UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

BP - Public Database
Notice of Proposed Rulemaking (NPR)
The contents of this document will be discussed at the Open Commission Meeting on Wednesday, April 7, 2010

VOTE SHEET

DATE: MAR 3 1 2010

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Maruta Budetti, Executive Director
Cheryl A. Falvey, General Counsel
Philip L. Chao, Assistant General Counsel

FROM: Melissa V. Hampshire, Assistant General Counsel
Patricia Viera, Attorney
Mary House, Attorney

SUBJECT: **Draft Notice of Proposed Rule – Publicly Available Consumer Product Safety Information Database**

Attached for the Commission's consideration is a draft *Federal Register* notice that would issue a notice of proposed rule establishing a publicly available consumer product safety information database. Section 212 of the Consumer Product Safety Improvement Act of 2008 amended the Consumer Product Safety Act to add a new section 6A requiring the Commission to establish and maintain a publicly available, searchable database on the safety of consumer products and other products or substances regulated by the Commission. The draft proposed rule would interpret the various statutory requirements pertaining to information to be included in the database and also would establish provisions regarding submitting reports of harm; providing notice of reports of harm to manufacturers; publishing reports of harm and manufacturer comments in the database; and procedures for identifying and dealing with confidential and materially inaccurate information.

Please indicate your vote on issuance of the attached draft notice of proposed rule.

A. Approve publication of the draft notice in the *Federal Register* without change.

_____ _____
(Signature) (Date)

Note: This document has not been reviewed or accepted by the Commission.
Initials RH Date 3/31/2010

CPSA 6(b)(1) CLEARED for PUBLIC
NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED 3/31/10
EXCEPTED BY: PETITION RULEMAKING ADMIN. PRODG
WITH PORTIONS REMOVED: _____

B. Do not approve publication of the draft notice in the *Federal Register.*

_____ _____

(Signature) (Date)

C. Publish the draft notice in the *Federal Register* with changes (please specify).

_____

_____

_____

_____ _____

(Signature) (Date)

D. Other (please specify).

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice:
(1) Notice of Proposed Rule – Publicly Available Consumer Product Safety Information Database

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

This document has been
electronically approved and signed.

Date: March 31, 2010

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Maruta Z. Budetti, Executive Director

FROM : Mary Kelsey James, *et al.*

SUBJECT : Proposed Rule on the Publicly Available Consumer Product Information Database

Contents

RH 3/31/2010

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

INTRODUCTION

Section 212 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA", Pub. L. 110-314) amends the Consumer Product Safety Act ("CPSA") to add a new section 6A. Section 6A of the CPSA requires the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") to establish and maintain a publicly available, searchable database on the safety of consumer products, and other products or substances regulated by the Commission, which is accessible to the public through the Commission's web site. Pursuant to section 6A(a)(3) of the CPSA, the public database must be established not later than 18 months after the Commission submits a plan to Congress regarding the database under section 6A(a)(2). Such plan was submitted to Congress on September 10, 2009, which means the database must be established not later than March of 2011.

This memorandum contains the staff's recommendations for interpreting the statutory requirements for inclusion of the following information in the publicly available database:

- reports of harm relating to the use of consumer products or other products or substances regulated by the Commission;
- information derived by the Commission from mandatory and voluntary recall notices;
- manufacturer and/or private labeler comments regarding reports of harm; and
- additional information the Commission has determined is in the public interest to include in the public database.

This memorandum also contains the staff's recommended interpretation of the statutory requirements for:

- providing notice of reports of harm to the relevant manufacturer or private labeler;
- reporting incidents of harm to the public in the public database;
- and procedures for dealing with confidential and materially inaccurate information.

The staff's recommendations have been incorporated into the attached notice of proposed rulemaking ("NPR") regarding the publicly available consumer product information database ("public database"). Also, attached for your review and consideration are the staff's recommended responses to comments received in response to a public hearing held on November 10, 2009, and a public workshop held January 11 and 12, 2010, which have been incorporated into the NPR.

STAFF RECOMMENDATIONS REGARDING INTERPRETATION OF SECTION 6A OF THE CPSA, AS AMENDED BY SECTION 212 OF THE CPSIA[1]

[1] Staff recommends that the notice of proposed rulemaking solely address issues of statutory interpretation of section 6A of the CPSA. Although the Commission has solicited, and will continue to solicit comments from the public with regard to the design of the public database, design issues devoid of substantive implications for the database are not addressed as part of the rulemaking.

Section 212 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") (Pub. Law 110-314) amended the Consumer Product Safety Act ("CPSA") to create a new section 6A of the CPSA, titled "Publicly Available Consumer Product Safety Information Database." Section 6A(a)(1) of the CPSA states that the Commission shall "establish and maintain a database on the safety of consumer products, and other products or substances regulated by the Commission...." The statute provides that the database must be publicly available, searchable, and accessible through the Commission's website.

I. Content Requirements

Pursuant to section 6A(b)(1) of the CPSA, the public database must contain:

(i) reports of harm, meaning reports of injury, illness, or death, or reports of any risk of injury, illness or death as determined by the Commission, relating to the use of consumer products or other products or substances regulated by the Commission;

(ii) information derived by the Commission from voluntary and mandatory recall notices; and

(iii) comments that a manufacturer or private labeler of a consumer product wants to include about a report of harm involving its product. Further, section 6A(b)(3) of the CPSA requires the Commission to include in the database, consistent with the requirements of section 6(a) and (b)of the CPSA, any additional information it determines to be in the public interest. Each of the statutory content requirements is set forth below along with the staff's recommendations.

A. Reports of Harm Relating to the Use of Consumer Products or Other

1. What is a "Report of Harm"?

Although the statute requires that the public database include "reports of harm," the statute uses the term without definition. *See, e.g.*, section 6A(b)(1)(A) of the CPSA ("Reports of harm relating to the use of consumer products, and other products or substances regulated by the Commission, that are received by the Commission..."). Based on the minimum information required for a report of harm to be included in the public database as set forth in section 6A(b)(2)(B) of the CPSA[2], the staff concludes that Congress uses the term "reports of harm" to refer to what the Commission currently regards as consumer product incident reports, or incident reports. Accordingly, the staff recommends that the rule define "report of harm" as follows:

[2] To be included in the public database, the statute requires that the following information be provided: a description of the consumer product; identification of the manufacturer or private labeler; a description of the harm relating to the consumer product; contact information of the person submitting the report; verification that information in the report is true and accurate; and consent to include the report in the public database. Section 6A(b)(2)(B) of the CPSA.

Report of harm means any information provided by a person or entity regarding an injury, illness, or death, or any risk of injury, illness or death as determined by the Commission, relating to the use of a consumer product or other product or substance regulated by the Commission. A report of harm may also be referred to as a consumer product incident report, or incident report.

2. *Who may submit reports of harm?*

Section 6A(b)(1)(A) of the CPSA requires the public database to include reports of harm relating to the use of consumer products or other products or substances regulated by the Commission received by the Commission from:

(i) consumers;
(ii) local, State, or Federal government agencies;
(iii) health care professionals;
(iv) child service providers; and
(v) public safety entities.

Staff notes the breadth of the entities listed in section 6A(b)(1)(A) of the CPSA and concludes that the list is intended to be non-restrictive. Accordingly, staff recommends that, except for information collected through the National Electronic Injury Surveillance System ("NEISS"), which is information collected by selected hospital emergency rooms, and except for information collected through Death Certificates, all reports of harm (or "incident reports") related to use of a consumer product or other substance regulated by the Commission, be collected through the same incident report form, regardless of who is submitting the report of harm[3].

Selected information from all reports of harm that meet the minimum statutory requirements for inclusion in the public database, regardless of source, should be available in the public database, which should be accessible through the Commission's web site as set forth in more detail below.

Note that the staff recommends collecting more information on each report of harm than it recommends the Commission report back out to the public. For example, although the Commission will collect Personally Identifiable Information (PII) from each submitter, such contact information cannot, by law, be reported in the public database.

Collection of all reports of harm on the same incident report form is a change from the current system employed by the CPSC, where currently a separate form exists on the CPSC's website for:

(i) Consumers;
(ii) State Attorneys General and Health Departments, Fire, Police and Insurance Investigators;
(iii) Physicians and Health Care Professionals for patient injuries and deaths;

[3] Information reported by firms under section 15 and in other voluntary reporting will be accepted in the same way that it is processed today. This staff memo does not address revisions to section 15 and other voluntary reporting.

(iv) Coroners and Medical Examiners (MECAP reports). The staff recommends that these individual website forms be consolidated into one collection form located in one location on the public website.

The staff recommends the following non-exhaustive list of examples of persons or entities that may fall within the specified list of persons for each statutorily-enumerated class of persons at section 6A(b)(1)(A) of the CPSA that may enter a report of harm into the public database:

> (i) *consumers* include, but are not limited to, the user of the consumer product for which a report of harm is submitted, family member or relative, parent, guardian, friend, or observer;
>
> (ii) *local, State, or Federal government agencies* include, but are not limited to, state attorneys general, social services, child protective services, state agencies, other federal agencies including DoD (military), or school systems;
>
> (iii) *health care professionals* include, but are not limited to, medical examiners, coroners, physicians, nurses, physician's assistants, hospitals, chiropractors, acupuncturists, elder care assistants, private care providers, midwives, or poison control centers;
>
> (iv) *child service providers* include, but are not limited to, day care centers, day care providers, child-care providers, pre-kindergarten school or care providers; and
>
> (v) *public safety entities* include, but are not limited to, police, fire, ambulance, emergency medical services, federal law enforcement or other public safety official.

In addition to the statutorily-enumerated list of submitters, the staff proposes that the following additional categories of persons be allowed to enter reports of harm into the public database under the rubric of "Other" and that the Commission capture the type of person entering the report:

> (vi) *Other* submitters include, but are not limited to, attorneys, professional engineers, investigators, non-governmental organizations, consumer advocates and advocacy organizations, and trade complaints.

In the case of media reports for incidents related to the use of consumer products, the staff enters such information in Injury or Potential Injury Incident (IPII). Unless reported independently or subsequently verified by the staff, staff does not believe that these news-related entries will ever meet the statutory minimum for inclusion in the public database, because such information will not always contain a detailed description of the consumer product, manufacturer, or harm, nor will it contain contact information for the victim, the incident reporter's verification of accuracy, or the incident reporter's consent to publish the information.

Exceptions

a. NEISS Data

Staff concludes that NEISS data should not, at this time, be migrated to the public database. NEISS data is already publicly available for search on the Commission's web site. NEISS should remain separately searchable since its records are collected from a statistically selected sample of US emergency rooms and its primary value is in producing national estimates of product related injuries. Moreover, only a very small percentage of the records include any information to identify the brand or manufacturer of the product(s) involved. Most brand names provided in NEISS records either pertain to products outside CPSC jurisdiction (e.g. drugs, cars) or are brand names that are commonly used to generically reference a product.

b. Death Certificates

The staff recommends that death certificate data purchased from the fifty states and District of Columbia also should not, at this time, be migrated to the public database. These records have limited detail concerning the circumstances of the fatal injury (for example, "drowned in hot tub") and rarely mention the brand name of an involved product. Those that are mentioned are usually genericized trademarks.

c. Reports from Minors

The staff recommends that minors under the age of 18 not be allowed to submit a report of harm in the public database without the consent of a parent or guardian as the named contact person. First, a minor below the age of 18 is not of the legal age of consent in many jurisdictions, and thus may not be able to meet the minimum statutory requirement for inclusion of information in the public database. Second, the staff wants the information to be accurate, and having a parent or guardian review the information may improve accuracy. Third, the report of harm may include sensitive information about an injury, risk of injury, or medical treatment related to a minor that a parent or guardian would want to review or have knowledge of before a minor submitted such information for publication in the public database.

In order to ensure that an adult can be reached for verification of the information submitted, the staff recommends that unless a parent or guardian consents, no information about a minor be published in the public database.

b. How can reports of harm be submitted to the CPSC?

Section 6A(b)(2) of the CPSA provides that the Commission must allow reports of harm for submission in the publicly-searchable database also be able to be submitted to the CPSC electronically, telephonically, or via paper-based means. As discussed above, the Commission has already begun the process of creating a new web-based system for the entry of reports of harm. Set forth in more detail below is the staff's recommendations with regard to the various methods of submission of reports of harm for the public database.

a. Web-based submissions

Except as set forth above, staff recommends that all submissions of reports of harm be submitted via a consolidated incident report form available on the CPSC's web site. This form will be available on the CPSC's web site at all times the CPSC's web site is operational.

The staff further recommends that users who have started, but not completed, a report of harm be given the option of saving and completing a report of harm at a later time. For example, users can begin the process of entering a report of harm, but may need to acquire additional information before submitting the report for inclusion in the public database. Staff recommends they be provided an option for saving the draft report of harm and returning to complete the information at a later time.

The staff recommends that the Commission collect and maintain all reports of harm, even from anonymous submitters and reports that are incomplete. However, only reports of harm that meet the minimum criteria for publication in the public database, as set forth below, will be available for review and search in the public database. Reports of harm that do not meet the minimum requirements will be maintained for appropriate Commission use. [4]

b. Paper Submissions

Paper submission of incident reports are currently submitted through letters to the Commission. These reports are usually received via US Postal Mail by the Office of the Secretary. The Office of the Secretary sends paper submission either to the Directorate of Epidemiology for coding and response or, in the case of a submission relating to a product not regulated by the Commission, to the appropriate federal regulatory agency.

In order to be included in the public database, all reports of harm, regardless of how they are received by the Commission, must meet certain minimum requirements, which include, among other things, that reports be verified by the submitter for accuracy and that the submitter consent to inclusion of the report in the public database[5]. Accordingly, the staff recommends that paper submissions which do not follow the incident report form being developed for the CPSC web site, be returned to the submitter for further completion, verification and consents. The staff recommends

[4] Appropriate "Commission use" as used throughout this document means the collection and use of data for all required or intended purposes of sections 5(a) and 6A of the CPSA, including but not limited to: (i) continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products, and (ii) support for development and improvement of voluntary standards, rulemaking proceedings, information and education campaigns, and administrative and judicial proceedings for enforcement of the statutes, standards, and regulations administered by the Commission

[5] When a submitter is submitting an incident report, it may choose not to consent to its publication in the public database. This is the case for all means of submission – online, paper, and telephone.

the Commission continue to follow its existing procedures for notification under section 6(c) of the CPSA to manufacturers.

c. Telephonic submissions

Telephonic submissions of a report of harm are currently reported through the Consumer Hotline. The staff recommends that this call center continue to collect reports of harm, but that all callers be advised that a report of harm may be submitted via an on-line form located on the CPSC's website. In addition, callers that do not want to submit a report via the web site should also be given the option to continue submission of a report of harm via telephone call.

Should a caller wish to continue submission of a report of harm via telephone, call center personnel should enter information reported by a submitter directly into an internal version of the web-based incident report form for reports of harm. Reports of harm reported telephonically must still be verified by the submitter and the submitter must still consent to inclusion of the information in the publicly-available database. The means of verification and consent will be supported by the technology solution.

As with paper-based submissions, the time frame for notifying a manufacturer or private labeler regarding the report of harm and for inclusion in the public database does not begin to run until the CPSC receives the minimum statutorily-required information.

c. What minimum information must be provided for a report of harm to be published in the public database?

Pursuant to section 6A(b)(2)(B) of the CPSA, in order to be included in the publicly-searchable database, reports of harm must include, at a minimum:

(a) a description of the consumer product(or other product or substance regulated by the Commission);
(b) the identity of the manufacturer or private labeler of the consumer product(or other product or substance regulated by the Commission);
(c) a description of the harm relating to the use of the consumer product (or other product or substance regulated by the Commission);
(d) contact information for the person submitting the report;
(e) a verification by the person submitting the information that the information submitted is true and accurate to the best of the person's knowledge; and
(f) consent by the person submitting the information that such information be included in the database.

Set forth below is the staff's recommended interpretation of these minimum information requirements.

a. Description of the consumer product

Staff recommends that, at minimum, a description of the consumer product mean a word or phrase that distinguishes the product as a consumer product (as defined in section 3 of the CPSA) or a component part of a consumer product, or that distinguishes the product as a product or substance regulated by the Commission. Any report of harm describing a product that is not a consumer product or other product or substance regulated by the Commission should not be included in the public database. Such information should be forwarded to the appropriate state or federal agency, and, if possible, the submitter should be notified.

The description of a consumer product may, but need not, include the name of the product, model, serial number, manufacturer date, date code, date of purchase, price, photograph, retailer, or other descriptive information about the product. The staff recommends that all such additional information be captured and stored about the consumer product, and that a photograph, in particular, be encouraged to aid in identification of the manufacturer, but that such additional information not be required for inclusion of a report in the public database. All that is required is a word or phrase that distinguishes the product as a consumer product, a component part thereof, or that distinguishes the product as a product or substance regulated by the Commission.

b. Identification of manufacturer or private labeler

The CPSA broadly defines a manufacturer as "any person who manufacturers or imports a consumer product." Section 3(a)(11) of the CPSA. "The term 'manufactured' means to manufacture, produce, or assemble." Section 3(a)(10) of the CPSA. Accordingly, a manufacturer appropriately includes any person that "manufacture[s], produce[s], ... assemble[s]" or "imports" a consumer product, which includes "any article, or component part thereof." The term "private labeler" is defined as "an owner of a brand or trademark on the label of a consumer product which bears a private label."

Staff recommends that to meet the minimum requirement for identification of the manufacturer or private labeler, a consumer must enter the name of any one or more manufacturers or private labelers, as defined in section 3 of the CPSA, of the consumer product or other product or substance regulated by the Commission. Unless the submitter fails to enter the name of a manufacturer or private labeler, any company information which distinguishes the entity is sufficient.

c. Description of the harm related to use of the consumer product

The staff recommends that in order for a report of harm to meet the minimum requirement to describe the harm related to the use of the consumer product or other product or substance regulated by the Commission, the submitter must provide a brief narrative description of the illness, injury or death, or risk of illness, injury or death, related to use of the consumer product. Any description of a harm or potential harm to person is sufficient to meet the minimum qualification.

As with the description of the consumer product, the staff recommends that the Commission collect additional data related to the harm, including the date and severity of the

injury, and whether medical treatment was sought. While this information is helpful to the Commission in analyzing the nature of the incident, the staff recommends any description of harm be sufficient to meet the minimum requirements for publication in the public database.

d. Contact information for person submitting report

The staff recommends that the following minimum contact information should be required of a submitter of a report of harm in order for the incident they report to be published in the public database:

- First name;
- Last name; and
- Complete mailing address.

Additionally, submitters will be strongly encouraged to enter an email address and a phone number for follow-up purposes. By statute, this or any other contact information cannot be displayed in the public database and may only be provided to manufacturers if the submitter consents.

The majority of the staff on the rulemaking committee recommends requiring a name and complete mailing address of submitters because of the value of geographic location information in the case of a decision by the Commission to engage in further investigation of an incident.

A minority of staff members on the rulemaking committee advocate only requiring a name and telephone number or a name and an email address that is verifiable. These staff members feel that minimizing the hurdles for inclusion of reports of harm in the public database is more important than verifying the accuracy of every report, especially in cases where valid reports of harm are excluded because the reporter does not want to provide additional personal identifying information. Requiring only a telephone or email address would not preclude the Commission from collecting zip code or state information to aid in identifying patterns of consumer product safety issues.

On balance, the majority of the staff believes that requiring a mailing address is not burdensome to the submitter and should not deter any valid submission of a report of harm for inclusion in the public database. Moreover, even if an individual chooses not to provide a complete mailing address, the report of harm is not lost. Although it will not appear in the public database in this case, it will still be captured and maintained for appropriate Commission use.

e. Verification that the information is true and accurate

The staff recommends that for each incident report submitted, the submitter be prompted to affirmatively check a box indicating that it has reviewed the report and that it is verifying that the information contained in the report is true and accurate to the best of its knowledge. The staff suggests the following prompt or a different but substantially similar prompt for submitters of reports of harm.

"Please carefully review all of the information entered above to ensure the information is correct and complete. By submitting this information to the CPSC you are certifying that the information entered is true and accurate to the best of your knowledge."

This same prompt can appear on email and paper-based forms for verification purposes, although the paper-based form should require the submitter's signature.

The staff further recommends that, at the time of submission of the web-based form, the form prompt users to complete any of the minimum required fields for inclusion in the public database, but allow the submitter to continue without completing these fields if desired, especially in cases where the submitter has not consented to inclusion of the report of harm in the public database.

f. Consent to include information in the public database

Staff recommends that the following information and options, or substantially similar information and options, related to consent to inclusion in the public database and consent to release of contact information the manufacturer or private labeler be available for selection on every report of harm:

Consent 1:

> May we include your report ***without your name and contact information*** in CPSC's Public Database?
>
> --Yes, you may include my report.
> --No, do not include my report.

Consent 2:

> Would you like us to release your name and contact information to the product manufacturer or private labeler?
>
> -- Yes, you may release my name and contact information to the product manufacturer.
> --No, do not release my name and contact information to the product manufacturer.

d. What additional information should the Commission collect relating to a report of harm?

In addition to the minimum required information outlined above, the staff recommends that the Commission collect and maintain the information that is listed in Attachment B. Much of this information is currently collected, but the staff suggests collecting several new categories

of information. The web-based information collection form will be enhanced by technology allowing submitters to make choices from lists of information, rather than requiring free-text entries and narratives in every field.

Information collected for each report of harm:

The data fields that are to be collected in a report of harm are enumerated in the table in Attachment A. In addition to the fields that will be collected, the table lists the fields that will be displayed publicly from incident reports that meet the minimum criteria. The table also lists the name of new fields that are not currently collected but will be in the new system.

e. What information collected on a report of harm should not be made available for search and retrieval in the public database?

Although the staff recommends collecting all of the information outlined in Attachment B, the following fields should not be available for search or retrieval in the public database.

- Name and contact information of the submitter, pursuant to section 6A(b)(6).
- Victim's name and contact information, except for the victim's State, consistent with section 6A(b)(6). Allowing the victim's State to display on public search pages will enable users to view any geographical patterns of incident reports that are relevant to them.
- Photographs which, in the determination of the Commission, are not in the public interest including photographs that depict a person or injury;
- Medical records;
- Confidential information, as determined by the Commission;
- Materially inaccurate information, as determined by the Commission; and/or
- Any other information submitted on or with a report of harm whose inclusion in the Consumer Product Safety Database the Commission determines is not in the public interest to publish.

B. Mandatory and Voluntary Recall Notices

Section 6A(b)(1)(B) of the CPSA requires that the database contain "[i]nformation derived by the Commission" from voluntary and mandatory corrective actions taken by a manufacturer, of which the Commission has notified the public. The statute requires that the database contain information about "corrective actions" or recalls about which the Commission has already notified the public.

The Commission currently notifies the public about corrective actions pursuant to a press release, which contains categories of information relevant to consumers in identifying a recalled product, identifying the hazard associated with the product, and understanding any remedy associated with the recall. The staff proposes to interpret section 6A(b)(1)(B) of the CPSA to require that the information categories presented on recall notice press releases be available and searchable in the public database, and that consumers be able to access the press releases from the public database. This would allow consumers and other users to search in one place to view all information the Commission has with regard to related consumer products.

Although there may be other information "derived by the Commission" related to voluntary and mandatory corrective actions, no other information is consistently made public by the Commission. Thus, the staff concludes that Congress primarily intended for the Commission to make recall information available to consumers through the public database.

C. Manufacturer/Private Labeler Comments

Section 6A(c)(1) of the CPSA requires that the Commission transmit a report of harm that meets the minimum requirements set forth in section 6A(b)(2)(B) of the CPSA, to the manufacturer or private labeler identified "to the extent practicable," "not later than 5 business days" after the Commission receives the report of harm. The recommended interpretation and procedure for transmitting reports of harm to manufacturers is discussed in more detail below in section II.A. If the Commission transmits a report harm to a manufacturer or private labeler, that entity then has the opportunity to comment on information contained in the report of harm pursuant to section 6A(c)(2)(A) of the CPSA.

