the **Consumer Product Safety** Act.

Dated: June 1, 2001.

Sadye E. Dunn,

Secretary, **Consumer Product Safety Commission**.

[FR Doc. 01-14299 Filed 6-6-01; 8:45 am]

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TAB B

TAB B

[Federal Register: June 7, 2001 (Volume 66, Number 110)]
[Proposed Rules]
[Page 30655-30656]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr07jn01-7]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1115

Substantial **Product** Hazard Reports

AGENCY: **Consumer Product Safety Commission**.

ACTION: Proposed revision to interpretative rule.

SUMMARY: Section 15(b) of the **Consumer Product Safety** Act, 15 U.S.C. 2064(b), requires manufacturers, distributors, and retailers of **consumer** products to report potential **product** hazards to the **Commission**. The **Consumer Product Safety Commission** publishes a proposed revision to its interpretative rule advising manufacturers, distributors, and retailers how to comply with the requirements of section 15(b). The proposed revision points out that information concerning products manufactured or sold outside of the United States that may be relevant to the existence of potential defects and hazards associated with products distributed within the United States should be evaluated and may lead to a report under section 15(b).

DATES: Comments from the public are due no later than July 9, 2001.

FOR FURTHER INFORMATION CONTACT: Marc Schoem, Director, Division of Recalls and Compliance, **Consumer Product Safety Commission**, Washington, DC 20207, telephone--(301) 504-0608, ext. 1365, fax.--(301) 504-0359, E-mail address--mschoem@cpsc.gov.

SUPPLEMENTARY INFORMATION: Section 15(b) of the **Consumer Product Safety** Act (CPSA), 15 U.S.C. 2064(b) requires manufacturers, distributors, and retailers of **consumer** products to report potential **product** hazards to the **Commission**. In 1978, the **Commission** published an interpretative rule, 16 CFR 1115, that clarified the **Commission**?s understanding of this requirement and that established policies and procedures for filing such reports and proffering remedial actions to the **Commission**. That rule talks generally about the types of information a firm should evaluate in considering whether to report, but does not specifically address information about experience with products manufactured or sold outside of the United States. Neither the statute, nor the rule itself, suggests that firms need not evaluate such information and, when appropriate, report to the **Commission** under section 15(b).

Over the past several years, the **Commission** has received section 15(b) reports that have included information on experience with products abroad. When appropriate, the agency has initiated recalls based in whole or in part on that experience. In addition, the Firestone tire recall of 2000 focused public attention on the possible relevance of information generated abroad to the **safety** of products used in the United States. Accordingly, to assure that firms who obtain

information generated abroad are aware that they should consider such information in deciding whether there is a need to report under section 15(b), the staff recommended that the **Commission** issue a policy statement to this effect. On January 3, 2001, the **Commission** solicited comments on a proposed policy statement summarizing the **Commission**'s position that, under section 15(b), information concerning products sold outside of the United States may be relevant to defects and hazards associated with products distributed within the United States.

On May 17, 2001, after receiving and analyzing the comments, the **Commission** voted to issue a final policy stating that information concerning products manufactured or sold outside of the United States which may be relevant to the existence of potential defects and hazards associated with products distributed within the United States should be evaluated and may be reportable under section 15(b). The **Commission**'s analysis of those comments and the final policy statement are published elsewhere in this edition of the Federal Register.

The **Commission** believes that members of the public should fully understand their obligations under the law. In the context of the obligation to evaluate and, if necessary, to report information from outside the United States under section 15(b), the **Commission** believes that it can best accomplish this objective by amending the existing interpretative rule to reflect the substance of the policy statement. Accordingly, the **Commission** proposes to amend the interpretative rule as

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specified below. Although the **Commission** previously accepted and analyzed public comment on this subject when it issued the policy statement, the policy statement did not offer a specific amendment to the interpretative reporting rule. The **Commission** has, therefore, elected to solicit public comment on the proposed amendment, even though, as an amendment to an interpretative rule, notice and comment is not required under the Administrative Procedure Act. To assist members of the public who wish to comment, the **Commission** has included the text of the final policy statement in this notice.

Guidance Document on Reporting Information Under 15 U.S.C. 2064(b) About Potentially Hazardous Products Manufactured or Distributed Outside the United States

Section 15(b) of the **Consumer Product Safety** Act (CPSA), 15 U.S.C. 2064(b), imposes specific reporting obligations on manufacturers, importers, distributors and retailers of **consumer** products distributed in commerce. A firm that obtains information that reasonably supports the conclusion that such a **product**:

Fails to comply with an applicable **consumer product safety** rule or with a voluntary **consumer product safety** standard upon which the **Commission** has relied under section 9 of the CPSA,

Contains a defect that could create a substantial **product** hazard as defined in section 15(a)(2) of the CPSA, 15 U.S.C. 2064(a)(2), or

Creates an unreasonable risk of serious injury or death

must immediately inform the **Commission** unless the firm has actual knowledge that the **Commission** has been adequately informed of the failure to comply, defect, or risk.

The purpose of reporting is to provide the **Commission** with the information it needs to determine whether remedial action is necessary to protect the public. To accomplish this purpose, section 15(b) contemplates that the **Commission** receive, at the earliest time possible, all available information that can assist it in evaluating

potential **product** hazards. For example, in deciding whether to report a potential **product** defect, the law does not limit the obligation to report to those cases in which a firm has finally determined that a **product** in fact contains a defect that creates a substantial **product** hazard or has pinpointed the exact cause of such a defect. Rather, a firm must report if it obtains information which reasonably supports the conclusion that a **product** it manufactures and/or distributes contains a defect which could create such a hazard or that the **product** creates an unreasonable risk of serious injury or death. 15 U.S.C. 2064(b)(2) and (3); 16 CFR 1115.4 and 6. Nothing in the reporting requirements of the CPSA or the **Commission**'s interpretive regulation at 16 CFR part 1115 limits reporting to information derived solely from experience with products sold in the United States. The **Commission**'s interpretative rule enumerates, at 16 CFR 1115.12(f), examples of the different types of information that a firm should consider in determining whether to report. The regulation does not exclude information from evaluation because of its geographic source. The **Commission** interprets the statutory reporting requirements to mean that, if a firm obtains information that meets the criteria for reporting listed above and that is relevant to a **product** it sells or distributes in the U.S., it must report that information to the CPSC, no matter where the information came from. Such information could include incidents or experience with the same or a substantially similar **product**, or a component thereof, sold in a foreign country.