Pursuant to section 6A(c)(2)(B) of the CPSA, a manufacturer or private labeler can request that such comment be included in the public database. The CPSA further provides that "Except as provided in paragraph (4)(A)," comments requested for inclusion in the public database "shall ... [be made] available in the database at the same time as ... [the report of harm] or as soon as practicable thereafter."

Accordingly, the statute requires that if all five of the minimum content requirements for inclusion in the public database are met, the identified manufacturer or private labeler must be

(i) provided the report of harm within five (5) business days, to the extent practicable;
(ii) given the opportunity to provide a comment on the information in the report of harm;
(iii) have the opportunity to decide whether or not their comment will be displayed in the public database; and
(iv) if the comment is made before the report of harm is included in the database, the comment should be published in the database at the same time as the report of harm, or as soon as practicable thereafter.

While the Commission has an express time limitation to transmit a report of harm to the manufacturer or private labelers, the CPSA does not specify an express time limit for a manufacturer to comment on a report of harm. Accordingly, the staff recommends that the

Commission, in its discretion, may choose not to publish a manufacturer or private labeler comment to the database if such comment is received more than one year after transmission of the report of harm to the manufacturer or private labeler, where it determines it is in the public interest to do so.

If a manufacturer or private labeler submits a comment on a report of harm to the Commission, and requests that such comment be made available in the public database, it must be made available at the same time as the report of harm if it is received before the report of harm is posted. However, like reports of harm, manufacturer comments may be deleted or corrected if they contain materially inaccurate information.[6]

The staff recommends that, as a matter of course, manufacturer comments on a report of harm be published with the report of harm, or as soon as they are received after the report of harm has been published. However, the staff recommends that manufacturers be given the opportunity to flag comments for further Commission review where an allegation is made that the report of harm contains either materially inaccurate or confidential business information. This process will create a queue of comments for Commission review, while allowing the majority of reports of harm and manufacturer comments to be included in the public database without delay.

Several other procedural issues surrounding manufacturer comments which are not specifically required by section 6A of the CPSA have been raised. First, is the question of whether or not a manufacturer will be asked to verify the truth and accuracy of comments submitted about a report of harm, just as submitters of reports of harm are asked to verify the truth and accuracy of incident reports. Second, is the question of whether the Commission should notify the submitter of the report of harm when a manufacturer has commented on the report and requested publication of the comment. Finally, is the question of whether manufacturers who so request, should be notified with regard to all reports of harm, regardless of the quantity or quality of information received by the Commission. This is the current practice.

Because manufacturers must consent to inclusion of a comment in the public database, just as submitters of reports of harm must consent to inclusion of a report in the public database, the staff recommends that the same approach and procedure be followed in both instances, such that both manufacturers and submitters of reports of harm must verify the truth and accuracy of each comment or report of harm before it will be posted in the public database. The staff does not assume that only a submitter of a report of harm would need to verify the truth and accuracy of their report and that manufacturers will always be truthful and accurate even if they are not so prompted. Although not statutorily required, no extra burden exists on the CPSC to implement such a requirement when a comment is submitted by a manufacturer.

It has been suggested that a manufacturer need only verify the truth and accuracy of information entered into the database once, upon registration with a manufacturer portal part of the public database. Staff recommends, however, that because it is unclear whether the same

[6] Section 6A(c)(4)(A) of the CPSA sets forth the statutory requirements regarding materially inaccurate information. A discussion of materially inaccurate information, and a recommendation for interpreting the phrase "Except as provided in paragraph (4)(A)" is discussed in more detail below in sections II.C and II.E.

person representing a manufacturer will enter comment information each time, and because a prompt regarding whether the comment should be made public must be made for each comment, that each comment contain a check box to affirmatively choose both verification of truth and accuracy and whether or not the comment should be displayed in the public database. The staff recommends that the same type of consent mechanism (marking a check box) be used for both submitters of reports of harm and manufacturers for each comment and/or report of harm.

With regard to notifying the submitter of a report of harm when a manufacturer submits a comment that will be made available to the public, the staff recommends that at the time a report of harm is submitted that contains the minimum required information, the submitter be informed that such report will be sent to the manufacturer for review and comment. At that time, the submitter should be given the option of whether they would like to be notified of a manufacturer comment. If it chooses "yes," it must submit an email address for such notification. Even if a submitter does not have an email address, users always have the option to view its report on the CPSC's web site once it is posted

D. Additional Information Which is in the Public Interest To Include in the Public Database

Section 6A(b)(3) of the CPSA, entitled "Additional Information," states that, in addition to including reports of harm, information derived from mandatory and voluntary recall notices, and manufacturer comments regarding reports of harm in the public database, "the Commission shall include...consistent with the requirements of section 6(a) and (b), any additional information it determines to be in the public interest." Accordingly, the staff considered what additional information collected and maintained by the Commission other than information that is specifically excluded by section 6A(f)(2) of the CPSA,[7] is in the public interest to make available in the public database.

Section 6A of the CPSA appears to contemplate a database that allows consumers and other users to access Commission information from a single, user-friendly, and easy to use web interface without having to search in multiple databases for the information. The staff considered a variety of internal sources of additional information that may be in the public interest to include. However, the staff concluded that the incorporation of CPSC technical research, reports on emerging hazards, and other staff-generated research into the Public Database be studied further and after careful discussion with Executive Management and the Commission, be placed in the potential scope of future releases of the Public Database.

[7] Section 6A(f)(2) of the CPSA states that the provision excepting reports of harm submitted for inclusion in the database from the provisions of section 6(a) and (b) "shall not be construed to exempt from the requirements of section 6(a) and (b) information received by the Commission under—(A) section 15(b); or (B) any other mandatory or voluntary reporting program established between a retailer, manufacturer, or private labeler and the Commission."

II. Procedural Requirements

A. Transmitting Reports of Harm to the Manufacturer or Private Labeler

Pursuant to section 6A(c)(1) of the CPSA, the Commission must transmit a report of harm that meets all of the minimum qualifications for inclusion in the public database set forth in section 6A(b)(2)(B) of the CPSA to the manufacturer or private labeler identified in the report, "to the extent practicable," not later than 5 business days after receiving a report.

1. How and when will the manufacturer or private labeler be notified regarding a report of harm?

As per statute, the staff recommends that reports of harm that contain the minimum required information be sent to the identified manufacturer or private labeler no later than the fifth business day after completion of the report of harm.

In order to accommodate the short time frame permitted for manufacturer notification by the statute, the staff recommends that manufacturers and private labelers be given the opportunity to register with the Commission for receipt of notifications of reports of harm via electronic or other means. Registration with the CPSC will allow firms to designate how they would like to be notified of a report of harm, including (1) email and website portal, or (2) regular U.S. mail.

Additionally, the staff recommends that the public database have a manufacturer portal which allows manufacturers to

(i) view all reports of harm identifying its products, and

(ii) to submit comments, including allegations of material inaccuracies and confidential business information, regarding reports of harm. However, staff recommends that all manufacturers and private labelers still be allowed to submit comments via other methods as well, to accommodate firms that do not have internet access.

A condition of the registration will be a "Terms of Use" or similar agreement that will provide guidance on the requirements outlined in the statute that limits the manufacturer's or private labeler's use of the submitter's contact information. A manufacturer or private labeler who receives name and contact information for the submitter of a report of harm and/or a victim must not use or disseminate such information to any other party for any other purpose other than verification of information contained in a report of harm. Verification of information contained in a report of harm must not include activities such as sales, promotion, marketing, warranty, or any other commercial purpose, or any other product-safety purpose not related to verifying the factual details set forth in a specific report of harm.

For manufacturers and private labelers who have not registered their communication preferences, when CPSC receives a report of harm, resource permitting, CPSC will research and

attempt to identify manufacturer or private labeler contact information. In cases of successful identification, CPSC will forward the report of harm with a request for comment and information on how to register to facilitate timely communication regarding such reports and their opportunity to comment in the future.

The statute requires that a report of harm be transmitted to the manufacturer "to the extent practicable" within five business days. The Commission has already interpreted the phrase "to the extent practicable" in 16 CFR § 1101.26. This rule interprets the phrase as used in section 6(b)(1) of the CPSA requiring that to the extent practicable, the Commission provide manufacturers and private labelers notice and opportunity to comment before disclosing information from which the public can ascertain readily their identity. In that context, the Commission provided two examples of when it is *not* practicable to provide notice and opportunity to comment:

(i) when the Commission has taken reasonable steps to assure that the company is out of business and has no identifiable successor, and

(ii) when the information disclosed is testimony in response to a court order during litigation where the Commission is not a party.

The staff recommends that the Commission take a similar approach in this rule, and has identified circumstances where it is not practicable to transmit a report of harm to a manufacturer or private labeler within the five business day time period. These circumstances are:

(i) when the Commission determines that a manufacturer or private labeler is out of business with no identifiable successor;

(ii) when the consumer misidentifies a manufacturer or private labeler, however, as set forth below, the Commission may take steps to correct the misidentified manufacturer or private labeler; or

(iii) when the Commission has incorrect contact information for a manufacturer or private labeler which must be updated.

(iv) when the Commission cannot locate valid contact information at all for a manufacturer or private labeler

2. What information from a report of harm will be provided to the manufacturer or private labeler?

Section 6A(c)(1) of the CPSA provides that the Commission shall transmit to the manufacturer or private labeler identified in the report of harm "the report, subject to subsection (b)(6)...." The staff recommends interpreting this section to allow that, except for the requirements set forth in section 6A(b)(6) of the CPSA, which pertains to the submitters contact information, the entire report of harm be transmitted to the manufacturer or private labeler.

With regard to section 6A(b)(6) of the CPSA, although contact information for the person submitting a report of harm is required in order for the report to be included in the database, this section provides that the Commission may not disclose the name, address, or other contact information of any individual or entity that submits a report of harm. However, the Commission

may provide such contact information to the manufacturer or private labeler of the product with the "express written consent" of the person who submitted the report of harm.

As addressed above, the staff recommends that submitters be given the option to consent to release of their contact information to the manufacturer or private labeler at the time the report of harm is submitted for inclusion in the public database. Additionally, if the submitter of the report of harm is not the victim, but has provided the victim's contact information, the staff recommends that the victim's contact information not be disclosed to a manufacturer or private labeler without the victim's express consent.

3. Limitations on use of contact information

If the submitter of a report of harm and/or a victim provides express written consent to disclose their contact information to a manufacturer or private labeler, section 6A(b)(6) of the CPSA provides that "[c]onsumer information provided to a manufacturer or private labeler under this section may not be used or disseminated to any other party for any purpose other than verifying a report ...[of harm]."

Staff recommends that this section be interpreted to require that a manufacturer or private labeler shall not use contact information for submitters of reports of harm for any other purpose than verifying information submitted in a report of harm. Accordingly, manufacturers and private labelers, or any agent or representative of such entity, shall not use contact information for sales, marketing, warranty, or any other commercial or product-safety purposes other than verifying information contained in a report of harm.

Consumer groups have suggested that the word "verifying" in the statute be interpreted narrowly, to prevent a manufacturer from investigating facts contained in a report of harm, or from discussing a resolution of the product safety issue with the consumer. The staff recommends against a narrow interpretation for several reasons.

First, consumers have a choice in providing their contact information to manufacturers, and they also have a choice in how they want to interact with manufacturers if contacted. Second, the Commission cannot determine for consumers how or if they want to resolve a product safety issue with the manufacturer. The Commission should avoid policing the interactions of private parties, and would have a difficult time enforcing regulations that attempted to do so.

4. By what means should the CPSC communicate and enforce this limitation?

As set forth above, the staff recommends interpreting the statute to limit a manufacturer's use of contact information for any purpose other than verifying information submitted in a report of harm. Accordingly, manufacturers and private labelers, or agent or representative of such entity, shall not use contact information for sales, marketing, warranty, or any other commercial or product-safety purpose. In order to communicate and enforce this provision, the staff recommends that manufacturers and private labelers be required to affirmatively agree to this

condition, either in an on-line agreement when they log in to the on-line manufacturer portal, or via paper-based means, the first time they are exposed to such contact information.

B. Manufacturer/Private Labeler Designation of Confidential Information

A manufacturer or private labeler may review a report of harm for confidential information and request that portions of the report be designated confidential. If the Commission determines that the report does contain trade secret, commercial or confidential information as set forth in the statute, the Commission must redact such information in the report before it is published in the database. If, however, the Commission determines that the designated information is not confidential, the Commission must notify the manufacturer or private labeler and include the information in the public database. A manufacturer or private labeler must bring suit against the agency in an appropriate U.S. district court in order to seek removal of the information.

At the public workshop manufacturers requested that the Commission issue specific criteria that it will use to review designation of confidentiality, and to explain in detail what manufacturers will need to demonstrate to prove a confidentiality claim. In addition, manufacturers requested that they be allowed to "flag" a comment that a report contains confidential information for further Commission review.

Because reports of harm are submitted by the public, it is unlikely that a report of harm will contain confidential business information. Section 6A(c)(3)(A) of the CPSA provides that "except as provided in paragraph (4)(A) [alleging that a report of harm contains materially inaccurate information]," "the Commission shall make the report available in the database not later than the 10th business day after the date on which the Commission transmits the report ...[to the manufacturer]" if it meets the minimum requirements for inclusion set forth in section 6A(b)(1)(A) of the CPSA.

Unlike a claim that a report contains materially inaccurate information which the Commission could read to delay submission into the public database, a claim that a report of harm contains confidential business information should not delay inclusion of a report of harm into the public database. Moreover, sections 6(a) and (b) of the CPSA, with regard to confidential business information, do not apply to reports of harm submitted for inclusion in the public database. Therefore, the staff recommends that manufacturers and private labelers be given a brief and definite period of time in which to claim that a report of harm contains confidential business information: (i) because such claim will be rare and unlikely, and (ii) to facilitate staff review before the 10-day period for publication expires.

The Commission has already promulgated regulations, at 16 CFR § 1015.18(c)-(e), with regard to exemptions from FOIA disclosure based on a claim of confidential business or trade secret information. The Commission has many years of experience applying this rule to prevent the disclosure of confidential business and trade secret information.

Accordingly, the staff recommends adopting the similar language for the rule interpreting section 6A(c)(2)(C) of the CPSA, as set forth below:

> (a) Each request for redaction of language submitted in a report of harm from disclosure under 5 U.S.C. 552(b)(4), as set forth in section 6A(c)(2)(C) of the Act, as a trade secret or privileged or confidential commercial or financial information must:
>
> (1) Specifically identify the exact portion(s) of the report of harm claimed to be confidential;
>
> (2) State whether the information claimed to be confidential has ever been released in any manner to a person who was not an employee or in a confidential relationship with the company;
>
> (3) State whether the information so specified is commonly known within the industry or is readily ascertainable by outside persons with a minimum of time and effort;
>
> (4) State the company's relationship with the victim and/or submitter of the report of harm and how the victim and/or submitter of the report of harm came to be in possession of such information;
>
> (5) State how the release of the information so specified would be likely to cause substantial harm to the company's competitive position; and
>
> (6) State whether the person submitting the request for confidentiality is authorized to make claims of confidentiality on behalf of the person or organization concerned.
>
> (b) No request to redact confidential information from a report of harm pursuant to 5 U.S.C. 552(b)(4) should be made by any person who does not intend in good faith to assist the Commission in the defense of any judicial proceeding that might thereafter be brought to compel the disclosure of information which the Commission has determined to be a trade secret or privileged or confidential commercial or financial information.

The staff recommends that manufacturers and private labelers that wish to submit allegations of confidential business information be able to mark or "flag" their submissions through the on-line manufacturer portal or, on paper, for staff review. In the cases of both on-line "flagging" and paper "flagging," the manufacturer or private labeler should be presented with an electronic description reminder or paper description reminder that contains the language of the criteria above.

In the case of the on-line "flagging" in the manufacturer portal, the manufacturer/private labeler representative who is flagging the entry should be presented with a prompt that conveys the information in the criteria above. Further, the manufacturer/private labeler representative should be presented with a pop-up box that requires the representative to populate text boxes that are associated with each section (items 1 through 6) of the criteria language above. These populated fields will be reviewed by appropriate Commission staff when they are submitted in this manner.

In the case of paper "flagging," the manufacturer/private labeler representative must provide written support that specifically answer each section (items 1 through 6) of the criteria language above.

The rule should provide that no staff review will occur unless an electronic submission is clearly "flagged" with a selection of "CONFIDENTIAL CLAIM/REVIEW FOR CONFIDENTIAL INFORMATION" or the same language is included in bold, all caps, in the header of a paper response document.

C. Designation of Materially Inaccurate Information

The statute sets forth two provisions on materially inaccurate information. One section, section 6A(c)(4)(A) of the CPSA, deals with claims of inaccurate information made *before* a report of harm or manufacturer comment is submitted for inclusion in the public database, and the other, section 6A(c)(4)(B) of the CPSA, deals with claims of inaccurate information made *after* a report of harm or manufacturer comment has already been released into the public database.

Before the report of harm or comment is submitted in the database, the Commission has three options for dealing with materially inaccurate information. If it makes such a determination, section 6A(c)(4)(A) of the CPSA provides that "[i]f, prior to making a report ...[of harm] or [manufacturer] comment ... available in the database, the Commission determines that the information in such report or comment is materially inaccurate, the Commission shall:

(i) decline to add the materially inaccurate information to the database;
(ii) correct the materially inaccurate information in the report or comment and add the report or comment to the database; or
(iii) add information to correction inaccurate information in the database."

After a report of harm or manufacturer comment has already been released in the public database, the statute provides that "[i]f the Commission determines, after investigation, that information previously made available in the database is materially inaccurate or duplicative of information in the database, the Commission shall, not later than seven business days after such determination:

(i) remove such information from the database;
(ii) correct such information; or
(iii) add information to correct materially inaccurate information in the database."

1. What is "materially inaccurate information"?

The staff recommends that the rule define materially inaccurate information in relationship to both reports of harm and manufacturer comments separately as follows:

Materially inaccurate information in a report of harm means information that is inaccurate or misleading in any relevant and sufficiently significant way such that it incorrectly identifies the consumer product, the manufacturer or private labeler, or the harm or potential harm related to use of the consumer product. In order to be material, the inaccuracy must create, or have the potential to create, substantial confusion among database users regarding what product is being identified, what entity manufactured or sold the product, or what the related hazard or safety risk is to product users.

Materially inaccurate information in a manufacturer comment means information that is inaccurate or misleading in any relevant and sufficiently significant way such that it incorrectly conveys, for example, the nature, scope, or cause of a product hazard, the status of a Commission or manufacturer or private labeler investigation, that the manufacturer or private labeler is not responsible for the product or the hazard, that the manufacturer or private labeler is engaging in a corrective action (when such action has not been approved by the Commission or its staff), or that the manufacturer has taken, or promised to take, any other action with regard to the product. In order to be material, the inaccuracy must create, or have the potential to create, substantial confusion among database users regarding the nature, scope or cause of a product hazard, status of an investigation, firms responsible for manufacturing, importing, distributing, selling or holding for sale the consumer product, liability or responsibility for the product risk or hazard, the status of a corrective action or recall, or the nature of any action taken or promise made by a manufacturer or private labeler with regard to a consumer product.

The Commission, in its sole discretion, shall determine what, if any, information contained in a completed report of harm or manufacturer comment is materially inaccurate.

The Commission, in its sole discretion, shall determine what, if any, information in a report of harm or a manufacturer comment is irrelevant or extraneous to the central purpose of the report of harm or a manufacturer comment, and therefore subject to Commission redaction. For example, information included in a report of harm which does not assist other database users to understand what product is identified, what entity manufactured or sold the product, or what the related hazard or safety risk is to product users, may be redacted by the Commission. Irrelevant information is not, by definition, materially inaccurate information. However, the Commission reserves the right, but not the obligation, to remove irrelevant information.

With regard to reports of harm, the staff's definition of materially inaccurate information focuses on inaccuracies contained in three of the statutorily required fields for inclusion in the public database. These three fields, the description of the consumer product, the identity of the manufacturer, and the description of the harm or potential harm, contain the core data for incident reports such that any inaccuracies will affect the quality and categorization of the report, and affect the Commission's ability to track product-related defects. While the Commission

retains the right to review the entire report of harm for material inaccuracies, the staff recommends that the Commission focus resources on core data fields. Manufacturers and private labelers have the ability to submit comments to the extent they dispute other, non-material, information contained in the report of harm. The staff's intent is to discourage manufacturers and private labelers from alleging that a majority of the reports of harm in the public database contain material inaccuracies that require staff review.

With regard to manufacturer comments, the staff's definition of materially inaccurate information focuses on inaccuracies in which a manufacturer or private labeler attempts to use the opportunity to comment to misinform or confuse database users regarding the nature of the product hazard or their relationship to the product, the product hazard or actions being taken in relationship to the product. The list provided in the definition is by way of example only, and is not intended to be exhaustive. Accordingly, the staff recommends that the Commission retain the authority to review all reports of harm and manufacturer comments for material inaccuracies, which will be determined by the Commission in its sole discretion.

Finally, based upon comments received at the public workshop, the staff anticipates that both manufacturers and consumers will allege that reports and comments contain "material" inaccuracies, which may more aptly be characterized as irrelevant or extraneous information, or information not central to the purpose of the report of harm or the comment. The Commission does not have the resources to review and redact every report of harm or comment submitted for irrelevant information. The staff recommends that in these cases, unless the information rises to the level of a "materially inaccuracy," that manufacturers use their ability to comment to address the issue rather than involve Commission resources. However, the Commission should retain the discretion to review and redact information in the public database for irrelevant information. For example, the Commission must have the discretion to remove lewd and lascivious language or photographs.

2. *What information must a person or company provide to support its claim that a report of harm or manufacturer comment contains materially inaccurate information?*

Similar to the allegation of confidential information, the staff recommends adopting a set of criteria that persons alleging a material inaccuracy must follow to make a claim. In addition, the staff recommends that manufacturers and private labelers that submit allegations of materially inaccurate information in a report of harm be able to mark their submissions in the electronic manufacturer portal or, on paper, for staff review. The rule should provide that no staff review will occur unless an electronic submission is clearly "flagged" in the manufacturer portal with a selection of "REVIEW FOR MATERIALLY INACCURATE INFORMATION" or the same language is included in bold, all caps, in the header of a paper document.

The staff recommends the following criteria for all users claiming that a report of harm or a manufacturer comment contains materially inaccurate information:

(1) Specifically identify the exact portion(s) of the report of harm or the comment claimed to be materially inaccurate;

(2) State the basis for the allegation that such information is materially inaccurate;

(3) Provide evidence, which may include documents, statements, electronic mail, internet links, photographs, or any other evidence, sufficient for the Commission to make a determination that such information is materially inaccurate;

(4) For alleged material inaccuracies in a report of harm, state how the release of the information so specified would be likely to cause substantial confusion among database users regarding what product is being identified, what entity manufactured or sold the product, what the related hazard or safety risk is to product users, or identify any other substantial confusion among database users likely to arise out of the release of such information which supports the claim that the information is materially inaccurate;

(5) For alleged material inaccuracies in a manufacturer or private labeler comment, state how the release of the information so specified would be likely to cause substantial confusion among database users regarding the nature, scope or cause of a product hazard, status of an investigation, firms responsible for manufacturing, importing, distributing, selling or holding for sale the consumer product, liability or responsibility for the product risk or hazard, the status of a corrective action or recall, the nature of any action taken or promise made by a manufacturer or private labeler with regard to a consumer product, or identify any other substantial confusion among database users likely to arise out of the release of such information which supports the claim that the information is materially inaccurate; and

(6) State whether the person submitting the allegation of material inaccuracy is authorized to make claims of confidentiality on behalf of the person or organization concerned.

In the case of the on-line "flagging," the manufacturer/private labeler representative who is flagging the entry should be presented with a pop-up box that requires the representative to populate text boxes that are associated with each section (items 1 through 6) in the criteria language above. These populated fields will be reviewed by appropriate Commission staff when they are submitted in this manner.

In the case of paper "flagging," the manufacturer/private labeler representative must provide written support that specifically answers each section (items 1 through 6) of the criteria language above.

3. What time period does the Commission have to review such a claim?

Section 6A(c)(4)(A) of the CPSA does not set forth any time frame for Commission review of alleged material inaccuracies made *before* a report of harm or manufacturer comment is published in the public database. The statute does provide, however, that the Commission

must make a determination with regard to the material inaccuracy before the report of harm or comment is published.

Accordingly, in order to make such determination and not to substantially delay reports of harm from inclusion in the public database 10 days after they are transmitted to a manufacturer or private labeler, as set forth above, the staff recommends that the Commission attempt to resolve claims of material inaccuracies made before a report of harm is posted.

The staff recommends that the report of harm be delayed from inclusion in the public database until such review is complete and the Commission has made a determination with regard to the validity of the claim of material inaccuracy. If claims of material inaccuracy are complete, the staff should have sufficient information from which to make the determination without undue delay.

Section 6A(c)(4)(B) of the CPSA clearly sets forth that claims of material inaccuracy or duplicative information made *after* a report of harm or comment is published in the database require that the Commission both investigate the claim and make a determination with regard to the claim. After such determination by the Commission as to the validity of the claim, the statute provides that the CPSC must take corrective action within seven business days. The staff recommends interpreting the statute to require that once a determination of validity of the claim has been made, the Commission has seven business days to correct the information in the public database. The staff specifically notes that the statute does not require that the Commission investigate the claim, make a determination as to the validity of the claim, and update the public database all within seven days of receiving a claim of inaccurate information.

If the Commission determines that a report of harm or manufacturer comment contains materially inaccurate information *before* it is made available in the public database, the Commission, under section 6A(c)(4)(A) of the CPSA, must:

(i) decline to add the materially inaccurate information;
(ii) correct the materially inaccurate information; or
(iii) add information to correct the materially inaccurate information.

For information already available in the public database, if, after investigation, the Commission determines that such information is materially inaccurate or duplicative, the Commission must, within seven business days of such determination:

(i) remove such information from the public database;
(ii) correct such information; or
(iii) add information to correct inaccurate information in the public database. Section 6A(c)(4)(B) of the CPSA.

4. What authorized actions can the Commission take with respect to materially inaccurate or duplicative information?

As reviewed above, section 6A(c)(4)(A) and (B) of the CPSA set forth the Commission's options for either deleting or correcting materially inaccurate or duplicative information in a report of harm or manufacturer comment. The staff recommends that the Commission, in its sole

discretion, select which option to employ. In making its determination, the Commission should strive to preserve the integrity of the report of harm or comment, and favor correction so that such information can be included in the public database whenever possible. When a report of harm or comment cannot be corrected to make it accurate however, the Commission may remove the information from the public database until such time further information is submitted or acquired which can be used to correct material inaccuracies. If such material inaccuracies can be removed, the report of harm or comment will be released into the public database.

D. Displaying Reports of Harm in the Public Database

1. When must a report of harm that meets the minimum information requirements be included in the publicly available database?

Section 6A(c)(3)(A) of the CPSA provides that "except as provided in paragraph (4)(A) [alleging that a report of harm contains materially inaccurate information]," "the Commission shall make the report available in the database not later than the 10th business day after the date on which the Commission transmits the report ...[to the manufacturer]" if it meets the minimum requirements for inclusion set forth in section 6A(b)(1)(A) of the CPSA. Accordingly, the Commission could read an allegation of inaccurate information as imparting the authority to delay the submission of a report of harm into the public database.

Staff recommends that reports of harm that meet the minimum qualifications be published in the public database on the 10th business day after such report of harm is transmitted to the manufacturer or private labeler without further Commission review.

2. What circumstances will delay a report of harm from publication in the public database?

Note that the 10 business day time period for publishing a report of harm in the public database is counted from the date of transmission of the report of harm to the manufacturer, not 10 business days from receipt of the report of harm. This means that the manufacturer or private labeler must be correctly identified, and the report transmitted by the Commission, before the 10-day time period begins to run.

Two circumstances may delay a report of harm from being published in the public database later than 10 business days after transmission to the manufacturer or private labeler. The first circumstance is a claim of confidential information by the named manufacturer or private labeler. The second is a claim of materially inaccurate information by the named manufacture or private labeler. The staff recommends that the Commission use its discretion to delay such reports of harm to allow completion of the staff's review of the claim, if necessary.

A. Displaying Manufacturer Comments in the Public Database

As reviewed in section I.C above, a manufacturer or private labeler may comment on the information contained in such report, and may request the comment to be included in the public database pursuant to sections 6A(c)(2)(A)-(B) of the CPSA. Unless the Commission determines

the comment to be materially inaccurate, the Commission must include the comment in the public database at the same time as the report of harm or as soon as practicable thereafter.

The staff recommends that all manufacturer comments that specifically request publishing in the public database be made available in the public database either: (i) on the same day as the report of harm, or (ii) at such time after the publishing of the report of harm that the comment is received. The staff recommends that unless the manufacturer or private labeler has flagged the comment for further CPSC review, alleging that the report of harm contains confidential or materially inaccurate information, the CPSC not obligate itself to review manufacturer comments before posting. This recommendation preserves Commission resources for analysis of data in the report of harm, but does not prevent compliance or consumers from viewing any comment a manufacturer desires to make about the report.

E. Data Search and Reporting

Under section 6A(b)(4) of the CPSA, the CPSC must categorize information available in the public database in a manner consistent with the public interest and in a manner to facilitate easy use by consumers. To the extent practicable, the database must be sortable and accessible by:

(i) the date on which the information is submitted for inclusion in the database;
(ii) the name of the consumer product (or other product or substance regulated by the Commission);
(iii) the model name;
(iv) the manufacturer's or private labeler's name; and
(v) such other elements as the Commission considers in the public interest.

Such other elements may include the data fields as described in Attachment B.

F. Notice and Disclosure

Section 6A(b)(5) of the CPSA requires that the "Commission shall provide clear and conspicuous notice to users of the database that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the database." The staff recommends that this disclaimer information be amended as follows, to ensure that database users understand that all information posted in the database by non-CPSC sources, including submitters of reports of harm and manufacturer comments, are not guaranteed for accuracy by the Commission:

> The CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the database, especially information submitted by non-CPSC sources, including all information submitted on reports of harm and comments submitted by manufacturers and/or private labelers.

Additionally, the staff recommends that, at minimum, such disclaimer be placed in the following locations:

- On the entrance screen for public users

- On all search result displays
- On all reports printed from the public database

G. Protecting Personally Identifiable Information and Limiting Lewd and Lascivious Language and/or Photographs

The staff recommends that the Commission take care to protect the Personally Identifiable Information (PII) of those who submit incident reports. Additionally, the staff recommends that the Commission take steps to limit the publishing of lewd and lascivious language and/or photographs that may accompany incident reports.

The staff recommends that all original incident reports, including free form text fields and attached files, including photographs and documents, be reviewed by resources under the direction of Commission staff. This review should take place before the expiration of the statutory timeframes governing transmission of incident reports to the manufacturer/private labeler.

For example, reviewers will:

- Identify and remove PII from the free form text fields
- Identify and remove photos or documents that convey PII
- Identify and remove lewd and lascivious language and/or photographs

The reviewers should have the capability to edit, amend, redact and ultimately publish components of the submitted report in order to protect PII and limit lewd and lascivious language and/or photographs.

This memo is the product of several months of dedicated work by the members of the Public Database Rulemaking Team. Members of this team spent many hours of hard work deliberating and drafting recommendations to the Commission. We would like to thank the members of this team including Kathleen Stralka, Cathy Irish, Todd Stevenson, Mary Toro, William Zamula, Tim Smith, Ming Zhu, and Al Anders. Also, in addition we would like to thank the Office of the Secretary and the Office of Public Affairs for their contributions.

H. Staff Responses to Comments on Public Database

CPSC received 22 submitted comments on a number of specific topics related to Section 6A of CPSA. The responses in this memo are organized by comment topic and correspond to the sections of the proposed rule. Only the sections we received comments on are discussed.

We have grouped comments based on their similarity and have numbered the comments to help distinguish between different comment themes.

A summary of the significant issues raised by the comments and the staff's responses appear below. The number assigned to each comment is for organizational purposes and does not signify the comment's value, importance, or order in which it was received.

Discussion and Response to Comments

Subpart B—Content Requirements

Section 1102.10: Reports of Harm

1. CPSC asked whether any category of persons should be excluded from submitting reports of harm for inclusion in the public database, and, if so, by what means.

Comments (Summary 1)
Two commenters responded that no category of persons should be excluded from submitting reports of harm. Another commenter responded that third party submitters may be one or more degrees separated from the events involved in a report and encouraged CPSC to consider how this might affect assessment of information that could be materially inaccurate. This commenter suggested that there should be transparency regarding relationships surrounding reports and the person filing the report. One commenter stated that anonymous reports should not be published since they cannot be verified. Two commenters proposed that only reports from those groups specified in Section 6A(b)(1)(A)(i)-(v) of the CPSA should be considered for inclusion in the database, and the Commission should clearly and narrowly define these categories. One commenter suggested that the report form should ask submitters to identify to which group under section 6A(b)(1)(A)(i)-(v) of the CPSA they belong. This commenter suggested that the CPSC should have a method for verifying that those filing reports are who they say they are. To assist in this, the commenter suggested that the CPSC should encourage submitters to consent to their contact information being shared with the manufacturer or private labeler.

Response
Staff notes the breadth of the entities listed in the statute and concludes that the list is intended to be non-restrictive. Accordingly, staff recommends that, except for information collected through the National Electronic Injury Surveillance System (NEISS), which is information collected by selected hospital emergency rooms, and except for information collected through Death Certificates, all reports of harm (or "incident reports") related to use of a consumer product or other substance regulated by the Commission, be collected through the same incident report

form, regardless of who is submitting the report of harm, and deposited into a central data warehouse for such information.

Staff recommends that product-related incident information be collected from all sources, including anonymous sources, but that only those reports that meet the statutorily required minimum information as set forth in the statute be published for review and access in the publicly-searchable portion of the database.

Staff recommends that the list of potential submitters be non-restrictive. Staff concluded that a completed report for posting in the Public Database include verification of information submitted and consent to submitter's contact information being shared with the manufacturer or private labeler.

2. CPSC asked whether reports of harm submitted by telephone or paper should meet the same statutory time frames for submission in the public database.

Comment (Summary 2)
CPSC received 5 comments, including 2 from the same commenter, responding that regardless of the means of transmission, all reports of harm should adhere to the same statutory time frames for submission in the public database.

Response
Staff concludes that in order to be included in the Public Database, all reports of harm, regardless of how they are received by the Commission, must meet certain minimum requirements, which includes, among other things, that reports be verified by the submitter for accuracy and that the submitter consent to inclusion of the report in the Public Database. Accordingly, the staff recommends that paper submissions which do not follow the incident report form being developed for the CPSC web site, be returned to the submitter for further completion, verification and consents.

Staff recommends that the "not later than five business days" time frame for notifying a manufacturer or private labeler of a report of harm involving one of its consumer products will not start to run until the CPSC receives a verified report of harm from the submitter of the report of harm.

3. CPSC asked what a description of the consumer product should entail and why.

Comment (Summary 3)
For the most part, all of the commenters responded that some combination of the following would provide a description of the consumer product: brand name, category of product (using an auto-fill function or drop-down menus), model number, serial number, and a text description of the product.

One commenter responded that the brand name (incl. "unknown"), category of product (auto-fill list), model number, serial number, serial/series number/code, manufacturer's identification, the date the item was purchased, where the item was purchased, country of origin,

manufacturer/distributor/private labeler name, UPC code, and a text description of the product should be included.

Two commenters suggested that industry should be encouraged to provide CPSC with product-identification information that can be incorporated into the database because the greater the specificity in product identification, the greater the ability CPSC and manufacturers to identify trends and patterns in the reports it receives.

Three commenters suggested that the database should permit submitters to upload photos and/or supporting documentation of the products related to the incident.

But one commenter suggested that CPSC should work with stakeholders to develop guidelines as to types of photos and/or supporting documentation that would and would not be permitted to be included in database.

Response
Staff agrees with the majority of the comments and has begun incorporating many of the recommendations into the development of the Public Database. The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The Incident Report form is being designed to provide on-line help to assist submitters with locating the product identification information such as brand name, model number, manufacturer name, and manufacture date code. The staff explored the feasibility of collecting detailed product identification information from the industry but ultimately decided that given the pace of change and dynamic nature of the consumer product universe, central maintenance of such information would be infeasible.

The Incident Report will allow submitters to attach photos and other approved file formats to supplement their report.

4. CPSC asked what contact information must be provided, at minimum, to meet the statutory requirement for inclusion in the database.

Comment (Summary 4)
All of the commenters agreed that a submitter should provide a name and address. Some of the commenters suggested that submitters should have to provide a telephone number and/or an email address as a secondary means of contact. One commenter also stated that when submitted online, the submitter should be asked to submit e-mail address, and that when submitted via telephone, the submitter should be asked to provide telephone number, but that submitters should be encouraged to submit phone number and/or e-mail address regardless of the method of

submission. This commenter also stated that if a report is made on behalf of minor, the info provided should be provided for the parent or guardian of that minor.

Response
Staff recommends that the minimum contact information that must be provided by a submitter of a report of harm for inclusion in the Public Database be the submitter's first name, last name, and complete mailing address. Additionally, submitters will be strongly encouraged to enter an email address and/or a telephone number for follow-up purposes.

Staff recommends that minors under the age of 18 not be allowed to submit a report of harm to the Public Database without the consent of a parent or guardian as the named contact person.

5. CPSC asked how the report form should address the issue of the submitter's verification of the information submitted.

Comments (Summary 5)
All of the commenters agreed that submitters should have to take affirmative steps to verify the accuracy of the submission.

One commenter suggested that verification and consent should be obtained separately (e.g., two separate questions) and that the CPSC should employ a procedure similar to that currently utilized by the Clearinghouse wherein a completed report of harm and verification would be mailed to the consumer which the consumer would then mail back. This commenter also suggested that the CPSC should consider sending an automated verification message to the submitter's e-mail address when submitted online, as this would allow the submitter to review the report, and require the submitter to respond to the message to verify the report and consent to its inclusion in database. Reports submitted by telephone should receive the submitter's verification and consent in writing, as per the current Clearinghouse procedure.

However, one commenter suggested that submitters who provide their reports via telephone should be able to verify truth and accuracy of statements over the telephone with CPSC staff. The same commenter proposed that unconfirmed or anonymous reports should, minimally, affirmatively acknowledge verification.

Response
Staff recommends that for each incident report submitted on-line, the submitter be prompted to affirmatively check a box indicating that they have reviewed the report and that they are verifying that the information contained in the report is true and accurate to the best of their knowledge. This same or similar statement mechanism will appear on email and paper-based forms for verification purposes, although the paper-based form may also require the submitter's signature. Staff recommends that in the case of telephone submissions, CPSC mail or email the completed form to the submitter for review and verification, including requiring the submitter's verification.

6. CPSC asked how the report form should address the submitter's consent for: (i) inclusion in the public database; and (ii) release of contact information to the manufacturer or private labeler, and whether there were any other issues related to the user's consent that the CPSC should consider.

Comment (Summary 6)
All of the commenters on this issue suggested that CPSC should utilize simple check boxes on the report form. Specifically, one commenter proposed that consent for inclusion should be required but release of contact information should be optional. This commenter also stated that the report form should clearly state that contact information will not be released to the public. This commenter also suggested that next to the check box for release of contact information to the manufacturer, the report form should include a statement that CPSC encourages consumers to cooperate with investigations.

Response
Staff recommends that Consent of release of information be obtained separately from verification. The staff recommends the following Consents be obtained separately on the form: consent to include information in the Public Database; consent to release of contact information to the manufacturer or private labeler; and, for requests received through FOIA, consent to release contact information to the general public.

7. CPSC asked what, if any, measures should the agency employ to prevent the submission of fraudulent reports of harm while not discouraging the submission of valid reports.

Comments (Summary 7)
All of the commenters on this issue expressed concern about the prevention of fraudulent reports of harm. Several commenters suggested a check box function expressly certifying the accuracy of the information in the report of harm but with reminders of the implications for submitting fraudulent or inaccurate information.

Two commenters were concerned about web-based robots spamming the database, and one suggested a security feature similar to those used on ticket websites (e.g., requiring user to type combination of letters and numbers appearing on screen) to ensure that an automated "robot" is not spamming the database with bogus info.

One commenter suggested that submitters should be required to affirmatively include a verification statement in narrative format as part of their description of the incident.

One commenter stated that CPSC should have method of verifying that submitter is who they say they are and not a competitor, interest group, or other motivated to "salt" the database, and that CPSC should run system checks to see whether multiple reports are received from same person.

Response
Staff agrees that preventing fraudulent reports is a high priority in the development of the Public Database. The development team has incorporated the following to address the issue. In the new Incident Report form, the user must check a box that indicates they certify their incident

report to be true and accurate to the best of their knowledge. This screen captures "Verification by Submitter" as one of the five types of information required by CPSIA, at a minimum, to publish incidents of harm in the Public Database. Once the "certify" box is checked, the "Submit" button becomes available at the bottom of the screen. The user clicks the "Submit" button to officially submit their incident report to the CPSC.

The database implementation team is working closely with the enterprise information security team to ensure the system utilizes industry best practices as well as complies with Federal and CPSC specific security requirements. Staff is considering implementation of CAPTCHA[8] types of challenge-response tests to ensure that the incident report form is not being generated by a computer. Staff is also examining technical options to detect if multiple reports are submitted from the same IP address.

8. CPSC asked whether the agency should design the online reporting form to ensure the capture of data that can be used in scientific statistical analysis and, if so, how.

Comments (Summary 8)
Two commenters agreed that the database could facilitate statistical analysis, stating that the data could be used to calculate incident rates, identify emerging hazard trends, improve CPSC's ability to identify risks and respond quickly, determine the effectiveness of safety standards and regulations, and further CPSC's IT modernization plan. One commenter responded that the database would not support the use of the data for scientific statistical analysis because of concerns regarding the validity of the data.

Response
Staff is designing database reporting options into the system that will enable public users to extract data sets of published incident report information. The extracted fields on these reports may be user-defined and exportable in a variety of standard file formats that will enable use with popular data analysis tools.

9. CPSC asked whether the report form should contain links to outside websites and, if so, why.

Comments (Summary 9)
CPSC received four comments in response to this question and all agreed that linking to outside websites could be problematic. Some commenters agreed that links could be helpful if such links were relevant to the product or complaint.

Response

Staff agrees with these comments and concludes that the report form should not contain links to outside, non-CPSC websites at this time.

10. CPSC asked how the agency should design the report form so that it is clear and easy for users to complete.

[8] Completely Automated Public Turing test to tell Computers and Humans Apart.

Comments (Summary 10)
Many of the commenters agreed that, for ease of use, the report form should contain as many drop-down menus, pop-up windows, help features, reminders, and auto-fill fields as possible and/or that required fields should be marked with an asterisk. Some commenters felt that the database should distinguish (statutorily) required fields from optional fields. Some commenters felt that the database should have as few required fields as possible, but provide additional fields that can be filled in if the submitter so chooses. Some commenters suggested it could be useful to allow narrative responses when seeking a description of a product or incident.

Others provided more basic suggestions for the design of the report form, such as the report form should use a large, easy-to-read font and language. In addition, one commenter suggested that CPSC should provide easy access to information about the database, including its purpose, its potential uses, and a guide on how to access information in the database and should include CPSC contact information, such as e-mail address and phone number, in plain sight for users who need assistance with the database.

One commenter proposed that submitters should have the option to review and edit the submission at any point in the process of filling out the report form.

Response
The staff agrees with these comments and the development team is incorporating many of the recommendations in the Public Database. The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The Incident Report form is being designed to provide on-line help to assist submitters with locating the product identification information such as brand name, model number, manufacturer name, and manufacture date code. The staff explored the feasibility of collecting detailed product identification information from the industry but ultimately decided that given the pace of change and dynamic nature of the consumer product universe, central maintenance of such information would be infeasible.

The form will also inform the user about the purpose, use, and how the collected information will be protected.

11. CPSC asked how the agency could ensure the accuracy of submitted data, from a system design perspective.

Comments (Summary 11)
Two commenters suggested that each report of harm be assigned a unique identifier. One commenter suggested that a report of harm could use two unique identifiers, one viewable in the

public database and one viewable only to submitters, manufacturers or private labelers, and the CPSC for the purposes of collecting further information regarding a report of harm.

One commenter suggested that anyone submitting a report of harm should be required to provide contact information. Submitters should be asked to create a user ID and password tied that can be linked to each report submitted by the user.

One commenter suggested that a submitter should identify to what group it belongs when filing a report of harm; for example, consumer, government agency, or health care professional.

Several commenters suggested the use of drop-down menus and/or auto-fill features for as many categories of information as possible throughout the report form to assist submitters in providing complete and accurate information. For instance, one commenter suggested using hazard codes similar to those used in the NEISS database and brand names using data already in CPSC's other databases, and creating a registry for manufacturers and others to provide their contact information. One commenter suggested unlimited free text incident descriptions. One commenter also suggested including data fields on the report form for CPSC-validated data as well as manufacturer/private labeler comments.

One commenter suggested allowing submitters to amend reports of harm as well as allowing manufacturers to submit comments for publication after the report of harm has been published. This commenter also suggested maintaining an audit trail every time report is modified.

One commenter stated that claims of material inaccuracy should be focused on the submitter and identification of the consumer product, and not on the reported problem with the consumer product. This commenter suggested that reports of hard should not be blocked, removed, or otherwise flagged when a manufacturer makes a claim of material inaccuracy.

Response
Staff has incorporated many of these suggestions into the system design. Each report will have a unique identifier number.

The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

The staff is developing a process to identify, confirm, and register companies that wish to use the online manufacturer portal that is being designed to facilitate communicate between CPSC and

manufacturers. Manufacturer registration, contact/account management, e-mail communication, and ability to flag information are all functionalities being considered for the portal. Manufacturers will be able to choose their preferred method of communication (email or postal mail) with the CPSC. Manufacturers will designate a Point of Contact within their organization to receive notification from the CPSC. An audit trail will be maintained for all changes made in the system.

The incident report form was designed with the minimum number of required fields, marked by an asterisk, while encouraging user to supply additional information. For example, only after the users selects the option of posting the incident report to the public database does the system checks for the five required statutory elements of a complete incident report. The user is encouraged but required to register with an email and password. The staff recommends making the user's contact information optional for submitting an incident to the CPSC and a requirement for posting the incident report in the public database.

12. CPSC asked what the agency could do to ensure the ongoing and perpetual integrity of submitted data, from a system design perspective.

Comments (Summary 12)
Two commenters suggested that CPSC should use software "filters" to sort out redundancies and multiple submissions from the same source and to group multiple discrete reports for the same problem.

One commenter suggested that the CPSC publish the data in pdf format or other format not capable of manipulation.

One commenter stated that CPSC should ensure the database is a closed-loop that allows for feedback on, and modification of published data. Two commenters agreed that the database should allow for the ability to remove falsified or erroneous data.

One commenter proposed that manufacturer/private labeler's comments be aligned with, and published simultaneously with, the report of harm.

One commenter suggested that CPSC could generate notices, and/or seek comments, in relation to events that could occur with reports of harm, such as closure, retention time, and/or archiving. Another commenter believes that information should remain in the database indefinitely.

One commenter also stated that CPSC should provide notice to database users on every page, including printed copies, that the agency does not guarantee the accuracy, completeness, or accuracy of the database, and that printed pages should bear a date to reduce confusion between versions of reports.