Over the past several years, the **Commission** has received reports under section 15(b) that have included information on experience with products abroad, and, when appropriate, has initiated recalls based in whole or in part on that experience. Thus, a number of companies already view the statutory language as the **Commission** does. However, with the expanding global market, more firms are obtaining this type of information, but many may be unfamiliar with this aspect of reporting. Therefore, the **Commission** issues this policy statement to assist those firms in complying with the requirements of section 15(b) of the **Consumer Product Safety** Act.

Proposed Effective Date: The **Commission** proposes that this revision become effective 30 days after the date of publication of the revised final intepretative rule in the Federal Register.

List of Subjects in 16 CFR Part 1115

Administrative practice and procedure, Business and industry, **Consumer** protection, Reporting and recordkeeping requirements.

In accordance with the procedures of 5 U.S.C. 553 and under the authority of the **Consumer Product Safety** Act, 15 U.S.C. 2051 et seq., the **Commission** proposes to amend part 1115 of title 16, Chapter II, of the Code of Federal Regulations as follows:

PART 1115--SUBSTANTIAL **PRODUCT** HAZARD REPORTS

1. The authority citation for part 1115 continues to read as follows:

Authority: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2070, 2071, 2073, 2076, 2079 and 2084.

2. Section 1115.12(f) introductory text is revised to read as follows:

Sec. 1115.12 Information which should be reported; evaluating substantial **product** hazards.

* * * * *

(f) Information which should be studied and evaluated. Paragraphs (f)(1) through (7) of this section are examples of information which a subject firm should study and evaluate in order to determine whether it is obligated to report under section 15(b) of the CPSA. Such information may include information about **product** experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. All information should be evaluated to determine whether it suggests the existence of a noncompliance, a defect, or an unreasonable risk of serious injury or death:

* * * * *

Dated: June 1, 2001.

Sadye E. Dunn,

Secretary, **Consumer Product Safety Commission.**

[FR Doc. 01-14298 Filed 6-6-01; 8:45 am]

BILLING CODE 6355-01-P

TAB C

AW
mlc CRC

NAM CPSC Coalition

NAM National Association of Manufacturers

Associations Council

July 9, 2001

Mr. Marc Schoem
Director, Recalls and Compliance Division
Consumer Product Safety Commission
Washington, DC 20207
Fax: (301) 504-0359

Dear Mr. Schoem:

In response to the Consumer Product Safety Commission's request for comments to its June 7 "Proposed revision to interpretative rule" (66 Fed. Reg. 30655), the CPSC Coalition ("the Coalition") of the National Association of Manufacturers wishes to express its concern that the Commission has ignored special problems relating to foreign activities involving the marketing of consumer products. These issues were raised in comments filed by the Coalition in March 2001 in regards to the proposed "Policy Statement on Reporting Information Under 15 U.S.C. § 2064(b) About Potentially Hazardous Products Distributed Outside the United States" (66 Fed. Reg. 351).

Because the Commission's final policy statement of June 7 (66 Fed. Reg. 30715) does not appear to take the Coalition's various concerns into account, we re-submit our original comments. We urge the Commission, in its interpretative rule, to take into consideration the issues that might arise abroad, as presented in our comments.

Sincerely,

Stephen Gold

Stephen Gold
Executive Director, Associations Council
For the NAM CPSC Coalition

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NAM CPSC Coalition

NAM National Association of Manufacturers

Associations Council

March 5, 2001

Ms. Sadye E. Dunn
Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway, Room 502
Bethesda, MD 20814

Dear Ms. Dunn:

The Consumer Product Safety Commission Coalition ("the Coalition") of the National Association of Manufacturers ("NAM") submits these comments in response to the CPSC's proposed "Policy Statement on Reporting Information Under 15 U.S.C. § 2064(b) About Potentially Hazardous Products Distributed Outside the United States." Fed. Reg. 351 (Jan. 3, 2001). The Coalition comprises trade associations and corporations large and small that manufacture or sell consumer products. The Coalition welcomes the opportunity to discuss this important subject with the Commission.

I. Executive Summary

The members of the Coalition believe that the Consumer Product Safety Commission's ("the Commission") proposed policy statement of January 3 is flawed from both a procedural and a substantive perspective. Substantively, the policy statement seems both overly broad and vague, making it impossible to assess whether new law and new obligations are being created. If no new obligations or requirements are created, the appropriate course of action for the CPSC is to withdraw the statement and issue a clarification. If new obligations are created, however, then, procedurally, such action may result only from following the formal rulemaking requirements of the Administrative Procedure Act. We urge the Commission to withdraw this policy statement, and either issue a clarification to establish that no new obligations or modifications to existing rules are established; or initiate a more in-depth review of the issues and objectives raised by the policy statement, which could include a series of public workshops designed to develop an adequate record for any potential, relevant future regulatory action.

II. The Policy Statement is Flawed Procedurally and Substantively

The Coalition believes that the proposed policy statement is flawed both in terms of substance and form. The notice is drafted in a perfunctory and summary manner hardly inviting

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comment beyond simple acceptance or denial of the proposed policy statement. Indeed, readers of the proposed policy statement will have difficulty understanding what it represents. How exactly does a regulated industry interpret the reporting requirement for "information concerning products sold outside the United States that may be relevant to evaluating defects and hazards associated with products distributed within the United States" as reportable under § 15(b)? Interpreted one way, this could lead to new reporting requirements and expand the Commission's statutory authority – and, in the process, create new law without meeting the requisite procedural requirements.

A. The Policy Statement is Procedurally Flawed

The Commission notice of January 3 was issued in the form of a general policy statement. Under § 553(b)(A), general statements of policy are exempt from notice-and-comment requirements. To be labeled as a policy statement, federal courts have asserted that

> [a] general statement of policy ... does not establish a "binding norm." It is not finally determinative of the issues or rights to which it is addressed. The agency cannot apply or rely upon a general statement of policy as law because a general statement of policy only announces what the agency seeks to establish as policy.

Pacific Gas & Electric Co. v. Federal Power Commission, 506 F.2d 33, 38 (D.C. Cir. 1974). In other words, a policy statement indicates how an agency intends to exercise a discretionary function – assuming the agency has statutory authority to do so. However, to the extent that the Commission's proposed policy statement is a binding rule, and could lead to new legal obligations for regulated entities, the statement could readily be interpreted as creating new law. It is well accepted that when new law is developed by an administrative agency, the process outlined for rulemaking within the Administrative Procedure Act, 5 U.S.C. § 553, must be followed to ensure public discussion and due process for regulated entities. These include a notice of public rulemaking;[1] and a notice-and-comment period that provides for public participation. In promulgating the rule, the agency must consider relevant matter presented by the comment period, and must adopt a concise general statement of its basis and purpose.

In this case, the Commission has issued a proposed rule that does not sufficiently meet the APA test. While the public has been invited to comment on the so-called "policy statement," the notice as it stands does not require the Commission to weigh the merits of the comments, to formally publish the rule in the Federal Register or C.F.R., or to offer a statement of basis and purpose about why it reached its conclusions. Indeed, as Commissioner Mary Sheila Gall points out in her dissent, the Commission has attempted to communicate its message in such a way that there is minimal public scrutiny or discussion. We should not allow this form of guidance to be used as a backdoor manner of regulating absent rulemaking procedures.

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[1] Including (1) a statement of time, place, and nature of public rulemaking procedures, (2) reference to the legal authority under which the rule is proposed, and (3) either the terms or substances of the proposed rule or a description of the subjects and issues involved. 5 U.S.C. § 553(b).

The reporting requirements that the Commission discusses in its policy statement are a matter of sufficient importance that a more active attempt to solicit the views of interested parties should be sought before a policy statement is published. So many substantive questions are raised, as will be seen below, that due process could only be afforded if the Commission provides for full discussion of the many issues to ensure useful public comment. The Commission's notice should be open to the possibility of differing views, and should not so confidently claim that the policy statement is a "straightforward reading" of the Consumer Product Safety Act ("CPSA").

B. The Policy Statement is Substantively Flawed

Not only does the policy statement likely violate the APA, the substance of the proposed policy statement is both complex and unclear within the backdrop of the requirements of § 15(b) of the CPS Act.

The CPSA provides, *inter alia*, that a manufacturer, importer, distributor and retailer of consumer products – regardless of the size of the company – must notify the Commission immediately if it obtains information which reasonably supports the conclusion that a product distributed in commerce:

- Fails to meet a consumer product safety standard or banning regulation;
- Contains a defect which could create a substantial product hazard to consumers;
- Creates an unreasonable risk of serious injury or death.

15 U.S.C. § 2064.

In the context of these legal requirements, the text of the policy statement raises many questions.

- In the case of a multinational corporation whose U.S.-based parent or subsidiary sells the same (or substantially similar) product in the U.S., does the Commission intend under 16 C.F.R. § 1115.14 to impute knowledge of safety-related information received by overseas employees of that corporation?[2] May it do so? (Members of the Coalition believe the Commission should not, because the information is not necessarily transmitted back to the U.S. for a variety of reasons. Indeed, many companies have thousands – if not hundreds of thousands – of employees of subsidiaries or affiliated companies, agents, and distributors. Thus, the fact that an employee in another country has information about a "similar" product – one which still may have significant differences in design and manufacture from its American counterpart – does not mean that the information exists back in headquarters.)
- Does the Commission intend to apply the same-time computation standards under 16 C.F.R. § 1115.14 in such circumstances? May it do so?

[2] Even the regulations contained in Part 1115 of Subchapter B of Title 16, Code of Federal Regulations, are interpretive, and non intended to promulgate new obligations in accordance with the APA. 16 C.F.R. § 1115.1.

- Does the Commission, under 16 C.F.R. § 1115.13, intend to ask U.S. firms to produce documents and answer detailed questions related to product safety, incidents, manufacture, distribution, sales, and design of products that are under the control of related or overseas entities, or that are produced under a contractual arrangement with the U.S. firm, outside this country? May it do so?
- Does the Commission contend that U.S.-based firms investigate possible safety-related issues outside the U.S. to the same extent as those occurring within the U.S.? May it do so?
- Does the Commission expect all employees and agents of companies which sell consumer products in the U.S., but who are working overseas, to be fully cognizant of the requirements of § 15 and to adhere to U.S. reporting obligations on pain of penalty violations? May it do so?
- How does the Commission intend to take into account information developed outside the U.S. in determining whether or not a civil penalty investigation will be initiated, or whether a civil penalty will be sought?

The issue of "substantial similarity" also raises key questions. Vast differences exist in applicable regulatory requirements, safety requirements, and voluntary or third-party standards around the world. Under the policy statement, who has the burden of proof on the issue of product similarity? And does the proposed standard of product similarity meet the legal standard under the statute that requires manufacturers, distributors, retailers and importers to report on defects or substantial hazards associated with products distributed in commerce in the U.S.?