One commenter stated that CPSC should establish guidelines for agency staff or contractors who will be interacting with the database.

One commenter proposed that any changes to the database should require ample public notice and accommodate new data in ways that will not alter prior data structures.

Response
The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes.

The system will feature tools for CPSC staff to perform redundancy and de-duplification functions.

The public database will feature prominent notice that the agency does not guarantee the accuracy, completeness, or adequacy of the contents of the database.

13. CPSC asked how the agency should address incomplete reports of harm, from a system design perspective.

Comments Summary (13)
CPSC received a variety of comments in response to this question. Some commenters suggested that incomplete reports of harm (i.e., those lacking the requisite minimum info) should not be included in the database and/or submitters should be cued via an auto-reminder function when required fields are incomplete.

Other commenters proposed that CPSC should accept forms with incomplete info and/or seek to fill gaps through further research. Two commenters suggested that the CPSC can and should, if appropriate, act on information in these submissions.

Response
Staff is designing the system to prompt the submitter when the required information for inclusion in CPSC's Public Database has not been completed. In addition, staff recommends including language in the Public Database to encourage submitters to complete the minimally required information for inclusion in the Public Database.

Although incomplete reports will not be published in the Public Database, staff recommends that incomplete reports be stored for appropriate Commission use.

14. CPSC asked whether the report form should check for inaccurate information and, if so, how.

Comments (Summary 14)
One commenter responded that the CPSC need not check for inaccurate information if it utilizes a security feature such as those that require a user to type a combination of letters and numbers appearing on screen.

Another commenter suggested that in order to check for inaccurate information, e-mail addresses could be validated for proper format and against illegitimate use, database fields could be validated (e.g., system check for blank fields, etc.), and by the use of drop-down menus to accurately link a manufacturer to a brand and vice versa.

Response
Staff agrees with these recommendations. One of the security features under consideration is using CAPTCHA types of challenge-response tests to ensure that the incident report form is not being generated by a computer. The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

15. CPSC asked what means the agency could employ to ensure that the correct manufacturer and/or private labeler is identified in a report of harm.

Comments (Summary 15)
One commenter suggested that the following information would aid in identifying the product and the manufacturer: brand name, product name, type of product, model number or name, serial number (if available), product description, and product age. Another commenter suggested the use of drop-down menus in order to accurately link manufacturers to products and vice versa.

One commenter suggested that CPSC should rely on the manufacturer to confirm their identity in relation to the product identified in the report of harm. This commenter also suggested that CPSC allow companies to register their contact information with CPSC in order to minimize agency resources. This commenter also proposed that retailers be treated similarly since retailers oftentimes have as much product information as manufacturers, if not more.

Response
The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

The staff explored the feasibility of collecting product identification information from the industry to link manufacturers to products and ultimately recommends that manufacturers maintain that information to provide better data quality and consistency. One key piece of relevant feedback received from manufacturers during the staff workshop was that manufacturers

themselves often have difficulty keeping their model/product database accurate and up to date. Having CPSC maintaining a copy of this information would introduce additional complexity and risk.

Staff agrees with comments regarding company registration and is developing a process to identify, confirm, and register companies.

16. CPSC asked what, if any, instructions to users should be included on the report form.

Comments (Summary 16)
Some commenters suggested that the instructions should be simple, identify all required information, and/or state that form cannot be processed without required information. Some commenters suggested that the report form contain pop-up boxes or links providing more detailed explanations of type of info sought. Other commenters suggested that the report form should notify submitters when required fields are left blank.

Three commenters proposed that the report form should instruct the submitter to answer questions as thoroughly and completely as possible, as well as of the importance of providing full and complete information, and/or instruct submitters to reference documents associated with the purchase and use of the product while filling out the form.

One commenter proposed that the report form should indicate what information is required to make a report of harm eligible for inclusion in database.

One commenter suggested that the report form should include a clear explanation of the privacy protections of the submitted information and the importance of these reports to the CPSC. This commenter suggested that the report form should be clear to consumers that they have the right to decline consent to sharing their contact information with the manufacturer and that doing so does not affect the ability of a report to be published.

Several commenters proposed that the instructions on the report form should inform the submitter of the benefits of allowing the manufacturer to contact them to verify the report and also encourage submitters to do so. One commenter proposed the following script be included on the report form:

> "Manufacturers sometimes find it helpful to speak directly with consumers to investigate safety issues and obtain information regarding reported incidents with their products. May we disclose your name and contact information to the manufacturer or private labeler?"

Another commenter suggested that if a submitter declines to share contact information with a manufacturer, there should be a field indicating as much on the report form. Other commenters felt that the submitters should be provided with this option but without bias, allowing consumers to make their own choice.

Response

The staff agrees with the comments regarding making the form simple and easy to use. The Incident Report form provides on-line help to assist submitters with locating the product identification information such as brand name, model number, and manufacture name and date code. The staff explored the feasibility of collecting product identification information from the industry and ultimately recommends that having manufactures maintain that information will provide better data quality and consistency.

The form was designed with the minimum number of required fields, marked by an asterisk, while encouraging the user to supply additional information. For example, only after the users selects the option of posting the incident report to the public database does the system check for the five required statutory elements of a complete incident report.

The form will also inform the user about the purpose, use, and protection of information being collected by the CPSC and how the manufacturer might use the information provided should he or she choose to release it to the manufacturer.

Section 1102.10: Reports of Harm (additional comments)

CPSC received a number of additional comments not in response to any particular question but related to the overall issue of Section 1102.10 "Reports of Harm."

Comments
Several commenters stated that the scope of database is limited to reports of harm and not to reports relating to general product quality, service issues, or other types of quality complaints, that the harm must relate to the use of the consumer product, and/or that the database is limited to the information the Commission determines is reasonably related to the safety of consumer products as indicated by specific reports of harm caused by those products and that the CPSC should establish guidelines to this end. Along these lines, one commenter suggested that the software utilized in the database could be structured to guide or prompt submitters to supply the information necessary to constitute a report of harm.

One commenter suggested that consideration should be given to limiting the reporting of "old" or "stale" data not contemporaneously related to the occurrence of the alleged incident. Three commenters suggested a one-year statute of limitations to file a report of harm. Another commenter proposed that the database should not contain a statute of limitations at all.

One commenter also suggested that the database should be engineered to automatically publish reports within the required 10 business days of receipt.

Response
Staff recognizes that the scope of the database is limited to reports of harm. Instructions and guidance throughout will prompt the submitter to adhere to this scope.

CPSC will review all reports of harm regardless of the date of the incident described by the submitter.

Staff considered options for automatic publishing of reports of harm. However, considerations around publishing Personally Identifiable Information in free form text boxes limited staff's design options in this regard.

Section 1102.12: Manufacturer Comments

17. CPSC asked what means the agency should employ to allow manufacturers and private labelers to submit comments regarding a report of harm or to designate confidential information, and what issues should the agency consider when developing such a process.

Comments (Summary 17)
One comment stated that CPSC should allow electronic submissions accommodating text, photos, and other documents as attachments.

One commenter suggested that CPSC should ensure that only the applicable manufacturer or private labeler should be able to submit comments regarding a report. This commenter suggested that electronic means would be expected to facilitate making comments. This commenter also suggested that unique identifying information associated with a report should only be available to submitters, manufacturers or private labelers, and CPSC, and it should be required to offer comments and, also, that different types of users could have different "views" of the data. Finally, this commenter suggested that the database should provide a mechanism for designating confidential information, redacting, and exchanging redacted versions of reports.

Two commenters requested a clearly identified process with criteria to determine whether certain content is confidential business information. This commenter also suggested that CPSC should consider allowing manufacturers to "flag" reports that it believes to be confidential business information.

Similarly, one commenter stated that the CPSC should establish a means for submitting comments and designating confidential information. The report of harm and manufacturer's comments should be aligned so that the manufacturer's comments appear in same field as (alongside) the submitter's. This commenter also suggested that a manufacturer should be able to designate into what it believes is materially inaccurate or confidential via a clear method (e.g., flag system) and, if Commission reviews manufacturer's confidentiality request and determines report contains confidential info, it must redact that info from the report of harm and must not publish the report to database until makes a determination as to confidentiality; if the CPSC determines it is not confidential, it must notify manufacturer. This commenter also suggested that CPSC should establish a means for manufacturers to submit proposed redactions of confidential info and, if determined that it is indeed confidential, the agency should have a method for ensuring info remains confidential (e.g., not disclosed under the FOIA).

One commenter stated that if confidential business information does happen to be submitted for posting, manufacturers and private labelers must demonstrate confidentiality and submit supporting info to show that the info is entitled to confidential treatment. This commenter also stated that a manufacturer's comments to a report of harm should also contain a verification of truth and accuracy by the manufacturer.

One commenter stated that accuracy should start and end with the submitter and the product identification, and that the CPSC should not verify the accuracy of, and should not allow manufacturers to comment on, the report of harm.

Response
The staff agrees with the comments and is taking the suggestions into consideration in the following ways:

- The system will allow users to submit text, photo, and other approved types of documents as attachments.
- Only the registered contact from a manufacturer or private labeler can submit comments regarding a report.
- Each report will have a unique identifier.
- There will be role-based access and views into the data.
- Manufacturers will have the ability to flag for CPSC review those reports they believe contain confidential information.

Section 1102.16: Additional Information.

18. CPSC asked what additional categories of information should be included in the public database and why.

Comments (Summary 18)
Two commenters proposed that information regarding the product such as manufacturer, the type of product, the product brand, model number or name, serial number, UPC code, date of purchase, product code date or equivalent designation on the product, and place or purchase; date of incident; location of incident; whether manufacturer or private labeler was contacted prior to submission of the report; verification that the label instructions were followed when using the product; and a brief description of the circumstances of the incident, including how the product was being used at the time of the reported incident, a description of what happened, whether the submitter used any other products or devices along with the product involved in the incident, how much the product was used over what period of time (if applicable), description of harm incurred during the incident, the types of symptoms or injuries sustained, and the type of medical care sought, if applicable.

Two commenters proposed that recalls be included in the database, while another commenter proposed that the database include information derived by the Commission from CPSA Section 15 reports.

Two commenters were in favor of including CPSC technical research, reports on emerging hazards, and other staff-generated research that will improve the public's understanding of consumer product safety. One commenter stated that the Commission should make all staff research completed within the past 5 years publicly accessible within 30 days of completion and, if not in the database itself, linked in the database.

One commenter suggested that CPSC should address how it will integrate pre-database incident data into the new system. Along these lines, one commenter suggested that NEISS data should be included in the database, while another commenter responded that CPSC should not add categories of information beyond that required by the CPSIA but, rather, should focus its efforts on ensuring the quality of, and timely reporting of, required information.

Finally, one commenter felt that the CPSC should accept information submitted anonymously by whistleblowers and, if the information was determined to be valid, the information should be part of the public database.

Response
Staff designed the Incident Report form to collect information regarding the incident such as manufacturer; the type of product; the product brand; model number; serial number; date of purchase; manufacturer code date; place of purchase; date of incident; location of incident; whether manufacturer or private labeler was contacted prior to submission of incident report and, if not, is there a plan to contact them; a brief description of the circumstances of the incident; a description of harm incurred during the incident; the types of symptoms or injuries sustained; and the type of medical care sought, if applicable.

After the user successfully submits the incident, the system will alert the user of any recalls that are related to the incident reported and provide options for the user to subscribe to the recalls.gov subscription list and possibly other lists, web services, or agency publications.

The incorporation of CPSC technical research, reports on emerging hazards, and other staff-generated research into the Public Database is being studied for future releases of the system.

The database will accept information submitted anonymously but staff recommends that anonymous reports not be published.

19. CPSC asked what, if any, information could not be included in the public database pursuant to the statute and why.

Comments (Summary 19)
Several commenters stated that the database should exclude reports filed under section 15(b) of the CPSA. One commenter also stated that information received under any other mandatory or voluntary reporting program established between retailer, manufacturer, or private labeler and the CPSC could not be included in the database, as well as information exempt from disclosure under FOIA, trade secrets, and other confidential information.

Two commenters stated that reports of harm and/or comments involving products that fall outside the scope of CPSC regulatory authority should not be included in the database.

One commenter was concerned that the status of CPSC investigations, including the existence of the investigation, should not be included in the database. This commenter also felt that the database should not contain the resolution and/or remedy provided to individual submitters and

that status updates should only be allowed by manufacturers providing comments. Finally, this commenter stated that third-party comments would not be appropriate for the database.

Response
Staff recommends that all reports of harm meeting the minimum statutory requirements be included in the Public Database. All other reports of harm should be collected for appropriate Commission use. Reports of harm that fall outside the scope of CPSC regulatory authority will be referred to an appropriate agency or entity with notification of such action to the submitter.

20. CPSC asked what, if any, disclaimers or qualifications should appear on the report form.

Comments (Summary 20)
Comments in response to this question fell into two categories. The first category of comments concerned the need for a disclaimer either on all screen views during the process of submitting a report form or at least at the end on the completed report form. Commenters felt that that the disclaimer should inform users of the database that CPSC has not verified the truth or accuracy of reports in the database. One commenter felt that there should be an acknowledgment check box for the submitter to select upon completion of a report to certify the truth and accuracy of the report prior to submission.

The second category of comments concerned the need to inform users how reports of harm, and specifically any personal information contained therein, would be used by CPSC. One commenter suggested that users should be informed that the report of harm itself would be contained in a publicly viewable database. Other commenters were concerned that users should be informed that their contact information would never be publicly available and would only be shared with manufacturers if submitters gave express consent.

Response
Staff recommends that notice should be provided to users of the Public Database that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the database. In addition, staff recommends that the submitters of a report of harm verify that the information they have provided is accurate to the best of their knowledge.

Staff recommends that the Public Database include detailed information for submitters regarding how their contact information will be used.

21. CPSC also asked what specific disclaimers the agency should make with regard to the accuracy of the information contained in the public database and why, and where should such disclaimers appear and why.

Comments (Summary 21)
CPSC received a variety of comments in response to this question. Several commenters felt that all publicly viewable pages in the database should contain a disclaimer that CPSC has not verified the truth or accuracy of the reports in the database.

One commenter recommended that that Commission use the statutorily required disclaimer consistently on each report on the database.

One commenter was concerned about a disclaimer for materially inaccurate information. This commenter suggested that when a report is claimed to contain materially inaccurate information, the report should be marked on every page to indicate it as such. When an existing report is removed or corrected because of a claim of materially inaccurate information, public notice should be made to those who already viewed the report.

Finally, one commenter suggested that printed reports of harm from the database should contain a print date in order to reduce confusion between versions of reports of harm or manufacturer comments.

Response
The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the public database. The Public Database will contain a notice to this effect.

Additionally, the staff recommends that such notice be placed in the following locations, at minimum:

- On the entrance screen for public users
- On all search result displays
- On all reports printed from the Public Database

Printed reports of harm will contain a print date.

Subpart C—Procedural Requirements

Section 1102.20: Transmission of reports of harm to the identified manufacturer or private labeler

22. CPSC asked whether, given the statutory timeframe for notification, manufacturers and private labelers should be able to ''register'' contact information with the Commission for the purpose of notification of a report of harm and, if so, what form of contact information should be acceptable, i.e., electronic mail only. CPSC also wanted to know what other issues along these lines should be considered.

Comments (Summary 22)
The majority of the commenters who responded to this question agreed that registration would help facilitate manufacturer notification. Only one commenter responded that electronic mail only would be acceptable.

Response
Staff recommends that the Commission provide a mechanism for manufacturers and private labelers to register their contact information and their preferred method to be contacted by the Commission.

23. CPSC asked how the agency could ensure that manufacturers and/or private labelers do not use a submitter's contact information for purposes other than verification of a report of harm, and by what means could CPSC enforce such a provision.

Comments (Summary 23)
Two commenters suggested that CPSC could emphasize that misuse of contact information would not be tolerated and that CPSC would take any necessary action to prosecute violators.

One commenter proposed that CPSC reiterate the restrictions and appropriate uses for consumer contact information in all forms sent to manufacturers, while another commenter proposed that CPSC publish a list of uses of contact information that would be deemed to abuses of that information. This commenter also suggested that CPSC could create a webpage for submitters to report abuse.

Response
Staff concludes that the intent of the statute to provide contact information for the submitter to the manufacturer is for the sole purpose of verifying the report of harm. The Commission may, at its discretion, determine means by which it will enforce this provision.

Subpart B—Content Requirements

Section 1102.22: Opportunity for manufacturer comment

24. CPSC asked what means the agency should employ to notify manufacturers and private labelers regarding a report of harm within the five day statutory time frame.

Comments (Summary 24)
The majority of commenters agreed that electronic mail notification would be the most effective means of notification, although others felt that it should be according to the preference (electronic mail, telephone, fax) of the manufacturer or private labeler.

Two commenters were concerned that notification should reach the intended recipient and suggested that CPSC develop procedures for when electronic mail is undeliverable and/or to confirm that individuals receiving notification are authorized contacts for the manufacturers and private labelers.

Response
As part of the public outreach effort, staff is developing a process to identify, confirm, and register companies. A Manufacturer Portal is being designed to facilitate communication between CPSC and manufacturers. Manufacturer registration, contact/account management, e-mail communication, and the ability to flag information that may be confidential or materially inaccurate are all functionalities being considered for the portal. Manufacturers will be able to choose their preferred method of communication (email or postal mail) with the CPSC. Manufacturers will designate a Point of Contact within their organization to receive notification from the CPSC.

The implementation team is working closely with enterprise information security team to secure electronic communication.

25. CPSC asked what, if any, circumstances could arise which could restart any of the timeframes contemplated in the statute with regard to manufacturer notification and responses.

Comments (Summary 25)
One commenter suggested that if submitter provides new or supplemental info to CPSC before initial report is published this would delay publication of the report of harm in the database. Another commented suggested that if there is a valid claim by the manufacturer that a report of harm is invalid, incomplete, or inaccurate, the CPSC should take steps to suspend any statutory time limits until the claim could be adjudicated by the Commission. One commenter proposed that the Commission "restart" the statutory timeframes if notification goes to the wrong manufacturer or private labeler, if incomplete information is provided in the report form, or if the submitter corrects the original report form, especially where information in a required field has been changed.

Response
Staff recommends that, in cases where a determination of Materially Inaccurate or Confidential Information has been made or in review, the Commission, in its discretion, may withhold a report of harm in part or in full until such a determination is made final.

Section 1102.26: Designation of materially inaccurate information

26. CPSC asked, given the statutory timeframe, how the agency should review claims of materially inaccurate information.

Comments (Summary 26)
Two commenters felt that there should be a process for reviewing, modifying, or removing materially inaccurate information. One commenter felt that a claim of materially inaccurate information contained in a report of harm should not restart the 10-day statutory time period for posting of other information in the report form. One commenter felt that once the CPSC has a received a claim of materially inaccurate information contained in a report of harm, it should have a limited time to issue a decision or, in the alternative, it should remove the report of harm

until it does. Finally, one commenter felt that the CPSC could use its discretion to permit an extension of the 10-day period for publication in the database in circumstances where there is a challenge to the accuracy of the report.

Response
Staff recommends that if a request for determination of materially inaccurate information is timely submitted, the Commission should withhold the report of harm from publication in the Public Database until a determination is made regarding such request.

Staff recommends that if the Commission determines that the requested designated information in a report of harm or manufacturer comment contains materially inaccurate information before it is published, the Commission should in its discretion do the following: decline to add the materially inaccurate report of harm or manufacturer comment to the Public Database; redact the information, and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the database; correct the materially inaccurate information, and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the database; or, add the information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and, if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the Public Database.

Should the Commission make a determination of material inaccuracy after publication, staff recommends the following: removal of the entire materially inaccurate report of harm or manufacturer comment from the Public Database, including all associated documents, photographs, or comments; redaction of the materially inaccurate information and if the minimum requirements for publication are met, maintain the report of harm or manufacturer comment in the Public Database; correction of the materially inaccurate information and, if the minimum requirements are met, maintain the report of harm or manufacturer comment in the Public Database; or, add the information to the report of harm or the manufacturer comment to correct the materially inaccurate information and, if the minimum requirements for publication are met, maintain the report of harm or manufacturer comment in the Public Database.

27. CPSC asked whether the agency's responsibility with regard to materially inaccurate information is limited to reports of harm and manufacturer comments and why or why not.

Comments (Summary 27)
CPSC received one comment which stated that CPSC should exclude materially inaccurate information regardless of the source.

Response
Staff recommends that claims of materially inaccurate information should not limit the source of the claims to submitters and/or manufacturers.

28. CPSC asked what types of information would constitute materially inaccurate information.

Comments (Summary 28)
CPSC received numerous, specific examples of what could constitute materially inaccurate information contained in a report of harm, including: misidentification of the manufacturer or private labeler, misidentification of persons involved, or misidentification of the consumer product itself (including misidentification of brand name or model number or misuse modification of the product); and inaccuracy in the description of the incident.

Some commenters were also concerned that materially inaccurate information could comprise opinion statements about a consumer product's design or general safety, information not directly related to the incident such as conclusory or unsupported statements about product design, information in contradiction with generally accepted scientific principles, legal opinions, and reports of an injury or hazard caused by something other than the product identified in the report of harm. One commenter felt that any information that the staff determines to be falsified as well as any information that is inflammatory or invective could also constitute materially inaccurate information.

Several commenters also felt that the database should be a repository for fact-based information only. Similarly, one commenter felt that information that could not be substantiated, such as documentation or information supporting a report of harm, would constitute materially inaccurate information.

Others provided more general comments stating that materially inaccurate information would be inaccurate information that is substantial and important. Along these lines, some commenters suggested that CPSC provide a definition for "materially inaccurate information."

Response
Staff agreed on the following definition of materially inaccurate information in a report of harm: information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial confusion among Public Database users regarding: (1) the identification of a consumer product; (2) the identification of a manufacturer or private labeler; or (3) the harm or risk of harm related to the use of the consumer product

Staff agreed on the following definition of materially inaccurate information in a manufacturer comment: information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial confusion among Public Database users such as: (1) the nature, scope, liability, or cause of a harm or risk of harm related to the use of a consumer product; (2) the status of a Commission, manufacturer, or private labeler investigation; (3) the identity of the firm or firms responsible for the importation, manufacture, distribution, sale, or holding for sale a consumer product; (4) whether the manufacturer or private labeler is engaging in a corrective action (when such action has not been approved by the Commission); or, (5) whether the manufacturer has taken, or promised to take, any other action with regard to the product.

29. CPSC asked how the agency should process a claim that a report of harm or a manufacturer comment contains materially inaccurate information, both before and after such information has been made available in the public database.

Comments (Summary 29)
The majority of commenters agreed that CPSC should develop a transparent and efficient process for handling a claim of materially inaccurate information in a report of harm, including how redactions, corrections and/or removal of a report of harm will be addressed.

Correspondingly, many commenters also felt that CPSC should develop a parallel procedure for the inclusion of reports of harm in the database wherein CPSC staff would make affirmative verification that the report of harm was true and accurate. Several commenters felt that a report of harm could not be published in the database until the CPSC had verified that it was true and accurate.

Two commenters felt that CPSC should follow the procedures specified in the statute wherein upon a claim that a report of harm or comment contains materially inaccurate information, the CPSC must make a determination as to the accuracy of that report or comment and that the report or comment should not be published until such determination is made. Similarly, three commenters suggested that the CPSC should decline to post a report of harm involving a claim of material inaccuracy until an appropriate investigation of the claim had been made.

Another commenter proposed that the CPSC adopt a trial procedure during which it would permit extensions to the 10-day period for publication of reports of harm to the database where there has been a claim of material inaccuracy. This commenter suggested that the CPSC provide a means for manufacturers and private labelers to flag information in a report as being materially inaccurate and also provide a means to flag materially inaccurate information after it has been published to the database. This commenter recommended that the CPSC establish timeframes during which claims of materially inaccuracy will be resolved.