The notice does not deal with the myriad issues that arise when one considers full or partial application of § 15 to incidents, products or components sold outside the United States. The Coalition questions whether the Commission's view is that all the rules, including attribution of corporate knowledge and the time periods for reporting and taking action contained within §15 and its regulations are fully applicable to events and products outside of the U.S. If so, this is an expansive interpretation that probably is not supported by the law and that, in any case, must be discussed and understood in greater detail. This is an important issue that should be considered not only under the CPSA and related safety law, but also under federal laws that require regulatory review and analysis of small business impact, because these applications could significantly and adversely affect small American businesses that export and import products. Even larger businesses, including foreign-owned businesses that have substantial investment in the U.S., that are aware of the Commission's § 15 requirements, might be placed at a disadvantage to importing entities that have no understanding of § 15 and thus are unlikely to connect events overseas with any possible issues or reporting obligations in the United States.

Only a more in-depth analysis of the issues raised by the policy statement will provide clarity for the regulated community.

III. Recommendation

The Coalition understands the obligatory reporting requirements that are under § 15. If, however, the Commission intends to implement this policy statement by applying either new reporting requirements on U.S. companies based on overseas activities, or by modifying key aspects of existing regulations with which they must comply, both of which will be the basis for enforcement actions against them, then the policy statement fails to provide notice to regulate companies about how the Commission will fairly do this.

The Coalition recommends that the Commission withdraw this notice, and if interested in pursuing this route, it should initiate a more in-depth review of the issues and objectives raised by the policy statement. This could include a series of public workshops designed to develop an adequate record for any potential, relevant future regulatory action. The regulated community and other interested parties should be fully engaged in discussions with the Commission on the parameters of how events outside the U.S. are relevant, both legally and from a safety perspective, to both the safety of products in the United States and to relevant obligations under the CPS Act and related statutes administered by the CPSC. These discussions could lead to a proper and more carefully crafted notice, which would in turn lead to much more useful public comment.

IV. Conclusion

The Coalition believes the Commission's proposed policy statement is flawed from both a procedural and a substantive perspective. The Coalition urges the Commission to withdraw this notice of proposed policy statement, and either issue a clarification to establish that no new obligations or modifications to existing rules are established; or initiate a more in-depth review of the issues and objectives raised by the policy statement, which could include a series of public workshops designed to develop an adequate record for any potential, relevant future regulatory action.

The public, affected firms, and the Commission must all share a common understanding about the manner and circumstances in which firms must bring safety-related developments outside the United States to the Commission's attention, and the scope of the Commission's authority to inquire about or mandate responses to questions about foreign activities. Perhaps such discussions could form the basis on which the Commission could consider further regulatory action which truly advances the product safety goals we all share.

Sincerely,

Stephen Gold
Executive Director, Associations Council
For the NAM CPSC Coalition

B & F
BROWN & FREESTON, P.C.

July 6, 2001

Todd Stevenson
Acting Secretary,
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

Proposed Amendment to CPSC's
Substantial Product Hazard Reports
Title 16 C.F.R. Part 1115

Dear Mr. Stevenson:

The purpose of this letter is to provide comments on the Consumer Product Safety Commission's ("CPSC") proposed amendment to Title 16 C.F.R. Part 1115 published in the *Federal Register* of June 7, 2001 at pages 30655 – 30656[1].

This firm represents several clients who believe that the CPSC's proposal is overly broad and vague. Without agreeing that the CPSC has the authority to require any reporting of incidents or activities that occur outside the defined jurisdiction of the CPSC[2], the concern of our clients is that, despite the initial comments made when CPSC first announced its intention to publish a policy statement, the CPSC continues to blur its policy statement about duties of entities within the United States. Assuming *arguendo* that a company subject to the jurisdiction of the CPSC will evaluate information from any source, foreign or domestic, in determining its reporting duties under Section 15(b) of the Consumer Product Safety Act, 15 U.S.C. § 2064(b), the CPSC's attempts to provide guidance are still imprecise.

There are, at a minimum, two types of entities operating within the United States that are affected by the CPSC's latest proposal. First, some companies are headquartered in the United States. According to CPSC's proposal, these companies must obtain information from some corporate relation outside the United States before they can decide whether a foreign incident or claim provides a reason to report to CPSC under the provisions of Section 15(b). As the "parent" company of overseas entities, the U.S. headquartered company is in a position to require reporting of information about foreign incidents.

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1 Revised Section 1115.12(f).

2 *See, e.g.*, Sections 3(a)(10) and (14) of the Consumer Product Safety Act, 15 U.S.C. §§ 2052(a)(10) and (14).

Other entities operating in the United States, however, are themselves subsidiaries of companies based outside the United States. As such, these companies are not in any position to dictate reporting of product information from the parent company or related companies doing business outside the United States. This is particularly true when the product involved is designed and/or manufactured outside the United States. In the normal course of business, information about common products may be exchanged between the parent and its subsidiaries, but the United States-based company does not dictate the timing or substance of this process. Also, the concept of a defective product varies among different countries. For example, in other countries a problem experienced with a product because consumers do not follow care instructions or use directions is not considered a defect. Therefore, this information is unlikely to be considered noteworthy or worth circulating to global counterparts.

Therefore, United States-based subsidiaries have two concerns with CPSC's proposal – (1) the CPSC proposal does not acknowledge that the United States-based company cannot control the timing and content of information from parent or related companies and (2) if information eventually makes its way to a United States-based company and a report is made to the CPSC under Section 15(b), will CPSC focus on the time product information was available to another entity outside the United States? If the timeliness of reporting of United States-based entities is judged by the time information first became available outside the United States, this would be unfair and it would create an incentive for United States-based companies to do everything they could to avoid ever learning about foreign product experience. Clearly this would be against the spirit and intent of the CPSC's latest policy pronouncement.

Despite the CPSC's somewhat unrealistic allusion to the abilities of a worldwide computer based society[3], global systems for communicating among various branches of companies are expensive and cumbersome to maintain. The differences in language, custom and ways of doing business mean that such systems are established and maintained only when based on demonstrated need. The CPSC's comments in the Supplementary Information portions of the notices in the June 7 *Federal Register*[4] appear to assume the existence of global state-of-the-art communications devoted to product incidents. This is not the case in the real world. If, however, this is what CPSC believes is required by Section 15(b), it should clearly state this in its amendment. Even if a policy statement

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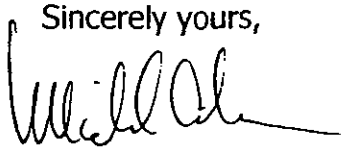
[3] CPSC, Issuance of Policy Statement, 66 *F.R.* 30715, June 7, 2001, at 30716.

[4] CPSC, Issuance of Policy Statement, 66 F.R. 30715 and CPSC, Substantial Product Hazard Reports, 66 F.R. 30655.

cannot be challenged through normal administrative rulemaking review, CPSC's intent should be clear enough to allow public comment and legislative review.

We respectfully request that CPSC directly and precisely respond to these concerns. The broad, vague language now used in the proposed amendment and the evasive analysis in the Supplementary Information accompanying CPSC's latest policy statements do more to raise concerns than address them.

Sincerely yours,



Michael A. Brown

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Charles A. Samuels
Government Relations Counsel
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July 9, 2001

BY EMAIL AND FAX

Marc Schoem, Esq.
Director, Recalls and Compliance Division
Office of Compliance, Room 610
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

RE: COMMENTS OF THE ASSOCIATION OF HOME APPLIANCE MANUFACTURERS ON PROPOSED REVISION TO INTERPRETATIVE RULE 16 C.F.R. PART 1115

Dear Mr. Schoem:

AHAM appreciates the opportunity to comment on the proposed revision to the Section 15 interpretative rule with regard to the relevance of foreign experiences to reporting on safety hazards or defects to the Commission.

AHAM has filed comments previously on this subject. We continue to believe that the Commission is mistakenly pursuing a cramped, begrudging rulemaking process when a more open and public dialogue on this subject would be desirable. In portions of the discussion to the final policy statement, the Commission, on the one hand, sloughs off industry comments about the difficulty of obtaining information from foreign sources and operations, but elsewhere seems to recognize the relevance of those considerations whom it engages in a post hoc determination of whether a Section 15 filing was necessary or timely. If the Commission is going to continue down the path of failing to consider more deeply and broadly the implications of its action, then we urge it to, at a minimum, include in the interpretative rule or in the preamble thereto, discussion of considerations and issues which might arise overseas.

The Commission should clearly state that although foreign situations may not be unique, it recognizes that within corporate and affiliate organizations there can be serious issues of employee or agent appreciation or knowledge of the legal and safety significance of information received and the reporting of such information to corporate management. Differences in products, consumer use and environmental and residential conditions also may affect the relevance of the foreign events relating to a product as well as the reasonable ability of

individuals and firms to grasp their possible significance in the United States. For example, consider the difference in cooking behaviors around the world.

We appreciate that the Commission believes that it is not creating new legal obligations, but interpreting existing law. Industry understands that reporting decisions in the United States are based on all information at our disposal, including information obtained from foreign sources. The difference of view between CPSC and AHAM lies in CPSC's apparent but incorrect assumption that manufacturers have duplicated their U.S. information network in all foreign countries.

We do not object to the CPSC reminding consumer product manufacturers and retailers that they need to consider non-U.S. information in making reporting discussions but the CPSC must recognize that the degree to which we can obtain and act on this information is a fact-specific, case-by-case decision. The term "reasonably" in Section 15(b) of the Act can only be considered in a fact-specific review.

These and other considerations should be explicitly mentioned in the interpretative rule or at least in the preambular discussion. It would go a long way to mitigating industry's legitimate fear that the Commission will mechanistically apply the precedents in the domestic marketplace to events which occur around the world.

AHAM welcomes the opportunity to discuss these issues further with the Commission and staff in order to ensure that the interpretative rule is as useful, fair and balanced as possible. We have not denied that foreign safety related incidents or other information relevant to products sold in the United States may affect a firm's reporting obligations. We are still concerned that the Commission appears to ignore special problems relating to foreign activities and assumes that the responsibilities and deadlines set forth in Section 15 and its interpretative regulations can apply perforce to these events and incidents.

Sincerely,

Charles A. Samuels

Charles A. Samuels
AHAM, Government Relations Counsel

cc: Michael Gidding, Esq.

WDC 217490v1

Comm Suite Product Hazard Reports

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July 9, 2001

VIA FACSIMILE AND U.S. MAIL

Mr. Todd A. Stevenson
Acting Secretary
Office of the Secretary
U.S. Consumer Product Safety Commission
Washington, DC 20207

Re: Proposed Revision to Interpretative Rule on Substantial Product Hazard Reports, 16 C.F.R. Part 1115 (66 Fed. Reg. 30655 (June 7, 2001))

Dear Mr. Stevenson:

I appreciate the opportunity to comment on CPSC's recent proposal to revise its interpretative rule regarding substantial product hazard reports, 16 C.F.R. §1115.12(f), to include reference to information concerning product experience outside the United States. 66 Fed. Reg. 30655 (June 7, 2001). Among the clients I represent are companies that distribute consumer products in the United States and are U.S. subsidiaries of multi-national corporations that have separate subsidiaries which distribute similar products in other countries. I am concerned that the Commission's proposed revision in the reporting rule is premised on unfounded assumptions and unrealistic expectations regarding such companies. In addition, despite its expressed intention, the proposal does not accurately reflect the substance of CPSC's recently adopted policy statement regarding the treatment of foreign information under Section 15 of the CPSA. The proposed revision instead sweeps more broadly and raises the potential for later interpretations that unfairly seek to impose wide-ranging compliance obligations on such companies. The proposed revision to the rule must be reconsidered and modified to rectify these problems.