On the other hand, two commenters felt that publication of a report of harm should take priority over verifying claims of materially inaccurate information. Additionally, one commenter suggested that the party contending the material inaccuracy bears the burden of demonstrating the materially inaccuracy and that CPSC should reject efforts to delay or deny posting of information based upon unsubstantiated claims of materially inaccuracy. One commenter felt that, if the CPSC publishes a report of harm over the manufacturer or private labeler's objections, the CPSC should provide the reasons for doing so.

One commenter wanted an opportunity to examine the consumer product in question during the pendency of an investigation into materially inaccurate information in a report of harm.

One commenter felt that if an inaccurate report was inadvertently published, it should be removed as soon as possible and that a simple retraction would not suffice, while another commenter felt that the CPSC could internally investigate it and post a clarification/disclaimer or delete the materially inaccurate information from the report of harm.

One commenter suggested that when a report of harm has been determined to contain materially inaccurate information, it should be marked on every page to indicate it was removed or corrected. When existing reports are removed or corrected because they contain materially

inaccurate information, public notice should be made to those who already viewed the report of harm. This commenter also suggested that if the CPSC receives a subpoena or FOIA request regarding a report of harm that has been corrected or removed, the CPSC should provide notice accordance with section 6(b) of the CPSA to the manufacturer or private labeler.

Response
Staff recommends that if the Commission makes a determination of materially inaccurate information prior to publication of a report of harm, in its discretion, decline to add the report of harm or manufacturer comment to the Public Database or, redact or correct the materially inaccurate information and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the Public Database.

If the Commission makes a determination of material inaccuracy after publication of a report of harm or manufacturer comment, the Commission should, in its discretion and within a time frame determined reasonable by the Commission, remove the report of harm or manufacturer comment from the Public Database or, redact or correct the report of harm or manufacturer comment and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment.

30. CPSC asked how the agency should allow a submitter or others to claim that a manufacturer has submitted materially false information.

Comments (Summary 30)
Two commenters recommended that CPSC assign a unique identifier to each report of harm to assist in making a claim of material inaccuracy, while another commenter suggested there is no need to highlight reports of harm whose accuracy is doubted since CPSIA contains reasonable protections to safeguard against inaccurate information.

Response
Staff has recommended incorporating the suggestion of a unique identifier into the design of the Public Database.

Section 1102.28: Publication of reports of harm

31. CPSC asked if a manufacturer or private labeler requested that a comment associated with the report of harm be made available in the public database, what, if any, circumstances would prevent such comment from inclusion in the public database.

Comments (Summary 31)
One commenter replied that CPSC should not publish any comments that are found to be falsified, inflammatory, invective, or legal opinions or comprise information patently violating generally accepted scientific principles. Another commenter replied that all comments should be included in the database as long as they do not contain trade secret or confidential information.

Response

Staff agrees that all comments that are requested for publication be included in the Public Database.

32. CPSC asked what, if any, authority does the agency have to withhold a report of harm from the public database if a manufacturer or private labeler claims the report contains materially inaccurate or confidential information.

Comments (Summary 32)
One commenter responded that CPSC is permitted to withhold a report of harm form the database if it agrees with the manufacturer or private labeler's claim.

Response
Staff recommends that should the Commission make a determination of materially inaccurate information or confidential information, the Commission should, at its discretion withhold or remove the information from the Public Database in whole or in part.

33. CPSC asked what data sets, including information from reports of harm and mandatory and voluntary recall notices, should be made available for public search and reporting and why.

Comments (Summary 33)
Some commenters agreed that all of the information submitted to the database except for personal and/or contact information contained in reports of harm should be made available for public search and reporting. One commenter wanted to make it clear that personal and/or contact information should never be disclosed to the public and only to a manufacturer or private labeler where there has been consent.

Several commenters agreed that voluntary and mandatory recall notices, and/or information derived as a result of such recall notices, should be searchable as well.

One commenter would like to be able to search the CPSC's NEISS data.

Two commenters wanted to be able to search for manufacturer and private labeler comments provided in response to a report of harm.

One commenter also suggested being able to search CPSC's "closed investigations" which the staff is interpreting as pertaining to investigations conducted by the Office of Compliance and Field Operations staff. One commenter would like to be able to search staff research.

One commenter noted that recall information should be provided separate from reports of harm, stating that recalls are often limited in scope and there is a risk that reports of harm could be inappropriately or inaccurately linked to recall information, while another commenter wanted searching to be limited to what the statute requires in as simple and accurate a format as possible.

Response

Staff recommends that all information and data sets that will be made available in the Public Database should be made searchable and sortable. The incorporation of additional categories of information into the Public Database is being studied for future releases of the system software.

34. CPSC asked in what formats the agency should make data available to the public and why.

Comments (Summary 34)
Several commenters agreed that the data should be downloadable and/or searchable in common, readily-available formats that do not require the purchase of specific, proprietary software. One commenter suggested providing the data in downloadable formats that would facilitate use by manufacturers in their own tracking systems.

Commenters would like to be able to search by general word entry, including advanced searches for data using search terms connected by both the words "AND" and "OR," and/or also by type/category of product, brand name, model name, model number, type of injury and other harm, approximate date of purchase, and product manufacture information.

Two commenters recommended making raw data available.

Response
Staff agrees and the system will provide search capabilities that include those suggested by the comments such as "fuzzy matching", search/sort by product category, manufacturer/private labeler/retailer (including common misspellings), model, date/type/location/severity of the product and hazard. The system will also provide downloadable access the data in multiple common formats.

35. CPSC asked what types of data analysis and reporting tools are being used by third party analysts in the public and industry, and what are those tools' relative merits and drawbacks.

Comments (Summary 35)
One commenter stated that it uses COGNOS Powerplay to analyze its data because it allows both web- and desktop-based access to data in its proprietary databases from an easy-to-use front-end. Also, data accessed via COGNOS Powerplay can be exported to Excel or other programs. This commenter indicated that the drawbacks include limited graphing capabilities and need for programmer to build COGNOS cubes that allow access to data.

One commenter responded that commercial software programs developed by Intertek and Safety Research and Strategies facilitate large database searches and result analysis. This commenter stated that Intertek's software is a web-based software package that enables users to easily analyze product injury data and is currently part of NEISS. This commenter recommended that CPSC utilize a software program that allows keyword searching, year-to-year comparisons, and trend analysis across all variables that NEISS tracks (injury type, body part, environment, age, outcome).

One commenter responded that the CPSC need not, and should not, facilitate analysis of preliminary data by third-party organizations.

Response
The staff recognizes the power of "crowd sourcing." The system will make the data available in multiple common formats for download so researchers and partner organizations can work with us to identify hazards and analyze trends. Staff is also planning to partner with research institutions to develop advanced algorithms for early warning and pattern recognition so smarter decisions can be made to better protect consumers.

Subpart E—Notice and Disclosure Requirements

Section 1102.44: Applicability of section 6(a) and (b) of the CPSA

36. CPSC asked under what circumstances the provisions of section 6(a) and (b) of the CPSA would be relevant to the provisions of section 6A of the CPSA, especially with regard to additional categories of information that may be included in the public database.

Comments (Summary 36)
Two commenters responded that the provisions of section 6(b) of the CPSA were not relevant/applicable to the database.

Two commenters responded that only reports of harm are exempt from sections 6(a) and (b) of the CPSA and any additional information included in the public database would have to comply with those sections.

Response
The Commission has to follow the provisions of sections 6(a) and (b) when determining what additional information is in the public interest to include in the Public Database.

Attachment A

Date: March 26, 2010

TO : Mary Kelsey James, Director,
Information Technology of Policy and Planning

THROUGH : Gregory B. Rodgers, Ph.D., Associate Executive Director, Directorate for Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator,
Directorate for Economic Analysis

FROM : William W. Zamula, Economist, Directorate for Economic Analysis

SUBJECT : Impacts on Business and Regulatory Flexibility Act Considerations

This memorandum addresses the impacts on businesses related to a Consumer Product Safety Commission (CPSC) Proposed Rule on the Publicly Available Consumer Product Information Database. This rule implements Congressionally-mandated requirements for the operation of the database. The memorandum also addresses concerns regarding impacts on small businesses as required by the Regulatory Flexibility Act.

Background

Section 212 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA", Pub. L. 110-314) amends the Consumer Product Safety Act ("CPSA") to add a new section 6A. Section 6A of the CPSA requires the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") to establish and maintain a publicly available, searchable database on the safety of consumer products, and other products or substances regulated by the Commission, which is accessible to the public through the Commission's web site. Pursuant to section 6A(a)(3) of the CPSA, the public database must be established no later than 18 months after the Commission submits a plan to Congress regarding the database under section 6A(a)(2

This rule is designed to facilitate public access to consumer product-related injury data. This rule could have some small effects on some manufacturers and importers of consumer goods under the CPSC's jurisdiction, including those defined as small businesses under the Small Business Administration (SBA) guidelines. Aggregate information about the total market for all products under CPSC's jurisdiction is not available. There are tens of thousands of manufacturers of consumer products, and there are potentially hundreds of thousands of wholesalers and retailers who import consumer products. Most would fall under the SBA definitions of a small business for manufacturers, wholesalers, and retailers, respectively. Generally, SBA defines a small business in the manufacturing sector as a firm having fewer than 500 employees. This definition applies to over 94 percent of manufacturing firms in the U.S. The definitions of a small business for wholesalers (fewer than 100 employees) and retailers (based on sales) differ from those of manufacturers, but the percentage of wholesalers and retailers falling under the small business definition is similar to the manufacturers'.

Impact on Businesses

Manufacturers and importers currently review incident reports under two circumstances: before inclusion in the CPSC's incident database and before release of an incident report to the public under a Freedom of Information Act (FOIA) request. Under the proposed rule, manufacturers and importers will also be allowed to review the incident reports prior to inclusion in the database. If manufacturers choose to respond to the CPSC, the average time spent would not likely be more than a few hours.

The rule could potentially impact businesses if the volume of incident reports increases as a result of consumers' increased accessibility to injury data provided by the Public Database, or if manufacturers choose to respond to a higher proportion of incident reports, or both. However, the possible increase in responses, if any, is unknown. To be included in the Database, consumers will be required to provide contact information, and key data elements, e.g., brand or manufacturer of the product. This should inhibit fraudulent, malicious, or otherwise excessive reporting.

Currently, there are about 15,000 incident reports mailed out to manufacturers and importers. Of those, about 40 percent of incident reports (6,000) receive comments from the manufacturer or importer. Given the hundreds of thousands of manufacturers and importers involved in producing and distributing consumer goods, the probability of a manufacturer or importer receiving even one incident report would not be high, even with a substantial increase in incidence reports. Since the level of incident reports is related to the number of products sold, the odds of receiving a report would probably be quite low for small businesses. While overall there may be more reports for manufacturers and importers to review, the increased level of effort for an individual company to respond should not be high, and for most manufacturers and importers, will be zero. Furthermore, manufacturers and importers are not obligated to review or take any action on the incident reports.

Under the Public Database Rule, manufacturers and importers will have less time to respond to incident reports and it may be more difficult for them to obtain a determination from the CPSC that an incident report is materially inaccurate. There will be no delays in the release of information, unlike the current process, since the incident reports will be automatically posted in the Public Database after verification. The manufacturer or importer will have only one opportunity to challenge the incident reports before they become publicly available. To facilitate incident reports reaching the proper contacts at manufacturers and importers in a timely matter, the Commission may develop a system of registration. However, this program, if it is implemented, will be purely voluntary and solely for the convenience of participating firms.

This does not mean that manufacturers and importers will use more resources because of the reduced time frame to respond to reports. Rather, they may simply compress their efforts into a shorter time frame. The incident report will have a standard CPSC disclaimer that CPSC has not verified the reports, and the manufacturers will have the opportunity to append their comments to

any negative reports. This should minimize any impacts from the more rapid release of incident report information to the public.

Small Business Impact

Any increase in incident reports will affect a very small percentage of small manufacturers and importers, and the additional burden (i.e. the burden relative to current efforts) of responding will be minimal, if not zero, for most. The reductions in time to review incident reports will impact very few small businesses, and generally will not require any additional resources. Because of their smaller sales volumes, small producers are less likely to experience any of these small impacts. Moreover, even if a small firm does choose to respond to an incident report, the amount of time to do so would not likely be more than a few hours, on average. For these reasons, the Commission could certify that the Public Database Rule will not have a significant economic impact on a substantial number of small entities.

Attachment B

INCIDENT REPORT FIELDS	CPSIA REQUIRED FIELDS FOR INCLUSION IN THE PUBLIC DATABASE
Submitter's Contact Information	
Organization/Agency	
First name	x (1)
Last Name	x (1)
Email	
Telephone	
Address (Country)	x (1)
Address (Street)	x (1)
Address (City)	x (1)
Address (State)	x (1)
Address (Zip Code)	x (1)
Are you at least 18 years old?	x (1)
If not, please provide the following information for an adult:	-
Adult's relationship to the submitter of this report	
First name	
Last Name	
Email	
Telephone	
Address (Country)	
Address (Street)	
Address (City)	
Address (State)	
Address (Zip Code)	
Medical Examiner / Coroner Information	
Medical Examiner/Coroner's Case Number	
Personnel who investigated the Incident:	-
First name	
Last Name	
Email	
Telephone	
Address (Country)	
Address (Street)	

Address (City)	
Address (State)	
Address (Zip Code)	
Cause of Victim's Death	
Date of Victim's Death	
Incident Information	
Date of Incident	
Locale	
Incident Location:	
Address (Country)	
Address (Street)	
Address (City)	
Address (State)	
Address (Zip Code)	
Incident, Hazard and Injuries Description	x (2)
Victims' Information	
How many victims were involved in the incident?	
Provide the following information for each of the victims:	-
Gender	
Age at the time of incident	
Victim's relationship to the Submitter of this report	
First name	
Last Name	
Email	
Telephone	
Address (Country)	
Address (Street)	
Address (City)	
Address (State)	
Address (Zip Code)	
Severity of Incident	
Primary Hazard	
Other Hazard	
Primary Injury	
Body Part	

Other Injury	
Other Body Part	
Product Information	
Product Category	
Product Description	x (3)
Where was the product purchased? (Retailer company name)	
Where was the product purchased? (Retailer state)	
When was the product purchased?	
What is the brand? (Private Labeler / Repackager)	
Provide the following information about the company who manufactured or imported the product:	-
Company Name	x (4)
Address (Country)	
Address (Street)	
Address (City)	
Address (State)	
Address (Zip Code)	
Please provide the following information, if you have it:	-
Product Model	
Serial #	
Manufacture Date	
Date Code	
Additional Information:	-
Do you still have the product?	
Where is the product located?	
Before the incident:	-
Was the product damaged?	
Was the product repaired?	
Was the product modified?	
Would you like to provide pictures of the product or other incident related documents?	-
Document	
Document Description	

Consents	
As outlined	x (5)
Verification	
As outlined	x (5)
[redacted]	
Date of report submission to CPSC	

Attachment

Draft Federal Register Notice
Publicly Available Consumer Product Safety Information Database
Notice of Proposed Rulemaking (NPR)

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1102

Publicly Available Consumer Product Safety Information Database

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission ("Commission," "CPSC," or "we) is issuing a notice of proposed rulemaking that would establish a publicly available consumer product safety information database ("database"). Section 212 of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") amended the Consumer Product Safety Act ("CPSA") to require the Commission to establish and maintain a publicly available, searchable database on the safety of consumer products, and other products or substances regulated by the Commission. The proposed rule would interpret various statutory requirements pertaining to the information to be included in the database and also would establish provisions regarding submitting reports of harm; providing notice of reports of harm to manufacturers; publishing reports of harm and manufacturer comments in the database; and dealing with confidential and materially inaccurate information.

DATES: Written comments must be received by **[insert date that is 60 days after date of publication in the FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. [**Insert CPSC docket number**], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice of proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mary Kelsey James, Director, Information Technology Policy and Planning, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7213; mjames@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The CPSIA requires the Commission to create and maintain a product safety information database that is available to the public. Specifically, section 212 of the CPSIA amended the CPSA to create a new section 6A of the CPSA, titled "Publicly Available Consumer Product Safety Information Database." Section 6A(a)(1) of the CPSA requires the Commission to establish and maintain a database on the safety of consumer products, and other products or substances regulated by the Commission. The database must be publicly available, searchable, and accessible through the Commission's website. Section 6A of the CPSA sets forth specific content, procedures, and search requirements for the publicly available database. In this proposed rule, the Commission sets forth its interpretation of the statutory requirements of section 6A.

For several decades, the Commission has gathered and maintained a database of consumer complaints known as consumer product incident reports involving a description of incidents related to the use of consumer products that fall within the scope of the Commission's jurisdiction. Pursuant to section 5(a) of the CPSA, the Commission collects information related to the causes and prevention of death, injury, and illness associated with consumer products. The Commission conducts studies and investigations

of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products. Also, pursuant to section 5(b) of the CPSA, the Commission may conduct research, studies, and investigations on the safety of consumer products and on improving the safety of such products. Currently, the Commission obtains information about product-related deaths, injuries, and illnesses from a variety of sources, including newspapers, death certificates, consumer complaints, and hospital emergency rooms. In addition, the Commission receives information from the public through its Internet Web site through forms reporting on product-related injuries or incidents. The data that the Commission collects and maintains on product safety has not been immediately available and searchable by the public. Before the CPSIA's enactment, the CPSA required that the Commission follow the notice provisions of section 6 of the CPSA before publicly disclosing any information that allowed the public to readily ascertain the identity of a manufacturer or private labeler of a consumer product. Section 6 of the CPSA contains requirements for giving notice of such information to the manufacturer or private labeler and providing an opportunity to comment on the information prior to public disclosure. Section 6 of the CPSA also requires the Commission to take reasonable steps to assure that disclosure of such information is accurate, fair in the circumstances, and reasonably related to effectuating the purposes of the CPSA. The Commission has applied the requirements in section 6 of the CPSA to Freedom of Information Act (FOIA) requests as well. *See Consumer Product Safety Commission et al. v. GTE Sylvania,* 447 U.S. 102 (1980). The Commission issued regulations interpreting the section 6 requirements at 16 CFR Part 1101. Thus, consumers currently have access to incident data through reports and studies

published by the Commission or through information provided in response to FOIA requests.

As stated earlier in part I of this document, section 6A of the CPSA requires the development and maintenance of a publicly available and searchable database. Section 6A of the CPSA specifically excludes any report submitted pursuant to the public database provisions from the notice requirements of section 6(a) and (b) of the CPSA.

Accordingly, the Commission invited input from its stakeholders before developing the proposed rule. A summary of the CPSC's work done to date on the public database, including a Report to Congress, Public Meetings, Federal Register Notices, Commission Actions and Public Comments, are available on the CPSC web site at http://www.cpsc.gov/about/cpsia/sect212.html.

On September 10, 2009, pursuant to section 6A(a)(2) of the CPSA, the Commission submitted a detailed implementation plan for the public database to Congress. The plan, titled "Implementation of a Searchable Consumer Product Safety Incident Database," set forth the Commission's strategy for establishing and maintaining the public database, including plans for the operation, content, maintenance, and functionality of the database. It also described the CPSC's plans for a public awareness campaign to promote the database, and contained an implementation schedule. Pursuant to section 6A(a)(3) of the CPSA, the Commission must establish the public database no later than 18 months after submission of its detailed implementation plan to Congress, or by March 2011.

On November 10, 2009, the Commission held a public hearing regarding the establishment of a public consumer product safety incident database. Consumer groups,

trade associations, research groups, and industry discussed their views on implementation of the public database. Written statements also were accepted. We received 14 comments, and these comments are available on the CPSC's website at http://www.cpsc.gov/library/foia/foia10/pubcom/pubdb.pdf. A webcast of the hearing can be viewed on the CPSC's website at http://www.cpsc.gov/webcast/previous.html. Issues presented at the hearing are discussed and responded to in more detail in section IV of this document below.

On January 11 and 12, 2010, the Commission staff hosted a two-day workshop to discuss implementation of section 6A of the CPSA, including data analysis and reporting; reports of harm; manufacturer notification and response; additional database content, and materially inaccurate information. A transcript of the workshops is available at ___, and a webcast of the workshops is available on the CPSC's website at ___. The CPSC also invited comments in conjunction with the workshop. We received 22 comments, and we summarize and respond to those comments in section IV of this document below.

II. Statutory Authority

The Commission is issuing this proposed rule pursuant to section 3 of the CPSIA which provides the Commission authority to issue regulations, as necessary, to implement the CPSIA.

III. Description of the Proposed Rule

The proposed rule would establish a new 16 CFR part 1102, "Publicly Available Consumer Product Database." The new part would consist of four subparts:

- Subpart A – Background and Definitions;
- Subpart B – Content Requirements;

- Subpart C – Procedural Requirements;
- Subpart D – Notice and Disclosure Requirements

We describe the provisions in each proposed subpart in detail immediately below in section III.A through D of this document.

A. Proposed Subpart A – Background and Definitions

1. Proposed § 1102.1 - Purpose

Proposed § 1102.1 would describe the purpose of the new "Publicly Available Consumer Product Safety Information Database." In brief, the proposal would state that part 1102 sets forth the Commission's interpretation, policy, and procedures with regard to the creation and maintenance of a Consumer Product Safety Information Database.

2. Proposed § 1102.4 – Scope

Proposed § 1102.4 would explain that the part 1102 applies to the content, procedure, notice, and disclosure requirements to be followed and all information published in the Consumer Product Safety Information Database.

3. Proposed § 1102.6 – Definitions

Proposed § 1102.6 would define certain terms. As a general matter, proposed § 1102.4(a) would explain that, except as provided in proposed § 1102.6(b), the definitions set forth in section 3 of the CPSA apply. For example, section 3(a)(11) of the CPSA defines a "manufacturer" as "any person who manufactures or imports a consumer product." Because section 3(a)(11) of the CPSA defines "manufacturer," any reference to "manufacturer" in proposed part 1102 would have the same meaning.

Proposed § 1102.6(b) would define certain terms or, in some cases, interpret terms already defined in section 3 of the CPSA. For example, section 3(a)(5) of the

CPSA defines "consumer product," in part, as "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise...." However, proposed § 1102.6(b)(3) would define "consumer product" as having the same meaning as defined in the CPSA, but would further explain that "consumer product" includes any other products or substances regulated by the Commission under the CPSA, Federal Hazardous Substances Act, Flammable Fabrics Act, the Poison Prevention Packaging Act, the Children's Gasoline Burn Prevention Act, the Virginia Graeme Baker Pool and Spa Safety Act, and any other statute that the Commission enforces. This further clarification is based on the statutory requirement in section 6A(b)(1)((A) of the CPSA for submission of reports of harm relating to the use of consumer products and other products or substances regulated by the Commission.

Proposed § 1102.6(b)(1) would define "additional information" as any information, other than reports of harm, that the Commission determines is in the public interest to include in the Consumer Product Safety Information Database.

Proposed § 1102.6(b)(2) would define "Commission" or "CPSC' as meaning the Consumer Product Safety Commission.

Proposed § 1102.6(b)(4) would define "Consumer Product Safety Database" as the publicly available searchable information database on the safety of consumer products required to be created and maintained by the Commission.

Proposed § 1102.6(b)(5) would define "harm" as any injury, illness, or death, or any risk of injury, illness or death as determined by the Commission.

Proposed § 1102.6(b)(6) would define "mandatory recall notice" as any notice to the public ordered by the Commission pursuant to section 15(c) of the CPSA relating to action the Commission orders to be taken by any manufacturer, distributor, or retailer about a consumer product.

Proposed § 1102.6(b)(7) would define "manufacturer comment" as a comment made by a manufacturer or private labeler in response to a report of harm received through the public database and transmitted by the CPSC to the manufacturer or private labeler.

Proposed § 1102.6(b)(8) would define "report of harm" as any information submitted to the Commission regarding an incident concerning an injury, illness or death, or any risk of injury, illness or death as determined by the Commission relating to the use of the consumer product.

Proposed § 1102.6(b)(9) would define "submitter of a report of harm" as any person or entity that submits information to the Commission through the database regarding any injury, illness, or death or any risk of injury, illness, or death as determined by the Commission relating to the use of a consumer product.

Proposed § 1102.6(b)(10) would define "voluntary recall notice" to mean any notice to the public relating to a voluntary corrective action taken by a manufacturer in consultation with the Commission where the Commission has notified the public of the manufacturer's voluntary corrective action.

Subpart B – Content Requirements

Proposed subpart B, "Content Requirements," would describe the database's contents. In general, section 6A(b) of the CPSA states that the database must include: (1) reports of harm; (2) information derived by the Commission from notice under section 15(c), and any notice to the public relating to a voluntary corrective action taken by a manufacturer, in consultation with the Commission, of which the Commission has notified the public; and (3) manufacturer comments received by the Commission on a report of harm and requested for inclusion into the database. Proposed §§ 1102.10 through 1102.14 would describe how such reports, information, and comments would become part of the database, and proposed § 1102.16, "Additional information," would discuss information that the CPSC may add to the database when adding such information would be in the public interest. Reports of harm that fall outside the scope of CPSC regulatory authority will be referred to an appropriate agency or entity with notification of such action to the submitter.

1. Proposed § 1102.10 – Reports of Harm

Proposed § 1102.10 would explain who may submit reports of harm in the public database. In brief, proposed § 1102.10(a) would identify those submitters specified in section 6A(b)(1)(A) of the CPSA and provide further clarification for those categories of persons that may fall within each of the identified groups. The list of persons under each group is not exclusive, and the proposed lists are intended to provide a greater understanding of the persons that could fall under each category. For example, "consumers" would include not only users of consumer products, but also family member, relatives, parents, guardians, friends, observers of a consumer product being used by another, and victims. The proposal would add a category of "other" to include

those persons who may not clearly fit within the statutorily identified categories; for example, "other" persons would include, but not be limited to, attorneys, professional engineers, investigators, non-governmental organizations, consumer advocates, consumer advocacy organizations, and trade associations.

Proposed § 1102.10(b) would describe how a report of harm can be submitted to the database. The proposal would describe four methods (internet, telephone, electronic mail, and paper) for submitting reports and when each submission will be construed as being complete. For example, proposed § 1102.10(b)(1) would explain that submitters using the internet will use an electronic form specifically developed to collect the report of harm in the database. As another example, proposed § 1102.10(b)(2) would explain how submissions over the telephone will be accepted and proposed § 1102.10(b)(4) would explain how the Commission will deal with written submissions.

Proposed § 1102.10(c)(1) through (c)(6) would describe the minimum requirements for publication of reports of harm in the database. The proposal identifies the required criteria of information that are referenced in section 6A(b)(2)(B)(i) through (v) of the CPSA and further elaborates on the type of information included under each category. For example, proposed § 1102.10(c)(1) would explain that a description of a consumer product must include a word or phrase sufficient to distinguish a product identified in a report of harm as a consumer product or a component of a consumer product or some other word or phrase to show it is a consumer product or a product or substance regulated by the Commission. This description could include the name (including the brand name) of the product. Other information, such as where the product was purchased, price paid,

model, serial number, date of manufacture (if known), date code or retailer is described as information that would be helpful to the description of a consumer product.

Proposed § 1102.10(c)(2) would describe that a report of harm must contain the identity of the manufacturer or private labeler in order for the report to be published. This section would further explain that the name of any company information sufficient to distinguish an entity will satisfy the minimum identification requirement and that contact information such a mailing address, phone number, or electronic mail address would satisfy the identification requirement.

Proposed § 1102.10(c)(3) would explain that a description of harm should include a narrative that describes the harm or risk of harm. The proposal would contain a nonexclusive list of examples of the types of harm that could be included. The proposal would allow for a description to include a risk of harm where no actual harm occurred. However, this proposed section would also explain that information unrelated to bodily harm or a risk of bodily harm, such as information on cost or quality of a consumer product, will not satisfy the regulatory requirement for a description of harm. Information such as the date on which the harm occurred or manifested itself, the severity of any injury or whether medical treatment was sought is identified as helpful information to include in a description.

Proposed 1102.10(c)(4), (5), and (6) would describe the minimum requirements for contact information, verification, and consent of the report of harm by the submitter. For contact information, the proposed §1102.10(c)(4) would require that a submitter of a report of harm provide his or her first and last name and a mailing address as required contact information for the report to be published. The proposed rule would explain that

submitters of reports of harm also may provide other contact information, such as an electronic mail address or a telephone number, but that such information is not required in order to publish the report.

Proposed § 1102.10(c)(5) would explain that submitters must verify the report of harm for publication and the verification statement follows the statutory outline. Verification would involve a submitter of a report of harm affirmatively agreeing that he or she has reviewed the information submitted in a report of harm and the check the box for verifying the information the report contains.

Proposed § 1102.10(c)(6) would explain that that submitter of a report of harm must consent to inclusion of the report of harm in the database in order for the report to be published. If no consent is provided by the submitter the report will not be published.

Proposed § 1102.10(d) would describe the information that will not be published in the database including the name and contact information of the submitter or a report of harm; the victim's name and contact information (if provided), photographs depicting a person or injury because of privacy concerns or because the Commission has determined that they are not in the public interest; medical records, confidential information; materially inaccurate information and any other material submitted on or with a report of harm that the Commission determines is not in the public interest to publish. This proposed section would identify criteria and explains that the public interest determination will be based on the criteria relating to whether or not the information helps database users to identify a consumer product; identify the manufacturer or private labeler of a consumer product; understand the risk of harm related to the use of a

consumer product, or understand the relationship between the submitter of a report of harm and the victim.

Proposed § 1102.10(e) would state that reports of harm submitted by persons under the age of 18 must include the consent of the parent or guardian of that person. The rationale for requiring consent on reports by a minor is premised on the notion that age of legal consent in many jurisdictions is 18. Review of a report or harm by a parent or guardian will also ensure that information about a harm or risk of harm is being disclosed publicly with the parent's consent addressing concerns related to privacy of such information. Further, if a parent or guardian reviews the report consent may also improve the accuracy of the information the report contains.

Proposed § 1102.10(f) would explain that information received related to a report of harm will be maintained for appropriate Commission use.

2. Proposed § 1102.12- Manufacturer Comments

Proposed § 1102,12(a) would state that manufacturers or private labelers who receive a report of harm transmitted from the CPSC may submit comments. Proposed § 1102.12(b) would propose that comments may be received via a proposed online manufacturer portal where the manufacturer can register to submit comments on a secure non-public portal that will be provided through the Commission's internet. The proposal also would specify that comments may be submitted via electronic mail or regular mail directed to the Commission's Office of the Secretary.

Proposed § 1102.12 (c)(1) through (c)(4) would specify that the Commission will publish a manufacturer's comments related to a report of harm if the comment specifically relates to a report of harm transmitted from the Commission, contains a

unique identifier assigned to it, contains the manufacturers verification of the truth and accuracy of their comment (similar to the verification required of a submitter of a report of harm) as well as their consent for publication in the database. The proposed rule would require a manufacturer to affirmatively request that its comment be published and to affirmatively consent to such publication in order for the manufacturer comment to be published in the database.

Proposed § 1102.12 (d) would explain that the Commission will publish a manufacturer's comments and the date such comments are submitted to the CPSC in the database.

Proposed § 1102.12(e) would explain that the Commission will not publish the actual consents and verifications obtained from the manufacturer for such publication.

3. Proposed § 1102.14 – Recall Notices

Proposed § 1102.14 would state that information in a voluntary or mandatory recall notice will be made accessible and searchable to the public in the database.

4. Proposed § 1102.16 – Additional Information

Proposed § 1102.16 would describe the criteria to be used to determine any additional information that will be published in the database consistent with the requirements of section 6(a) and (b) of the CPSA. The proposed criteria would focus the inquiry of the addition of other information in the database on whether or not the additional information would enable database users to understand a risk of harm or a harm related to any use of a consumer product; identify a consumer product; or identify a manufacturer or private labeler related to any use of a consumer product.

C. Subpart C – Procedural Requirements

Proposed subpart C, "Procedural Requirements," would describe the procedural requirements set forth in section 6A(c) of the CPSA related to the manufacturer notification and transmission. This proposed subpart would explain the procedural requirements for CPSC transmission of reports of harm to an identified manufacturer or private labeler; a description of the opportunity for comment by the manufacturer or private labeler identified on reports of harm; how designations of confidential information should be submitted and the criteria for how they will be reviewed; how materially inaccurate information should be designated and what the Commission will consider in reviewing any such claim both before and after posting a report of harm in the database; the timing of posting reports of harm in the database; and the timing and posting of manufacturers comments in the database.

1. Proposed § 1102.20 – Transmission of Reports of Harm to Identified Manufacturer or Private Labeler

Proposed § 1102.20 would explain what information in a report of harm will and will not be transmitted to a manufacturer or private labeler. As set forth in section 6A(b)(2)(B) of the CPSA, the name and contact information of the submitter will not be transmitted to a manufacturer or private labeler unless the submitter of a report of harm provides consent to transmit this information. The proposed rule also would prevent transmission of any photographs submitted with the report of harm unless the submitter specifically consents and further explains that medical records will not be provided without explicit consent from the person to whom such records pertain, or his or her parent, guardian or legally authorized representative.

Proposed § 1102.20(b) would describe the limitation on use of contact information by a manufacturer or private labeler. The proposed regulatory text would incorporate the limitation in section 6A of the CPSA on the use of submitter contact information by the manufacturer for any purpose other than verification of information contained in a report of harm. The proposed rule would describe activities that will not be considered as verification including sales, promotion, marketing or warranty activities or activities relating to a commercial purpose of the manufacturer. The proposal also would describe what is considered a verification purpose by relating the statutory criteria required for a report of harm to be published. For example, proposed § 1102.20(b)(1) through (b)(4) would explain verification could be related to the identity of the requester; the consumer product including name, serial or model number; the harm or risk of harm described in the report of harm; and/or a description of the incident related to the use of the consumer product.

Proposed § 1102.20(c) would explain the timing of transmission of reports of harm to the manufacturer. The proposal would adopt the statutory language that the reports will be transmitted to the manufacturer to the extent practicable within five business days after the Commission receives a completed report of harm. The proposal would identify circumstances where transmission of a report of harm to the manufacturer within five business days may be impracticable. The circumstances include: where the identified manufacturer or private labeler is out of business with no identifiable successor; the submitter misidentified the manufacturer or private labeler; the report of harm contained inaccurate or insufficient information for identification of a manufacturer

or private labeler or when the Commission cannot locate valid contact information at all for a manufacturer or private labeler.

Proposed § 1102.20(d) would describe a method for transmission of reports of harm to a manufacturer or private labeler based on registration by the manufacturer or private labeler in the online manufacturer portal. The proposal also would explain that a manufacturer or private labeler who has not registered for electronic transmission will receive reports of harm through the United States mail to a firm's principal place of business.

Proposed § 1102.20(e) would describe the process of manufacturer registration and explains that registrants can select a preferred method for receiving reports of harm in the database. The proposal would require that a manufacturer or private labeler provide updated contact information [specify how often/] and allows the registrant to select a specific method to receive reports of harm.

2. Proposed § 1102.22 –Manufacturer or Private Labeler Comment

Proposed § 1102.22 would explain that a manufacturer or private labeler may comment on information received about a report of harm. The proposal would allow the Commission, in its discretion, not to publish a manufacturer comment to the database that is received more than one year after transmission of the report of harm to the manufacturer or private labeler where it would not be in the public interest to do so. The proposal also would allow the Commission to limit the data size of comments, which may include attachments submitted where such comments and attachments may negatively impact the technology performance of the system.

3. Proposed § 1102.24 – Designation of Confidential Information

Proposed § 1102.24 would explain how the Commission will define "confidential information" and would set forth criteria which must be followed to assert a claim of confidentiality. The Commission notes that most reports of harm received from consumers will not likely contain confidential information. However, where such a claim for a portion of information on a report of harm is asserted, the proposal would require affirmative statements that would assist the Commission in an evaluation of the of the merits of the request.

Proposed § 1102.24(a) would interpret the terms "confidential information" in a manner similar to that in section 6(a) of the CPSA. The proposal would establish parameters for asserting and supporting a claim of a portion of a report of harm as confidential; these parameters follow closely the Commission's practice and procedure for such assertions in a FOIA context.

Proposed § 1102.24(b) would explain that a manufacturer may designate portions of information contained in a report of harm as confidential and would describes, at paragraphs (b)(1) through (b)(6), the statements required to support the claim of confidential information. If these statements are missing from any request, the Commission will consider the request to be incomplete and unsupported. For example, proposed § 1102.24(b)(1) would explain that a manufacturer or private labeler is required to specially designate those portions or the report of harm asserted to confidential. Proposed § 1102.24(b)(2) would require information on whether the asserted confidential portion of a report has ever been released to any person who was not an employee or in confidential relationship with the manufacturer or private labeler. Proposed § 1102.24(b)(3) would require an explanation on whether the asserted confidential portion

of the report is commonly known or readily ascertainable by outside persons with a minimum of time and effort. Proposed § 1102.24(b)(4) would require the manufacturer to explain the relationship, if any, between the submitter of the report of harm and the manufacturer or private labeler and how the submitter could have come into possession of such confidential information. Proposed § 1102.24(b)(5) would explain that manufacturer also must support a confidentiality claim by describing how release of the information could cause competitive harm. Any portion of information in a report of harm designated by a manufacturer to be confidential but lacking in the statements and information in section §1101.24 (b)(1) through (b)(6) will not be considered confidential.

Proposed § 1102.24(c) would describe manner of submission for portions of report of harm where confidentiality is asserted for a designated portion of a report of harm. This proposal would allow submission of a confidentiality in the same manner as manufacturer comments described in proposed § 1102.12(b) and would require the requests to be conspicuously labeled.

Proposed § 1102.24(d) would explain that a request for confidential treatment be made at any time after CPSC transmission to the manufacturers of a report of harm.

Proposed § 1102.24(e) would explain that a request for confidentiality should only be made by those who intend in good faith to assist in the defense of confidentiality by the Commission in any later judicial proceeding that could be sought to compel disclosure. This provision is similar to one found in the Commission's FOIA regulations concerning the assertion of confidentiality. The assertion of confidentiality must be legitimate, and the Commission believes that this provision requires firms to stand behind

their assertion where the Commission is being sued to protect a firm's confidential information.

Proposed § 1102.24(f) and (g) would describe the procedure to notify the manufacturer or private labeler of determinations on the claim of confidentiality. Proposed § 1102.24(f) would state that, if a portion of a report is deemed confidential, the Commission will notify the manufacturer or private labeler, redact the information deemed confidential, and publish the report of harm as redacted in the database.

Proposed §1102.24(g) would state that, if a portion of a report is not deemed confidential, the Commission will notify the manufacturer or private labeler of the Commission's determination and will publish the report of harm in the database.

Proposed § 1102.24(h) would explain the right of a manufacturer or private labeler to sue in the appropriate United States District Court to seek removal of alleged confidential information published in the Consumer Product Safety Database.

4. Proposed § 1102.26 – Designation of Materially Inaccurate Information

Proposed § 1102.26 would contain definitions and process for how claims of materially inaccurate information contained in reports of harm and manufacturer comments may be asserted and how they will be evaluated. Section 6A(c)(4) of the CPSA addresses materially inaccurate information in a report of harm as well as in a manufacturer's or private labelers comments.

Proposed § 1102.26(a)(1) would define "materially inaccurate information in a report of harm" as information that is inaccurate or misleading in a relevant and sufficiently significant way such that it creates or has the potential to create substantial confusion among database users. This proposed definition would tie the "substantial

confusion" element to required information in a report of harm, such as the identification of a consumer product, the identification of a manufacturer or private labeler, or the harm or risk of harm related to the use of the consumer product.

Proposed §1102.26(a)(2) would define "materially inaccurate information in a manufacturer comment" similar to the definition as used in a report of harm. This provision would explain such information as information that is inaccurate or misleading in a relevant and sufficiently significant way such that it creates or has the potential to create substantial confusion among database users. This proposed definition would tie the "substantial confusion" element to information in a manufacturer or private labeler comment that creates confusion about: (a) the nature, scope, liability or cause of a harm or risk of harm related to the use of a consumer product; (2)the status of a Commission, manufacturer, or private labeler investigation; (3) the identity of the firms responsible for importation and distribution and sale of a consumer product; (4) information about the corrective action that manufacturer or private labeler is engaging in when such corrective action has not been approved by the Commission; or (5) confusion in a comment about whether the manufacturer has taken or promised to take any other action with regard to the product.

Proposed § 1102.26(b) would allow any person or entity to request that a report of harm or manufacturer comment or portions thereof be excluded from the database or corrected by the Commission because such report or comment contains materially inaccurate information as defined in proposed § 1102.26(a). This section would require, at paragraphs (b)(1) through (b)(7), the statements required in order to support the claim

of materially inaccurate information. If these statements are missing from any request, the Commission would consider the request to be incomplete and unsupported.

Proposed § 1102.26(c) would explain the manner of submission for manufacturers and private labelers and all other requesters. This would allow manufacturers to submit a claim in the same manner as a comment submitted and would allow all other requesters to submit via electronic mail or written submission directed to the office of the Secretary.

Proposed § 1102.26(d) would allow submission of a request for a determination at any time and would allow the Commission to withhold a report of harm or comment from publication in the database until it makes a determination.

Proposed § 1102.26(e) would explain that a request for material inaccuracy should only be made by those who intend in good faith to assist in the defense of material inaccuracy by the Commission in any later judicial proceeding that could be sought to compel disclosure. This provision is similar to one found in the Commission's FOIA regulations concerning the assertion of confidentiality. The assertion of material inaccuracy must be legitimate and the Commission believes that this provision requires those seeking such a determination on information in a report of harm or manufacturer or private labeler comment to stand behind their assertion where the Commission is being sued to compel disclosure of such information.

Proposed § 1102.26(f) would describe the notice procedure the Commission will follow to notify the person or firm requesting a determination regarding materially inaccurate information of its determination *and* method of resolution after resolving such request.

Proposed § 1102.26(g) and (h) would outline the steps the Commission will take where it has made a determination of material inaccuracy. Proposed § 1102.26(g) would address a Commission determination where information in a report of harm or comment has not been published and would explain that the Commission may: (1) decline to add the report of harm or manufacturer comment to the database; (2) correct the materially inaccurate information; or (3) add information to the report of harm to correct the materially inaccurate information.

Proposed § 1102.26(h) would address a Commission determination where information in a report of harm or comment has been published and would explain that the Commission may, after an investigation, determine that information in a report of harm or manufacturer comment contains materially inaccurate information. The proposal would explain that the Commission may, within seven business days of such determination: (1) remove the report of harm or manufacturer comment from including any attachments from the database; (2) correct the materially inaccurate information and if other minimum requirements for publication are met maintain the comment or report of harm in the database; or (3) add information to the report of harm or comment to correct the materially inaccurate information and if other minimum requirements for publication are met maintain the comment or report of harm in the database.

Proposed § 1102.26(i) would state that the Commission's policy with respect to removing, correction, or adding information to correct materially inaccurate information is to preserve the integrity of the information received for publication in the database and that the Commission will favor correction and addition to correction over exclusion of reports in the database.

Proposed § 1102.26(j) would explain that the Commission will notify the requester and publish the report of harm or manufacturer comment (if not already published) if it meets the minimum requirements.

Proposed § 1102.26(k) would provide the Commission the discretion to review a report of harm or a manufacturer comment for materially inaccurate information on its own initiative following the same notices and procedures set forth in (g) through (j).

5. Proposed § 1102.28 – Publication of Reports of Harm

Proposed § 1102.28 would explain that reports of harm will be published in the database as soon as practicable, but no later than 10 days after such report of harm is transmitted by the CPSC to the manufacturer or private labeler. This provision would explain that reports may be published beyond 10 day time frame when the report of harm misidentifies or fails to identify all manufacturers or private labelers. The information would have to be corrected through the procedures for materially inaccurate information at proposed § 1102.28.

6. Proposed § 1102.30 – Publication of Manufacturer Comments

Proposed § 1102.30 would explain that the Commission will publish manufacturer comments would meet the minimum requirements in proposed § 1102.12(c) at the same time as a report of harm is published or as soon as practicable thereafter. The proposal would provide examples of circumstances which may make it impracticable to publish a manufacturer comment: (1) the Commission did not receive the comment until on or after the publication date of the report of harm or the Commission is resolving a claim that the manufacturer comment contains materially inaccurate information.

D. Subpart D – Notice and Disclosure Requirements

This subpart would contain information on the disclaimers that will be part of the database and any information viewed on it and well as the applicability of section 6(a) and (b) of the CPSA.

1. Proposed § 1102.42 - Disclaimers

Proposed § 1102.42 would set forth the type of disclaimer that will be used on the database and documents generated from it. This provision would require that the disclaimer be prominently and conspicuously displayed and that it be transmitted on any documents that are printed from the database.

2. Proposed § 1102.44 – Applicability of section 6(a) and (b) of the CPSA

Proposed § 1102.44(a) would explain that section 6(a) and (b) of the CPSA do not apply to the submission, disclosure, and publication of information provided in a report of harm. Proposed § 1102.44(b) would apply section 6(a) and (b) of the CPSA to information received by the Commission pursuant to section 15(b) of the CPSA and to information received by the Commission pursuant to any other voluntary or mandatory reporting program established between a retailer, manufacturer or private labeler.

IV. Comments on the Publicly Available Database and CPSC's Responses

We describe and respond to significant issues raised by the comments. To make it easier to identify comments and the Commission's responses, the word "Comment" will appear before each comment description, and the word "Response" will appear before the Commission's response. We have grouped comments based on their similarity and have numbered the comments to help distinguish between different comment themes.

The number assigned to each comment summary is for organizational purposes and does not signify the comment's value, importance, or order in which it was received.

Subpart B—Content Requirements

Section 1102.10: Reports of Harm

1. CPSC asked whether any category of persons should be excluded from submitting reports of harm for inclusion in the public database, and, if so, by what means.

Comments (Summary 1)

Two commenters responded that no category of persons should be excluded from submitting reports of harm. Another commenter responded that third party submitters may be one or more degrees separated from the events involved in a report and encouraged CPSC to consider how this might affect assessment of information that could be materially inaccurate. This commenter suggested that there should be transparency regarding relationships surrounding reports and the person filing the report. One commenter stated that anonymous reports should not be published since they cannot be verified. Two commenters proposed that only reports from those groups specified in Section 6A(b)(1)(A)(i)-(v) should be considered for inclusion in the database, and the Commission should clearly and narrowly define these categories. One commenter suggested that the report form should ask submitters to identify to which group under 6A(b)(1)(A)(i)-(v) they belong. This commenter suggested that the CPSC should have a method for verifying that those filing reports are who they say they are. To assist in this, the commenter suggested that the CPSC should encourage submitters to consent to their contact information being shared with the manufacturer or private labeler.

Response

We note the breadth of the entities listed in the statute and concludes that the list is intended to be non-restrictive. Accordingly, we recommend that, except for information collected through the National Electronic Injury Surveillance System (NEISS), which is information collected by selected hospital emergency rooms, and except for information collected through Death Certificates, all reports of harm (or "incident reports") related to use of a consumer product or other substance regulated by the Commission, be collected through the same incident report form, regardless of who is submitting the report of harm, and deposited into a central data warehouse for such information.

We recommend that product-related incident information be collected from all sources, including anonymous sources, but that only those reports that meet the statutorily required minimum information as set forth in the statute be published for review and access in the publicly-searchable portion of the database.

We concluded that a completed report for posting in the Public Database include verification of information submitted and consent to submitter's contact information being shared with the manufacturer or private labeler.