I. The Proposed Revision Does Not Reflect the Substance of the Policy Statement

On June 7, 2001, CPSC published its final policy statement entitled "Guidance Document on Reporting Information Under 15 U.S.C. 2064(b) About Potentially Hazardous Products Manufactured or Distributed Outside the United States," 66 Fed. Reg. 30715. By its terms, the policy statement explicitly contemplates the situation where a firm "obtains information" that meets the criteria for reporting under Section 15(b) which includes incidents or experience concerning a product sold in a foreign country:

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> "The Commission interprets the statutory reporting requirements to mean that, if a firm obtains information that meets the criteria for reporting listed above and that is relevant to a product it sells or distributes in the U.S., it must report that information to the CPSC, no matter where the information came from. Such information could include incidents or experience with the same or a substantially similar product, or a component thereof, sold in a foreign country." Id. at 30717 (emphasis added).

In contrast, CPSC's contemporaneously proposed revision to the reporting rule would add a sentence specifying that information which a firm should study and evaluate in order to determine whether it is obligated to report under Section 15(b) "may include information about product experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States." 66 Fed. Reg. at 30656. This proposed rule revision unaccountably omits the factual predicate set forth in the policy statement, i.e., that the firm has obtained such relevant information regarding product experience or performance in a foreign country. This omission raises the specter that the revised interpretative rule could later be read as imposing an obligation to establish the sort of "due diligence" systems to monitor and acquire foreign product-related information that CPSC now views as necessary for product experience and performance in the United States. Particularly in the case of a company which is the U.S. subsidiary of a multi-national corporate parent that has separate subsidiaries in other countries around the world, such an interpretation would be both unreasonable and unrealistic.

II. The Proposed Revision of the Reporting Rule is Based on the Unfounded Assumption that Foreign Product Information is Readily and Generally Available to U.S. Companies

In the preamble to the final policy statement, CPSC asserts that "business globalization and improvements in communication" have substantially reduced the impediments to obtaining product information from abroad. 66 Fed. Reg. at 30716. The Commission asserts further that firms frequently communicate via computer, telephone and fax machine with overseas customers, suppliers and "corporate relatives," and that there is thus no justification for the premise that obtaining foreign product information is more difficult than obtaining the same types of domestically generated information.

In fact, it is CPSC's assumption that foreign and domestic product information are equally accessible that has no justification or support. In the domestic context, both the suppliers and wholesale customers (such as dealers or retailers) of a product manufacturer or distributor have direct business relationships with the company and are themselves subject to CPSC jurisdiction. In contrast, manufacturers and distributors that are U.S. subsidiaries of multi-national parent companies with separate subsidiaries that distribute products in other countries have no direct business relationship with those separate distributor subsidiaries, although they may fall into the category of "corporate relatives" as used by CPSC. In addition, neither the parent company nor the separate subsidiaries in

other countries are themselves subject to CPSC jurisdiction. See 15 U.S.C. §2052(a)(10) and (14). This presents a very different situation with respect to the availability to the U.S. subsidiary of information regarding product experience or performance in foreign countries. CPSC has presented no factual support for its glib assertion that the advent of computers and fax machines has made readily and generally available to U.S. subsidiaries information regarding products distributed in foreign countries by separate subsidiary corporations with which they have no direct business relationship.

Indeed, one commenter on the policy statement raised this issue directly by contending that the statement potentially places a new and undue burden on U.S. companies to implement monitoring programs abroad comparable to those in the United States. 66 Fed. Reg. at 30715-16. CPSC in its preamble discussion only indirectly addressed this comment by first asserting that the policy statement imposes no burdens on firms that did not previously exist. It then cited one example involving a penalty that was imposed to settle allegations that a company failed to report foreign information relating to a defective water distiller in a timely manner. Id. at 30716. However, the Commission made clear that the firm "had learned about" the foreign information at issue substantially before it finally reported to the Commission. In other words, the example concerned a situation in which, as in the policy statement itself, the firm "obtains information" from a foreign country which is relevant to a U.S. product and allegedly meets the criteria for reporting.

The separate and additional issue of whether CPSC viewed the company as having an obligation to seek out and monitor such foreign information on a routine basis was simply not addressed. The Commission's blithe assertion that such information is as readily available as domestically generated customer complaints or warranty claims continues to raise the concern that under the proposed revision, it might interpret the CPSA as imposing such an unreasonable and open-ended obligation. While domestically generated information could perhaps be expected to reach U.S. companies from suppliers and retailers under established patterns of U.S. business relationships, a similar assumption simply cannot be made with respect to U.S. subsidiaries and information regarding the same or similar products distributed internationally by separate subsidiary companies.

III. The Proposed Revision Should be Reconsidered and Modified

As currently proposed, the CPSC's suggested revision to the interpretative rule regarding substantial product hazard reporting under Section 15(b) is susceptible to unreasonably broad interpretations and does not even accurately reflect the substance of CPSC's recently adopted policy statement. The proposed revision should be reconsidered and modified to rectify these problems. Moreover, because it concerns an interpretative rather than a substantive rule, the revision would not resolve the underlying jurisdictional question of whether CPSC has authority to require product reporting based on events or actions outside the United States. See 15 U.S.C. §2052(a)(10) and (14).

A key deficiency is the omission of the underlying factual predicate of the policy statement, i.e., the situation where a U.S. company obtains information regarding incidents or experience with a product sold in a foreign country that is relevant to the same or a substantially similar product sold or distributed in the U.S. At a minimum, the proposed revision to the reporting rule should be modified to make clear that it deals with instances where a firm actually "obtains" foreign information that is in fact relevant to a product sold or distributed in the United States. Any such revision to the rule should correspondingly make clear that a firm "obtains" such foreign information only when an employee of the firm capable of appreciating its significance actually receives it.

As previously noted, reconsideration and modification is necessary to avoid potentially unreasonable interpretations of the revised rule and to comport with the stated purpose that the revision should reflect the substance of CPSC's recently adopted policy statement.

IV. Conclusion

It is very important that the Commission reconsider and modify its proposed revision in the substantial hazard reporting rule in order to avoid unfounded assumptions and potentially unreasonable and burdensome interpretations. Without modification, the proposed revision will unfortunately have the counterproductive effect of creating uncertainty and confusion with respect to the reporting and compliance obligations of U.S. companies under Section 15(b) of the CPSA. Such an outcome is not in the interest of the Commission, the many thousands of affected firms that it regulates, or the public.

Sincerely,

Michael A. Wiegard

TAB D

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1115

Substantial Product Hazard Reports

AGENCY : Consumer Product Safety Commission.

ACTION : Final Amendment to Interpretative Rule

SUMMARY: Section 15(b) of the Consumer Product Safety Act, 15 U.S.C. § 2064(b), requires manufacturers, distributors, and retailers of consumer products to report possible substantial product hazards to the Commission. The Consumer Product Safety Commission publishes a final amendment to its interpretative rule advising manufacturers, distributors, and retailers how to comply with the requirements of section 15(b). The amendment points out that firms that obtain information concerning products manufactured or sold outside of the United States that may be relevant to the existence of potential defects and hazards associated with products distributed within the United States should evaluate that information and, if necessary, report under section 15(b).

EFFECTIVE DATE: This revision is effective [insert date that is 30 days after the date of publication of this notice in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Marc Schoem, Director, Division of Recalls and Compliance, Consumer Product Safety Commission, Washington. D.C. 20207, telephone - (301) 504-0608, ext. 1365, fax. - (301) 504-0359, E-mail address - mschoem@cpsc.gov.

SUPPLEMENTARY INFORMATION:

Section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. § 2064(b) requires manufacturers, distributors, and retailers of consumer products to report possible "substantial product hazards" to the Commission. In 1978, the Commission published in the FEDERAL REGISTER "Substantial Product Hazard Reports", 16 C.F.R. 1115, an interpretative rule that set forth the Commission's understanding of this requirement and established procedures for filing such reports and proffering remedial action to the Commission. That rule addresses the types of information a firm should evaluate in considering whether to report. It does not, however, specifically address information about experience with products manufactured or sold outside of the United States. The Commission has always expected that firms would report when they obtained reportable information, no matter where that information comes from. Neither the statute, nor the rule itself, suggests otherwise.

Over the past several years, the Commission has received reports under section 15(b) that included information on experience with products abroad and technical data concerning such products. When appropriate, the Commission has initiated recalls based in whole or in part on that experience. In addition, the Bridgestone/Firestone tire recall of 2000 focused public attention on the possible relevance of information generated abroad to safety issues in the United States. Accordingly, to assure that firms who obtain information generated abroad are aware that they should consider such information in deciding whether to report under section 15(b), on January 3, 2001, the Commission solicited comments in the FEDERAL REGISTER on a proposed policy statement. The statement set forth the Commission's position that firms should evaluate and, if appropriate, report to the Commission information concerning products

manufactured or sold outside of the United States that may be relevant to defects and hazards associated with products distributed within the United States

On June 7, 2001, after considering the comments, the Commission published in the FEDERAL REGISTER a final policy statement memorializing this position. Simultaneously, the Commission proposed for comment an amendment to codify this policy guidance as part of the Substantial Product Hazard Reports interpretative rule, 16 CFR 1115. The proposed amendment notes in substance that information about product experience, performance, design or manufacture outside the United States may be relevant to products sold or distributed in the United States. It further notes that firms should study and evaluate such information under section 15(b).

Discussion: The Commission received four comments in response to the proposed amendment. One of these commentors, the CPSC Coalition of the National Association of Manufacturers ("NAM"), resubmitted comments that it had presented in response to the Commission's January proposed policy statement. NAM's resubmission contended that the Commission's response to its comments to that proposal did not take the Coalition's concerns into account. However, NAM did not point to any specific inadequacy in the Commission's response, nor did it otherwise elaborate on its contention. The Commission, on the other hand, believes that its response to the NAM comments in the June 7 FEDERAL REGISTER notice was more than adequate. The NAM comments largely voiced the same hypothetical concerns that commentors on the original 1977 proposed interpretative rule on reporting raised. As the June 7 FEDERAL REGISTER notice points out, the Commission addressed the substance of those comments in the preamble to and text of the final rule in 1978. 43 FR 34988. The Commission

believes, therefore, that the NAM comments require no further response.

a. Imputing Knowledge: The three commentors other than NAM expressed concern that the proposed amendment treated information generated abroad in the same manner that the Commission views domestically obtained data. In the commentors's view, the amendment should have, but did not, take into account differences in data-gathering capabilities abroad from those within the United States, as well as perceptions of the significance of data that becomes available. The commentors requested that the final rule or its preamble recognize these differences. These commentors also noted that U.S. subsidiaries of foreign companies are often not in a position to require corporate parents to collect and/or forward safety related information to those subsidiaries. They further indicated that U.S. subsidiaries will not necessarily be aware of, or be able to obtain, information that other independent subsidiaries of a common foreign parent acquire. Again, the commentors suggested that the Commission recognize in the final rule or its preamble these possible impediments to the acquisition of information.

The issue of obtaining and evaluating information from abroad is pertinent to two aspects of reporting– timely reporting and corrective action. With respect to the first aspect – failing to report in a timely manner or not at all, the Commission believes that the commentors may have misconstrued the intent and scope of the proposed amendment. The Commission recognizes that a number of factors may affect the ability of a firm located in the United States to obtain information from abroad, including limitations on the availability of and access to information. The Commission also appreciates that the nature of corporate business relationships and affiliations may impact the ability of a firm to obtain such information. The Commission further

understands that training, experience, and corporate position, and differences in product design, use and operating environment from standard practices in the United States may affect the ability of recipients abroad to appreciate the significance of information that may relate to products to sold in the United States.

As commentors acknowledged in their written comments and in discussions with the Commission staff, the evaluation of compliance with the reporting obligations requires a case-by-case assessment of relevant facts, including those relating to the considerations identified above. The Consumer Product Safety Act provides the standard for this evaluation. In the context of reporting, section 20, 15 U.S.C. § 2069, only permits the assessment of civil penalties against a party who "knowingly" commits a prohibited act by failing to furnish information required by section 15(b). Section 20(d) of the act defines "knowingly" as "... (2) the presumed having of knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations."