2. CPSC asked whether reports of harm submitted by telephone or paper should meet the same statutory time frames for submission in the public database.

Comment (Summary 2)

CPSC received 5 comments, including 2 from the same commenter, responding that regardless of the means of transmission, all reports of harm should adhere to the same statutory time frames for submission in the public database.

Response

We conclude that in order to be included in the Public Database, all reports of harm, regardless of how they are received by the Commission, must meet certain minimum requirements, which includes, among other things, that reports be verified by the submitter for accuracy and that the submitter consent to inclusion of the report in the Public Database. We recommend that paper submissions which do not follow the incident report form being developed for the CPSC web site, be returned to the submitter for further completion, verification and consents.

We recommends that the "not later than five business days" time frame for notifying a manufacturer or private labeler of a report of harm involving one of its consumer products will not start to run until the CPSC receives a verified report of harm from the submitter of the report of harm.

3. CPSC asked what a description of the consumer product should entail and why.

Comment (Summary 3)

For the most part, all of the commenters responded that some combination of the following would provide a description of the consumer product: brand name, category of product (using an auto-fill function or drop-down menus), model number, serial number, and a text description of the product. One commenter responded that the brand name (incl. "unknown"), category of product (auto-fill list), model number, serial number, serial/series number/code, manufacturer's identification, the date the item was purchased, where the item was purchased, country of origin, manufacturer/distributor/private labeler name, UPC code, and a text description of the product should be included. Two commenters suggested that industry should be encouraged to provide CPSC with product-identification information that can be incorporated into the database because the

greater the specificity in product identification, the greater the ability CPSC and manufacturers to identify trends and patterns in the reports it receives. Three commenters suggested that the database should permit submitters to upload photos and/or supporting documentation of the products related to the incident. One commenter suggested that CPSC should work with stakeholders to develop guidelines as to types of photos and/or supporting documentation that would and would not be permitted to be included in database.

Response

We agree with the majority of the comments and have begun incorporating many of the recommendations into the development of the Public Database. The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The Incident Report form is being designed to provide on-line help to assist submitters with locating the product identification information such as brand name, model number, manufacturer name, and manufacture date code. The staff explored the feasibility of collecting detailed product identification information from the industry but ultimately decided that given the pace of change and dynamic nature of the consumer product universe, central maintenance of such information would be infeasible.

The Incident Report will allow submitters to attach photos and other approved file formats to supplement their report.

4. CPSC asked what contact information must be provided, at minimum, to meet the statutory requirement for inclusion in the database.

Comment (Summary 4)

All of the commenters agreed that a submitter should provide a name and address. Some of the commenters suggested that submitters should have to provide a telephone number and/or an email address as a secondary means of contact. One commenter also stated that when submitted online, the submitter should be asked to submit e-mail address, and that when submitted via telephone, the submitter should be asked to provide telephone number, but that submitters should be encouraged to submit phone number and/or e-mail address regardless of the method of submission. This commenter also stated that if a report is made on behalf of minor, the info provided should be provided for the parent or guardian of that minor.

Response

We recommends that the minimum contact information that must be provided by a submitter of a report of harm for inclusion in the Public Database be the submitter's first name, last name, and complete mailing address. Additionally, submitters will be strongly encouraged to enter an email address and/or a telephone number for follow-up purposes. We also recommend that minors under the age of 18 not be allowed to submit a report of harm to the Public Database without the consent of a parent or guardian as the named contact person.

5. CPSC asked how the report form should address the issue of the submitter's verification of the information submitted.

Comments (Summary 5)

All of the commenters agreed that submitters should have to take affirmative steps to verify the accuracy of the submission. One commenter suggested that verification and consent should be obtained separately (e.g., two separate questions) and that the CPSC should employ a procedure similar to that currently utilized by the Clearinghouse wherein a completed report of harm and verification would be mailed to the consumer which the consumer would then mail back. This commenter also suggested that the CPSC should consider sending an automated verification message to the submitter's e-mail address when submitted online, as this would allow the submitter to review the report, and require the submitter to respond to the message to verify the report and consent to its inclusion in database. Reports submitted by telephone should receive the submitter's verification and consent in writing, as per the current Clearinghouse procedure.

However, one commenter suggested that submitters who provide their reports via telephone should be able to verify truth and accuracy of statements over the telephone with CPSC staff. The same commenter proposed that unconfirmed or anonymous reports should, minimally, affirmatively acknowledge verification.

Response

We recommend that for each incident report submitted on-line, the submitter be prompted to affirmatively check a box indicating that they have reviewed the report and that they are verifying that the information contained in the report is true and accurate to the best of their knowledge. This same or similar statement mechanism will appear on

email and paper-based forms for verification purposes, although the paper-based form may also require the submitter's signature. We recommend that in the case of telephone submissions, CPSC mail or email the completed form to the submitter for review and verification, including requiring the submitter's verification.

6. CPSC asked how the report form should address the submitter's consent for: (i) inclusion in the public database; and (ii) release of contact information to the manufacturer or private labeler, and whether there were any other issues related to the user's consent that the CPSC should consider.

Comment (Summary 6)

All of the commenters on this issue suggested that CPSC should utilize simple check boxes on the report form. Specifically, one commenter proposed that consent for inclusion should be required but release of contact information should be optional. This commenter also stated that the report form should clearly state that contact information will not be released to the public. This commenter also suggested that next to the check box for release of contact information to the manufacturer, the report form should include a statement that CPSC encourages consumers to cooperate with investigations.

Response

We recommend that Consent of release of information be obtained separately from verification. The staff recommends the following Consents be obtained separately on the form: consent to include information in the Public Database; consent to release of contact information to the manufacturer or private labeler; and, for requests received through FOIA, consent to release contact information to the general public.

7. CPSC asked what, if any, measures should the agency employ to prevent the submission of fraudulent reports of harm while not discouraging the submission of valid reports.

Comments (Summary 7)

All of the commenters on this issue expressed concern about the prevention of fraudulent reports of harm. Several commenters suggested a check box function expressly certifying the accuracy of the information in the report of harm but with reminders of the implications for submitting fraudulent or inaccurate information.

Two commenters were concerned about web-based robots spamming the database, and one suggested a security feature similar to those used on ticket websites (e.g., requiring user to type combination of letters and numbers appearing on screen) to ensure that an automated "robot" is not spamming the database with bogus info. One commenter suggested that submitters should be required to affirmatively include a verification statement in narrative format as part of their description of the incident. One commenter stated that CPSC should have method of verifying that submitter is who they say they are and not a competitor, interest group, or other motivated to "salt" the database, and that CPSC should run system checks to see whether multiple reports are received from same person.

Response

We agree that preventing fraudulent reports is a high priority in the development of the Public Database. The development team has incorporated the following to address the issue. In the new Incident Report form, the user must check a box that indicates they certify their incident report to be true and accurate to the best of their knowledge. This

screen captures "Verification by Submitter" as one of the five types of information required by CPSIA, at a minimum, to publish incidents of harm in the Public Database. Once the "certify" box is checked, the "Submit" button becomes available at the bottom of the screen. The user clicks the "Submit" button to officially submit their incident report to the CPSC.

The database implementation team is working closely with the enterprise information security team to ensure the system utilizes industry best practices as well as complies with Federal and CPSC specific security requirements. We are considering implementation of CAPTCHA[1] types of challenge-response tests to ensure that the incident report form is not being generated by a computer. We will also examine technical options to detect if multiple reports are submitted from the same IP address.

8. CPSC asked whether the agency should design the online reporting form to ensure the capture of data that can be used in scientific statistical analysis and, if so, how.

Comments (Summary 8)

Two commenters agreed that the database could facilitate statistical analysis, stating that the data could be used to calculate incident rates, identify emerging hazard trends, improve CPSC's ability to identify risks and respond quickly, determine the effectiveness of safety standards and regulations, and further CPSC's IT modernization plan. One commenter responded that the database would not support the use of the data for scientific statistical analysis because of concerns regarding the validity of the data.

Response

We are designing database reporting options into the system that will enable public users to extract data sets of published incident report information. The extracted fields on

[1] Completely Automated Public Turing test to tell Computers and Humans Apart.

these reports may be user-defined and exportable in a variety of standard file formats that will enable use with popular data analysis tools.

9. CPSC asked whether the report form should contain links to outside websites and, if so, why.

Comments (Summary 9)

CPSC received four comments in response to this question and all agreed that linking to outside websites could be problematic. Some commenters agreed that links could be helpful if such links were relevant to the product or complaint.

Response

We agree with these comments and conclude that the report form should not contain links to outside, non-CPSC websites at this time.

10. CPSC asked how the agency should design the report form so that it is clear and easy for users to complete.

Comments (Summary 10)

Many of the commenters agreed that for ease of use the report form should contain as many drop-down menus, pop-up windows, help features, reminders, and auto-fill fields as possible and/or that required fields should be marked with an asterisk. Some commenters felt that the database should distinguish (statutorily) required fields from optional fields. Some commenters felt that the database should have as few required fields as possible, but provide additional fields that can be filled in if the submitter so chooses. Some commenters suggested it could be useful to allow narrative responses when seeking a description of a product or incident. Others provided more basic suggestions for the design of the report form, such as the report form should use a large,

easy-to-read font and language. In addition, one commenter suggested that CPSC should provide easy access to information about the database, including its purpose, its potential uses, and a guide on how to access information in the database and should include CPSC contact information, such as e-mail address and phone number, in plain sight for users who need assistance with the database. One commenter proposed that submitters should have the option to review and edit the submission at any point in the process of filling out the report form.

Response

We agree with these comments and are incorporating many of the recommendations in the Public Database. The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The Incident Report form is being designed to provide on-line help to assist submitters with locating the product identification information such as brand name, model number, manufacturer name, and manufacture date code. The staff explored the feasibility of collecting detailed product identification information from the industry but ultimately decided that given the pace of change and dynamic nature of the consumer product universe, central maintenance of such information would be infeasible.

The form will also inform the user about the purpose, use, and how the collected information will be protected.

11. CPSC asked how the agency could ensure the accuracy of submitted data, from a system design perspective.

Comments (Summary 11)

Two commenters suggested that a report of harm be assigned a unique identifier. One commenter suggested that a report of harm could utilize two unique identifiers, one viewable in the public database and one viewable only to submitters, manufacturers or private labelers, and the CPSC for the purposes of collecting further information regarding a report of harm. One commenter suggested that anyone submitting a report of harm should be required to provide contact information. Submitters should be asked to create a user ID and password tied that can be linked to each report submitted by the user. One commenter suggested that a submitter should identify to what group they belong when filing a report of harm; for example, consumer, government agency, or health care professional. Several commenters suggested the use of drop-down menus and/or auto-fill features for as many categories of information as possible throughout the report form to assist submitters in providing complete and accurate information. For instance, one commenter suggested using hazard codes similar to those used in the NEISS database and brand names using data already in CPSC's other databases, and creating a registry for manufacturers and others to provide their contact information. One commenter suggested unlimited free text incident descriptions. One commenter also suggested including data fields on the report form for CPSC-validated data as well as manufacturer/private labeler comments.

One commenter suggested allowing submitters to amend reports of harm as well as allowing manufacturers to submit comments for publication after the report of harm has been published. This commenter also suggested maintaining an audit trail every time report is modified. One commenter stated that claims of material inaccuracy should be focused on the submitter and identification of the consumer product, and not on the reported problem with the consumer product. This commenter suggested that reports of hard should not be blocked, removed, or otherwise flagged when a manufacturer makes a claim of material inaccuracy.

Response

We have incorporated many of these suggestions into the system design. Each report will have a unique identifier number.

The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

We are developing a process to identify, confirm, and register companies that wish to use the online manufacturer portal that is being designed to facilitate communicate between CPSC and manufacturers. Manufacturer registration, contact/account management, e-mail communication, and ability to flag information are all functionalities being considered for the portal. Manufacturers will be able to choose their preferred method of communication (email or postal mail) with the CPSC. Manufacturers will designate a Point of Contact within their organization to receive notification from the CPSC. An audit trail will be maintained for all changes made in the system.

The incident report form was designed with the minimum number of required fields, marked by an asterisk, while encouraging user to supply additional information. For example, only after the users selects the option of posting the incident report to the public database does the system checks for the five required statutory elements of a complete incident report. The user is encouraged but required to register with an email and password. We recommend making the user's contact information optional for submitting an incident to the CPSC and a requirement for posting the incident report in the public database.

12. CPSC asked what the agency could do to ensure the ongoing and perpetual integrity of submitted data, from a system design perspective.

Comments (Summary 12)

Two commenters suggested that CPSC should use software "filters" to sort out redundancies and multiple submissions from the same source and to group multiple discrete reports for the same problem.

One commenter suggested that the CPSC publish the data in pdf format or other format not capable of manipulation. One commenter stated that CPSC should ensure the database is a closed-loop that allows for feedback on, and modification of published data. Two commenters agreed that the database should allow for the ability to remove falsified or erroneous data. One commenter proposed that manufacturer/private labeler's comments be aligned with, and published simultaneously with, the report of harm. One commenter suggested that CPSC could generate notices, and/or seek comments, in relation to events that could occur with reports of harm, such as closure, retention time, and/or archiving. Another commenter believes that information should remain in the database indefinitely. One commenter also stated that CPSC should provide notice to database users on every page, including printed copies, that the agency does not guarantee the accuracy, completeness, or accuracy of the database, and that printed pages should bear a date to reduce confusion between versions of reports. One commenter stated that CPSC should establish guidelines for agency staff or contractors who will be interacting with the database. One commenter proposed that any changes to the database should require ample public notice and accommodate new data in ways that will not alter prior data structures.

Response

The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library,

which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes.

The system will feature tools for CPSC to perform redundancy and de-duplification functions. The public database will feature prominent notice that the agency does not guarantee the accuracy, completeness, or adequacy of the contents of the database.

13. CPSC asked how the agency should address incomplete reports of harm, from a system design perspective.

Comments Summary (13)

CPSC received a variety of comments in response to this question. Some commenters suggested that incomplete reports of harm (i.e., those lacking the requisite minimum info) should not be included in the database and/or submitters should be cued via an auto-reminder function when required fields are incomplete. Other commenters proposed that CPSC should accept forms with incomplete info and/or seek to fill gaps through further research. Two commenters suggested that the CPSC can and should, if appropriate, act on information in these submissions.

Response

We are designing the system to prompt the submitter when the required information for inclusion in CPSC's Public Database has not been completed. In addition, staff recommends including language in the Public Database to encourage submitters to complete the minimally required information for inclusion in the Public Database.

Although incomplete reports will not be published in the Public Database, we recommend that incomplete reports be stored for appropriate Commission use.

14. CPSC asked whether the report form should check for inaccurate information and, if so, how.

Comments (Summary 14)

One commenter responded that the CPSC need not check for inaccurate information if it utilizes a security feature such as those that require a user to type a combination of letters and numbers appearing on screen. Another commenter suggested that in order to check for inaccurate information, e-mail addresses could be validated for proper format and against illegitimate use, database fields could be validated (e.g., system check for blank fields, etc.), and by the use of drop-down menus to accurately link a manufacturer to a brand and vice versa.

Response

We agree with these recommendations. One of the security features under consideration is using CAPTCHA types of challenge-response tests to ensure that the incident report form is not being generated by a computer. The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

15. CPSC asked what means the agency could employ to ensure that the correct manufacturer and/or private labeler is identified in a report of harm.

Comments (Summary 15)

One commenter suggested that the following information would aid in identifying the product and the manufacturer: brand name, product name, type of product, model number or name, serial number (if available), product description, and product age. Another commenter suggested the use of drop-down menus in order to accurately link manufacturers to products and vice versa.

One commenter suggested that CPSC should rely on the manufacturer to confirm their identity in relation to the product identified in the report of harm. This commenter also suggested that CPSC allow companies to register their contact information with CPSC in order to minimize agency resources. This commenter also proposed that retailers be treated similarly since retailers oftentimes have as much product information as manufacturers, if not more.

Response

The Incident Report input screens being developed incorporate auto-fill functions, drop-down menus, and text fields where appropriate. For example, an auto-fill function will be provided for brand name, model name or number, manufacturer name, retailer name, and similar fields based on information we have collected in our database library, which will grow over time. Drop-down menus will be used for fields such as product category and type; injury severity, type, and location; and state and country codes. Text fields will be available for incident description and product description.

The system will utilize drop-down menus where possible to ensure data quality. The system will perform quality checks including, but not limited to, email address format, blank fields, invalid data format (characters in a number field), and state and zip code match.

We explored the feasibility of collecting product identification information from the industry to link manufacturers to products and ultimately recommends that manufacturers maintain that information to provide better data quality and consistency. One key piece of relevant feedback received from manufacturers during the staff workshop was that manufacturers themselves often have difficulty keeping their model/product database accurate and up to date. Having CPSC maintaining a copy of this information would introduce additional complexity and risk.

We agree with comments regarding company registration and is developing a process to identify, confirm, and register companies.

16. CPSC asked what, if any, instructions to users should be included on the report form.

Comments (Summary 16)

Some commenters suggested that the instructions should be simple, identify all required information, and/or state that form cannot be processed without required information.

Some commenters suggested that the report form contain pop-up boxes or links providing more detailed explanations of type of info sought. Other commenters suggested that the report form should notify submitters when required fields are left blank.

Three commenters proposed that the report form should instruct the submitter to answer questions as thoroughly and completely as possible, as well as of the importance of providing full and complete information, and/or instruct submitters to reference documents associated with the purchase and use of the product while filling out the form.

One commenter proposed that the report form should indicate what information is required to make a report of harm eligible for inclusion in database.

One commenter suggested that the report form should include a clear explanation of the privacy protections of the submitted information and the importance of these reports to the CPSC. This commenter suggested that the report form should be clear to consumers that they have the right to decline consent to sharing their contact information with the manufacturer and that doing so does not affect the ability of a report to be published.

Several commenters proposed that the instructions on the report form should inform the submitter of the benefits of allowing the manufacturer to contact them to verify the report and also encourage submitters to do so. One commenter proposed the following script be included on the report form:

> "Manufacturers sometimes find it helpful to speak directly with consumers to investigate safety issues and obtain information regarding reported incidents with their products. May we disclose your name and contact information to the manufacturer or private labeler?"

Another commenter suggested that if a submitter declines to share contact information with a manufacturer, there should be a field indicating as much on the report form. Other commenters felt that the submitters should be provided with this option but without bias, allowing consumers to make their own choice.

Response

We agree with the comments regarding making the form simple and easy to use. The Incident Report form will provide on-line help to assist submitters with locating the product identification information such as brand name, model number, and manufacture

name and date code. We explored the feasibility of collecting product identification information from the industry and ultimately recommend that having manufactures maintain that information will provide better data quality and consistency.

The form was designed with the minimum number of required fields, marked by an asterisk, while encouraging user to supply additional information. For example, only after the users selects the option of posting the incident report to the public database does the system checks for the 5 required statutory elements of a complete incident report. The form will also inform the user about the purpose, use, and protection of information being collected by the CPSC and how the manufacturer might use the information provided should he or she choose to release it to the manufacturer.

Section 1102.10: Reports of Harm (additional comments)

CPSC received a number of additional comments not in response to any particular question but related to the overall issue of Section 1102.10 "Reports of Harm."

Comments

Several commenters stated that the scope of database is limited to reports of harm and not to reports relating to general product quality, service issues, or other types of quality complaints, that the harm must relate to the use of the consumer product, and/or that the database is limited to the information the Commission determines is reasonably related to the safety of consumer products as indicated by specific reports of harm caused by those products and that the CPSC should establish guidelines to this end. Along these lines, one commenter suggested that the software utilized in the database could be structured to guide or prompt submitters to supply the information necessary to constitute a report of

harm. One commenter suggested that consideration should be given to limiting the reporting of "old" or "stale" data not contemporaneously related to the occurrence of the alleged incident. Three commenters suggested a one-year statute of limitations to file a report of harm. Another commenter proposed that the database should not contain a statute of limitations at all.

One commenter also suggested that the database should be engineered to automatically publish reports within the required 10 business days of receipt.

Response

We recognize that the scope of the database is limited to reports of harm. Instructions and guidance throughout will prompt the submitter to adhere to this scope.

CPSC will review all reports of harm regardless of the date of the incident described by the submitter.

We considered options for automatic publishing of reports of harm. However, considerations around publishing Personally Identifiable Information in free form text boxes limited staff's design options in this regard.

Section 1102.12: Manufacturer Comments

17. CPSC asked what means the agency should employ to allow manufacturers and private labelers to submit comments regarding a report of harm or to designate confidential information, and what issues should the agency consider when developing such a process.

Comments (Summary 17)

In response to this question, CPSC received one comment stating that CPSC should allow electronic submissions accommodating text, photos, and other documents as attachments. One commenter suggested that CPSC should ensure that only the applicable manufacturer or private labeler should be able to submit comments regarding a report. This commenter suggested that electronic means would be expected to facilitate making comments. This commenter also suggested that unique identifying information associated with a report should only be available to submitters, manufacturers or private labelers, and CPSC, and it should be required to offer comments and, also, that different types of users could have different "views" of the data. Finally, this commenter suggested that the database should provide a mechanism for designating confidential information, redacting, and exchanging redacted versions of reports.

Two commenters requested a clearly identified process with criteria to determine whether certain content is confidential business information. This commenter also suggested that CPSC should consider allowing manufacturers to "flag" reports that it believes to be confidential business information.

Similarly, one commenter stated that the CPSC should establish a means for submitting comments and designating confidential information. The report of harm and manufacturer's comments should be aligned so that the manufacturer's comments appear in same field as (alongside) the submitter's. This commenter also suggested that a manufacturer should be able to designate into what it believes is materially inaccurate or confidential via a clear method (e.g., flag system) and, if Commission reviews manufacturer's confidentiality request and determines report contains confidential info, it must redact that info from the report of harm, and must not publish the report to database

until makes a determination as to confidentiality; if the CPSC determines it is not confidential, it must notify manufacturer. This commenter also suggested that CPSC should establish a means for manufacturers to submit proposed redactions of confidential info and, if determined that it is indeed confidential, the agency should have a method for ensuring info remains confidential (e.g., not disclosed under the FOIA).

One commenter stated that if confidential business information does happen to be submitted for posting, manufacturers and private labelers must demonstrate confidentiality and submit supporting info to show that the info is entitled to confidential treatment. This commenter also stated that a manufacturer's comments to a report of harm should also contain a verification of truth and accuracy by the manufacturer.

One commenter stated that accuracy should start and end with the submitter and the product identification, and that the CPSC should not verify the accuracy of, and should not allow manufacturers to comment on, the report of harm.

Response

We agree with the comments and have taken the suggestions into consideration in the following ways:

- The system will allow users to submit text, photo, and other approved types of documents as attachments.
- Only the registered contact from a manufacturer or private labeler can submit comments regarding a report.
- Each report will have a unique identifier.
- There will be role-based access and views into the data.

- Manufacturers will have the ability to flag for CPSC review those reports they believe contain confidential information.

Section 1102.16: Additional Information.

18. CPSC asked what additional categories of information should be included in the public database and why.

Comments (Summary 18)

Two commenters proposed that information regarding the product such as manufacturer, the type of product, the product brand, model number or name, serial number, UPC code, date of purchase, product code date or equivalent designation on the product, and place or purchase; date of incident; location of incident; whether manufacturer or private labeler was contacted prior to submission of the report; verification that the label instructions were followed when using the product; and a brief description of the circumstances of the incident, including how the product was being used at the time of the reported incident, a description of what happened, whether the submitter used any other products or devices along with the product involved in the incident, how much the product was used over what period of time (if applicable), description of harm incurred during the incident, the types of symptoms or injuries sustained, and the type of medical care sought, if applicable.

Two commenters proposed that recalls be included in the database, while another commenter proposed that the database include information derived by the Commission from CPSA Section 15 reports.