The existing interpretative rule also provides guidance, consistent with section 20, on how the Commission will analyze the facts of each case. In its discussion of the imputation of knowledge to a firm, 16 C.F.R. 1115.11 notes that "the Commission will deem a subject firm to know what a reasonable person acting in the circumstances in which the firm finds itself would know." The section goes on to explain that this imputation extends to knowledge that a firm could have obtained, had it exercised due care to ascertain the truth of complaints or other

representations or conducted a reasonably expeditious investigation to evaluate the reportability of a death, grievous bodily injury, or other information.

Under section 115.11, the "reasonable person" standard applies to a firm's accountability for failure to obtain information that exists abroad. Considerations, such as those described above that may have affected the firm's ability to obtain or appreciate the significance of such information are certainly relevant to whether a firm acted reasonably in the circumstances. In view of the strictures in the statute and the existing interpretative regulation, the Commission believes that the commentors' fears that the Commission would not take such factors into account when assessing a firm's compliance with the reporting obligations are unfounded.

With respect to the second aspect of reporting – corrective action, as the June 7, 2001 final policy statement points out, such information may be relevant to the core issue of whether some form of remedial action is necessary to protect American consumers from defective products that present a substantial risk of death or injury. The Commission hopes that all of the commentors to the proposed amendment accept that, in evaluating potential hazards, firms should attempt to obtain all reasonably available information, including that from abroad, in a timely manner to assure that they can reach reasoned decisions. Indeed, one of the three commentors expressly stated its agreement with this proposition. The Commission believes that this perspective is appropriate, since the welfare of their domestic customers should be of paramount concern to U.S. companies.

b. "Obtaining" Information: The proposed amendment noted that information that a firm should study and evaluate in order to determine whether it is obligated to report information under section 15(b) "may include information about product experience, performance, design, or

manufacture outside of the United States that is relevant to products sold or distributed in the United States." Two commentors believed that the proposed amendment differed materially from the final policy statement because, unlike the policy statement, the amendment did not expressly note that firms had to have first obtained information from abroad for the obligation to evaluate the information to arise. The commentors feared that the omission signaled a possibility that, in evaluating a firm's compliance with the reporting requirements, the Commission might hold a firm responsible for not exercising due diligence to search for and obtain information that was available abroad, but that had not come to the firm's attention. The commentors therefore requested that the final amendment expressly state that a firm only needs to review information that it obtains.

The Commission believes that the amendment as proposed implicitly recognized that, in order to have an obligation to study and evaluate information, a firm must first obtain the information, or be reasonably expected to have obtained it because, for example, of the firm's relationship with or access to a firm or individual who possesses it. To alleviate the apparent confusion, however, the Commission has included in the final amendment an express statement that the information that should be evaluated includes information that a firm "has obtained, or reasonably should have obtained in accordance with section 1115.11" relating to product experience, etc. The Commission has not, however, limited this revision to cover only information that a firm has "actually" obtained, as one commentor requested. As is discussed infra, both the CPSA and the interpretative rule recognize that a firm need not have actually obtained information for obligations under section 15(b) to arise, if a reasonable person acting in the circumstances in which the firm finds itself would have obtained the information.

Accordingly, the Commission believes that these provisions that address the imputation of knowledge to a firm dictate against further limiting the revision to the amendment. Adopting the restriction suggested by the commentor, on the other hand, could encourage firms to avoid seeking reasonably available information that could ultimately support the need for those firms to take corrective action.

c. Recipients of Information: One commentor stated that the rule should reflect that a firm "obtains" information only when an employee of the firm capable of appreciating the significance of the information actually receives it. Section 1115.11 of the interpretative rule already states that " the Commission will deem a firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information." Because this provision already addresses the commentor's request, no addition revision to the final amendment is necessary.

d. Products Imported into the United States: Section 3(a)(4) of the CPSA, 15 U.S.C. § 2051(a)(4), classifies importers as "manufacturers" under the act, while section 15(b) itself imposes reporting obligations on manufacturers, distributors, and retailers of consumer products. The Commission notes that foreign manufacturers export many products into the United States directly to importers, distributors, and retailers. In these circumstances, the Commission reminds importers, distributors, and retailers that they also have obligations under section 15 to conduct reasonable and diligent investigations, and to evaluate and report information about possible safety defects based on information they obtain or should reasonably obtain, including information from outside the United States. Retailers and distributors should refer to section

1115.13(b) of the interpretative rule for procedures for reporting.

Effective Date: This revision becomes effective 30 days after the date of publication of the revised final interpretative rule in the FEDERAL REGISTER.

List of Subjects in 16 CFR Part 1115

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

In accordance with the procedures of 5 U.S.C. § 553 and under the authority of the Consumer Product Safety Act, 15 U.S.C. § 2051 et seq., the Commission amends part 1115 of title 16, Chapter II, of the Code of Federal Regulations as follows:

PART 1115 – SUBSTANTIAL PRODUCT HAZARD REPORTS

1. The authority citation for part 1115 continues to read as follows: Authority: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2070, 2071, 2073, 2076, 2079 and 2084.

2. Section 1115.12(f) is revised to read as follows:

§1115.12 Information which should be reported; evaluating substantial product hazards

* * * * *

...*(f) Information which should be studied and evaluated.* Paragraphs (f)(1) through (7) are examples of information which a subject firm should study and evaluate in order to determine whether it is obligated to report under section 15(b) of the CPSA. Such information may include information that a firm has obtained, or reasonably should have obtained in accordance with section 1115.11, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. All information should be evaluated to determine whether it suggests the existence of a noncompliance, a defect,

or an unreasonable risk of serious injury or death:

(1)..."

Dated: 2001

Todd Stevenson
Acting Secretary
Consumer Product Safety Commission