Two commenters were in favor of including CPSC technical research, reports on emerging hazards, and other staff-generated research that will improve the public's

understanding of consumer product safety. One commenter stated that the Commission should make all staff research completed within the past 5 years publicly accessible within 30 days of completion and, if not in the database itself, linked in the database. One commenter suggested that CPSC should address how it will integrate pre-database incident data into the new system. Along these lines, one commenter suggested that NEISS data should be included in the database, while another commenter responded that CPSC should not add categories of information beyond that required by the CPSIA but, rather, should focus its efforts on ensuring the quality of, and timely reporting of, required information.

Finally, one commenter felt that the CPSC should accept information submitted anonymously by whistleblowers and, if the information was determined to be valid, the information should be part of the public database.

Response

We have designed the Incident Report form to collect information regarding the incident such as manufacturer; the type of product; the product brand; model number; serial number; date of purchase; manufacturer code date; place of purchase; date of incident; location of incident; whether manufacturer or private labeler was contacted prior to submission of incident report and, if not, is there a plan to contact them; a brief description of the circumstances of the incident; a description of harm incurred during the incident; the types of symptoms or injuries sustained; and the type of medical care sought, if applicable.

After the user successfully submits the incident, the system will alert the user of any recalls that are related to the incident reported and provide options for the user to

subscribe to the recalls.gov subscription list and possibly other lists, web services, or agency publications.

The incorporation of CPSC technical research, reports on emerging hazards, and other staff-generated research into the Public Database is being studied for future releases of the system.

The database will accept information submitted anonymously but we recommend that anonymous reports not be published.

19. CPSC asked what, if any, information could not be included in the public database pursuant to the statute and why.

Comments (Summary 19)

Several commenters stated that the database should exclude reports filed under Section 15(b) of the CPSA. One commenter also stated that information received under any other mandatory or voluntary reporting program established between retailer, manufacturer, or private labeler and the CPSC could not be included in the database, as well as information exempt from disclosure under FOIA, trade secrets, and other confidential information.

Two commenters stated that reports of harm and/or comments involving products that fall outside the scope of CPSC regulatory authority should not be included in the database. One commenter was concerned that the status of CPSC investigations, including the existence of the investigation, should not be included in the database. This commenter also felt that the database should not contain the resolution and/or remedy provided to individual submitters and that status updates should only be allowed by manufacturers

providing comments. Finally, this commenter stated that Third-party comments would not be appropriate for the database.

Response

We recommend that all reports of harm meeting the minimum statutory requirements be included in the Public Database. All other reports of harm should be collected for appropriate Commission use. Reports of harm that fall outside the scope of CPSC regulatory authority will be referred to an appropriate agency or entity with notification of such action to the submitter.

20. CPSC asked what, if any, disclaimers or qualifications should appear on the report form.

Comments (Summary 20)

Comments in response to this question fell into two categories. The first category of comments concerned the need for a disclaimer either on all screen views during the process of submitting a report form or at least at the end on the completed report form. Commenters felt that that the disclaimer should inform users of the database that CPSC has not verified the truth or accuracy of reports in the database. One commenter felt that there should be an acknowledgment check box for the submitter to select upon completion of a report to certify the truth and accuracy of the report prior to submission. The second category of comments concerned the need to inform users how reports of harm, and specifically any personal information contained therein, would be used by CPSC. One commenter suggested that users should be informed that the report of harm itself would be contained in a publicly viewable database. Other commenters were concerned that users should be informed that their contact information would never be

publicly available and would only be shared with manufacturers if submitters gave express consent.

Response

We recommend that notice, consistent with statutory requirements, should be provided to users of the Public Database that the Commission does not guarantee the accuracy, completeness, or adequacy of the contents of the database and that the submitters of a report of harm verify that the information they have provided is accurate to the best of their knowledge.

We also recommend that the Public Database include detailed information for submitters regarding how their contact information will be used.

21. CPSC also asked what specific disclaimers the agency should make with regard to the accuracy of the information contained in the public database and why, and where should such disclaimers appear and why.

Comments (Summary 21)

CPSC received a variety of comments in response to this question. Several commenters felt that all publicly viewable pages in the database should contain a disclaimer that CPSC has not verified the truth or accuracy of the reports in the database.

One commenter recommended that that Commission use the statutorily required disclaimer consistently on each report on the database.

One commenter was concerned about a disclaimer for materially inaccurate information. This commenter suggested that when a report is claimed to contain materially inaccurate information, the report should be marked on every page to indicate it as such. When an

existing report is removed or corrected because of a claim of materially inaccurate information, public notice should be made to those who already viewed the report. Finally, one commenter suggested that printed reports of harm from the database should contain a print date in order to reduce confusion between versions of reports of harm or manufacturer comments.

Response

The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the public database. The Public Database will contain a notice to this effect. Additionally, the we will recommend that such notice be placed in the following locations, at minimum:

- On the entrance screen for public users
- On all search result displays
- On all reports printed from the Public Database

Printed reports of harm will contain a print date.

Subpart C—Procedural Requirements

Section 1102.20: Transmission of reports of harm to the identified manufacturer or private labeler

22. CPSC asked whether, given the statutory timeframe for notification, manufacturers and private labelers should be able to ''register'' contact information with the Commission for the purpose of notification of a report of harm and, if so, what form of contact information should be acceptable, i.e., electronic mail only. CPSC also wanted to know what other issues along these lines should be considered.

Comments (Summary 22)

The majority of the commenters who responded to this question agreed that registration would help facilitate manufacturer notification. Only one commenter responded that electronic mail only would be acceptable.

Response

We recommend that the Commission provide a mechanism for manufacturers and private labelers to register their contact information and their preferred method to be contacted by the Commission.

23. CPSC asked how the agency could ensure that manufacturers and/or private labelers do not use a submitter's contact information for purposes other than verification of a report of harm, and by what means could CPSC enforce such a provision.

Comments (Summary 23)

Two commenters suggested that CPSC could emphasize that misuse of contact information would not be tolerated and that CPSC would take any necessary action to prosecute violators.

One commenter proposed that CPSC reiterate the restrictions and appropriate uses for consumer contact information in all forms sent to manufacturers, while another commenter proposed that CPSC publish a list of uses of contact information that would be deemed to abuses of that information. This commenter also suggested that CPSC could create a webpage for submitters to report abuse.

Response

We conclude that the intent of the statute to provide contact information for the submitter to the manufacturer is for the sole purpose of verifying the report of harm. The Commission may, at its discretion, determine means by which it will enforce this provision.

Subpart B—Content Requirements

Section 1102.22: Opportunity for manufacturer comment

24. CPSC asked what means the agency should employ to notify manufacturers and private labelers regarding a report of harm within the five day statutory time frame.

Comments (Summary 24)

The majority of commenters agreed that electronic mail notification would be the most effective means of notification. Although others felt that it should be according to the preference (electronic mail, telephone, fax) of the manufacturer or private labeler. Two commenters were concerned that notification should reach the intended recipient and suggested that CPSC develop procedures for when electronic mail is undeliverable and/or to confirm that individuals receiving notification are authorized contacts for the manufacturers and private labelers.

Response

As part of the Public Outreach effort, we are developing a process to identify, confirm, and register companies. A Manufacturer Portal is being designed to facilitate communication between CPSC and manufacturers. Manufacturer registration,

contact/account management, e-mail communication, and the ability to flag information that may be confidential or materially inaccurate are all functionalities being considered for the portal. Manufacturers will be able to choose their preferred method of communication (email or postal mail) with the CPSC. Manufacturers will designate a Point of Contact within their organization to receive notification from the CPSC. We are working closely with enterprise information security experts to secure electronic communication.

25. CPSC asked what, if any, circumstances could arise which could restart any of the timeframes contemplated in the statute with regard to manufacturer notification and responses.

Comments (Summary 25)

One commenter suggested that if submitter provides new or supplemental info to CPSC before initial report is published this would delay publication of the report of harm in the database. Another commented suggested that if there is a valid claim by the manufacturer that a report of harm is invalid, incomplete, or inaccurate, the CPSC should take steps to suspend any statutory time limits until the claim could be adjudicated by the Commission. One commenter proposed that the Commission "restart" the statutory timeframes if notification goes to the wrong manufacturer or private labeler, if incomplete information is provided in the report form, or if the submitter corrects the original report form, especially where information in a required field has been changed.

Response

We recommend that in cases where a determination of Materially Inaccurate or Confidential Information has been made or in review, the Commission, in its discretion, may withhold a report of harm in part or in full until such a determination is made final.

Section 1102.26: Designation of materially inaccurate information

26. CPSC asked, given the statutory timeframe, how the agency should review claims of materially inaccurate information.

Comments (Summary 26)

Two commenters felt that there should be a process for reviewing, modifying, or removing materially inaccurate information. One commenter felt that a claim of materially inaccurate information contained in a report of harm should not restart the 10-day statutory time period for posting of other information in the report form. One commenter felt that once the CPSC has a received a claim of materially inaccurate information contained in a report of harm, it should have a limited time to issue a decision or, in the alternative, it should remove the report of harm until it does. Finally, one commenter felt that the CPSC could use its discretion to permit an extension of the 10-day period for publication in the database in circumstances where there is a challenge to the accuracy of the report.

Response

We recommends that if a request for determination of materially inaccurate information is timely submitted, the Commission should withhold the report of harm from publication in the Public Database until a determination is made regarding such request.

We also recommend that if the Commission determines that the requested designated information in a report of harm or manufacturer comment contains materially inaccurate information before it is published, the Commission should in its discretion do the following: decline to add the materially inaccurate report of harm or manufacturer comment to the Public Database; redact the information, and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the database; correct the materially inaccurate information, and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the database; or, add the information to the report of harm or the manufacturer comment to correct the materially inaccurate information, an, if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the Public Database.

Should the Commission make a determination of material inaccuracy after publication, we recommend the following: removal of the entire materially inaccurate report of harm or manufacturer comment from the Public Database, including all associated documents, photographs, or comments; redaction of the materially inaccurate information and if the minimum requirements for publication are met, maintain the report of harm or manufacturer comment in the Public Database; correction of the materially inaccurate information and, if the minimum requirements are met, maintain the report of harm or manufacturer comment in the Public Database; or, add the information to the report of harm or the manufacturer comment to correct the materially inaccurate information and, if the minimum requirements for publication are met, maintain the report of harm or manufacturer comment in the Public Database.

27. CPSC asked whether the agency's responsibility with regard to materially inaccurate information is limited to reports of harm and manufacturer comments and why or why not.

Comments (Summary 27)

CPSC received one comment in response to this question which stated that CPSC should exclude materially inaccurate information regardless of the source.

Response

We recommend that claims of materially inaccurate information should not limit the source of the claims to submitters and/or manufacturers.

28. CPSC asked what types of information would constitute materially inaccurate information.

Comments (Summary 28)

CPSC received numerous, specific examples of what could constitute materially inaccurate information contained in a report of harm, including: misidentification of the manufacturer or private labeler, misidentification of persons involved, or misidentification of the consumer product itself (including misidentification of brand name or model number or misuse modification of the product); and inaccuracy in the description of the incident.

Some commenters were also concerned that materially inaccurate information could comprise opinion statements about a consumer product's design or general safety, information not directly related to the incident such as conclusory or unsupported statements about product design, information in contradiction with generally accepted

scientific principles, legal opinions, and reports of an injury or hazard caused by something other than the product identified in the report of harm. One commenter felt that any information that the staff determines to be falsified as well as any information that is inflammatory or invective could also constitute materially inaccurate information. Several commenters also felt that the database should be a repository for fact-based information only. Similarly, one commenter felt that information that could not be substantiated, such as documentation or information supporting a report of harm, would constitute materially inaccurate information.

Others provided more general comments stating that materially inaccurate information would be inaccurate information that is substantial and important. Along these lines, some commenters suggested that CPSC provide a definition for "materially inaccurate information."

Response

We agreed on the following definition of materially inaccurate information in a report of harm: information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial confusion among Public Database users regarding: (1) the identification of a consumer product; (2) the identification of a manufacturer or private labeler; or (3) the harm or risk of harm related to the use of the consumer product.

We agreed on the following definition of materially inaccurate information in a manufacturer comment: information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial

confusion among Public Database users such as: (1) the nature, scope, liability, or cause of a harm or risk of harm related to the use of a consumer product; (2) the status of a Commission, manufacturer, or private labeler investigation; (3) the identity of the firm or firms responsible for the importation, manufacture, distribution, sale, or holding for sale a consumer product; (4) whether the manufacturer or private labeler is engaging in a corrective action (when such action has not been approved by the Commission); or, (5) whether the manufacturer has taken, or promised to take, any other action with regard to the product.

29. CPSC asked how the agency should process a claim that a report of harm or a manufacturer comment contains materially inaccurate information, both before and after such information has been made available in the public database.

Comments (Summary 29)

The majority of commenters agreed that CPSC should develop a transparent and efficient process for handling a claim of materially inaccurate information in a report of harm, including how redactions, corrections and/or removal of a report of harm will be addressed.

Correspondingly, many commenters also felt that CPSC should develop a parallel procedure for the inclusion of reports of harm in the database wherein CPSC staff would make affirmative verification that the report of harm was true and accurate. Several commenters felt that a report of harm could not be published in the database until the CPSC had verified that it was true and accurate.

Two commenters felt that CPSC should follow the procedures specified in the statute wherein upon a claim that a report of harm or comment contains materially inaccurate information, the CPSC must make a determination as to the accuracy of that report or comment and that the report or comment should not be published until such determination is made. Similarly, three commenters suggested that the CPSC should decline to post a report of harm involving a claim of material inaccuracy until an appropriate investigation of the claim had been made.

Another commenter proposed that the CPSC adopt a trial procedure during which it would permit extensions to the 10-day period for publication of reports of harm to the database where there has been a claim of material inaccuracy. This commenter suggested that the CPSC provide a means for manufacturers and private labelers to flag information in a report as being materially inaccurate and also provide a means to flag materially inaccurate information after it has been published to the database. This commenter recommended that the CPSC establish timeframes during which claims of materially inaccuracy will be resolved.

On the other hand, two commenters felt that publication of a report of harm should take priority over verifying claims of materially inaccurate information. Additionally, one commenter suggested that the party contending the material inaccuracy bears the burden of demonstrating the materially inaccuracy and that CPSC should reject efforts to delay or deny posting of information based upon unsubstantiated claims of materially inaccuracy. One commenter felt that if the CPSC publishes a report of harm over the manufacturer or private labeler's objections, the CPSC should provide the reasons for doing so.

One commenter wanted an opportunity to examine the consumer product in question during the pendency of an investigation into materially inaccurate information in a report of harm.

One commenter felt that if an inaccurate report was inadvertently published, it should be removed as soon as possible and that a simple retraction would not suffice, while another commenter felt that the CPSC could internally investigate it and post a clarification/disclaimer or delete the materially inaccurate information from the report of harm.

One commenter suggested that when a report of harm has been determined to contain materially inaccurate information, it should be marked on every page to indicate it was removed or corrected. When existing reports are removed or corrected because they contain materially inaccurate information, public notice should be made to those who already viewed the report of harm. This commenter also suggested that if the CPSC receives a subpoena or FOIA request regarding a report of harm that has been corrected or removed, the CPSC should provide notice accordance with Section 6(b) to the manufacturer or private labeler.

Response

We recommend that if the Commission makes a determination of materially inaccurate information prior to publication of a report of harm, in its discretion, decline to add the report of harm or manufacturer comment to the Public Database or, redact or correct the materially inaccurate information and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment in the Public Database.

If the Commission makes a determination of material inaccuracy after publication of a report of harm or manufacturer comment, the Commission should, in its discretion and within a time frame determined reasonable by the Commission, remove the report of harm or manufacturer comment from the Public Database or, redact or correct the report of harm or manufacturer comment and if the minimum requirements for publication are met, publish the report of harm or manufacturer comment.

30. CPSC asked how the agency should allow a submitter or others to claim that a manufacturer has submitted materially false information.

Comments (Summary 30)

Two commenters recommended that CPSC assign a unique identifier to each report of harm to assist in making a claim of material inaccuracy, while another commenter suggested there is no need to highlight reports of harm whose accuracy is doubted since CPSIA contains reasonable protections to safeguard against inaccurate information.

Response

We recommended and are incorporating the suggestion of a unique identifier into the design of the Public Database.

Section 1102.28: Publication of reports of harm

31. CPSC asked if a manufacturer or private labeler requested that a comment associated with the report of harm be made available in the public database, what, if any, circumstances would prevent such comment from inclusion in the public database.

Comments (Summary 31)

One commenter replied that CPSC should not publish any comments that are found to be falsified, inflammatory, invective, or legal opinions or comprise information patently violating generally accepted scientific principles. Another commenter replied that all comments should be included in the database as long as they don't contain trade secret or confidential information.

Response

We agree that all comments that are requested for publication be included in the Public Database.

32. CPSC asked what, if any, authority does the agency have to withhold a report of harm from the public database if a manufacturer or private labeler claims the report contains materially inaccurate or confidential information.

Comments (Summary 32)

One commenter responded that CPSC is permitted to withhold a report of harm form the database if it agrees with the manufacturer or private labeler's claim.

Response

We recommend that should the Commission make a determination of materially inaccurate information or confidential information, the Commission should, at its discretion withhold or remove the information from the Public Database in whole or in part.

33. CPSC asked what data sets, including information from reports of harm and mandatory and voluntary recall notices, should be made available for public search and reporting and why.

Comments (Summary 33)

Some commenters agreed that all of the information submitted to the database except for personal and/or contact information contained in reports of harm should be made available for public search and reporting. One commenter wanted to make it clear that personal and/or contact information should never be disclosed to the public and only to a manufacturer or private labeler where there has been consent.

Several commenters agreed that voluntary and mandatory recall notices, and/or information derived as a result of such recall notices, should be searchable as well.

One commenter would like to be able to search the CPSC's NEISS data.

Two commenters wanted to be able to search for manufacturer and private labeler comments provided in response to a report of harm.

One commenter also suggested being able to search CPSC's "closed investigations" which the staff is interpreting as pertaining to investigations conducted by the Office of Compliance and Field Operations staff. One commenter would like to be able to search staff research.

One commenter noted that recall information should be provided separate from reports of harm, stating that recalls are often limited in scope and there is a risk that reports of harm could be inappropriately or inaccurately linked to recall information, while another commenter wanted searching to be limited to what the statute requires in as simple and accurate a format as possible.

Response

We recommend that all information and data sets that will be made available in the Public Database should be made searchable and sortable. The incorporation of

additional categories of information into the public database is being studied for future releases of the system software.

34. CPSC asked in what formats the agency should make data available to the public and why.

Comments (Summary 34)

Several commenters agreed that the data should be downloadable and/or searchable in common, readily-available formats that do not require the purchase of specific, proprietary software. One commenter suggested providing the data in downloadable formats that would facilitate use by manufacturers in their own tracking systems. Commenters would like to be able to search by general word entry, including advanced searches for data using search terms connected by both the words "AND" and "OR," and/or also by type/category of product, brand name, model name, model number, type of injury and other harm, approximate date of purchase, and product manufacture information.

Two commenters recommended making raw data available.

Response

We agree and the system will provide search capabilities that include those suggested by the comments such as "fuzzy matching", search/sort by product category, manufacturer/private labeler/retailer (including common misspellings), model, date/type/location/severity of the product and hazard. The system will also provide downloadable access the data in multiple common formats.

35. CPSC asked what types of data analysis and reporting tools are being used by third party analysts in the public and industry, and what are those tools' relative merits and drawbacks.

Comments (Summary 35)

One commenter stated that it uses COGNOS Powerplay to analyze its data because it allows both web- and desktop-based access to data in its proprietary databases from an easy-to-use front-end. Also, data accessed via COGNOS Powerplay can be exported to Excel or other programs. This commenter indicated that the drawbacks include limited graphing capabilities and need for programmer to build COGNOS cubes that allow access to data.

One commenter responded that commercial software programs developed by Intertek and Safety Research and Strategies facilitate large database searches and result analysis. This commenter stated that Intertek's software is a web-based software package that enables users to easily analyze product injury data and is currently part of NEISS. This commenter recommended that CPSC utilize a software program that allows keyword searching, year-to-year comparisons, and trend analysis across all variables that NEISS tracks (injury type, body part, environment, age, outcome).

One commenter responded that the CPSC need not, and should not, facilitate third-party organizations in analyzing preliminary data.

Response

We recognize the power of "crowd sourcing". The system will make the data available in multiple common formats for download so researchers and partner organizations can work with us to identify hazards and analyze trends. We are also

planning to partner with research institutions to develop advanced algorithms for early warning and pattern recognition so smarter decisions can be made to better protect consumers.

Subpart D—Notice and Disclosure Requirements

Section 1102.44: Applicability of section 6(a) and (b) of the CPSA

36. CPSC asked under what circumstances the provisions of section 6(a) and (b) of the CPSA would be relevant to the provisions of section 6A of the CPSA, especially with regard to additional categories of information that may be included in the public database.

Comments (Summary 36)

Two commenters responded that the provisions of section 6(b) were not relevant/applicable to the database.

Two commenters responded that only reports of harm are exempt from sections 6(a) and (b) and any additional information included in the public database would have to comply with those sections.

Response

The Commission has to follow the provisions of section 6(a) and (b) when determining what additional information is in the public interest to include in the database.

V. Request for Comments

The CPSC has already invited comments on the publicly available database through a public hearing held on November 10, 2009 and through a series of public workshops held on January 11 and 12, 2010, and we considered the comments in

developing this proposed rule. This proposed rule would establish content and procedural requirements for the inclusion of information in the publicly available database. All interested persons are invited to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

VI. Environmental Impact

The Commission's regulations at 16 CFR Part 1021(5)(a) are considered to "have little or no potential for affecting the human environment," and environmental assessments and impact statements are not usually prepared. *See* 16 CFR 1021.5(c). The proposed rule contains the Commission's interpretation of the statutory requirements set forth in section 6A of the CPSA, as added by section 212 of the CPSIA, for the inclusion of information related to reports of harm involving the use of consumer products or other products or substances regulated by the Commission in a publicly available and searchable database. As such, the proposed rule is not expected to have an adverse impact on the environment. The Commission concludes that no environmental assessment or environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We particularly invite comments on: (1) Whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Publicly Available Consumer Product Safety Information Database

Description: The proposed rule would allow consumers to submit reports of harm involving the use of consumer products or other products or substances regulated by the CPSC and also allow manufacturers of such products or substances to comment on the reports of harm. The reports and comments would be part of a public database operated and maintained by the CPSC.

Description of Respondents: Persons who wish to submit reports of harm involving the use of consumer products or other products or substances regulated by the CPSC and manufacturers of such products or substances who wish to comment on those reports of harm, pursuant to section 6A of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2055a).

We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Minutes per Response	Total Burden, in Hours
16 CFR 1102.10(b)(1), (3) Reports of harm – electronic	11,534	1	11,534	12	2,307
16 CFR 1102.10(b)(2) Reports of harm – telephone	3,329	1	3,329	10	555
16 CFR 1102.10(b)(4) Reports of harm – paper	277	1	277	20	92
16 CFR 1102.12(b)(1), (2) Manufacturer comments – electronic	5,753	1	5,753	255	24,450
16 CFR 1102.12(b)(3) Manufacturer comments – paper	1,817	1	1,817	270	8,177
				Total	35,581

There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following:

The CPSC is in the process of developing the forms that will be used by consumers and manufacturers to submit reports and comments for inclusion in the database. Because those forms are still under development, for present purposes we based our burden estimates on our experience with similar forms and processes, and on

information gleaned from manufacturers. Specifically, the CPSC currently has an incident report form that consumers and others use to report consumer safety incidents to the agency. The CPSC provides most of those consumer complaints to the manufacturer, and the manufacturer may provide comments to the agency.

For present purposes, we assume that the public database will receive the same number of reports of harm as the CPSC received of incident reports in fiscal year 2009 and that the numbers by manner of submission to the CPSC (i.e., electronic, telephone, paper) will be the same. Thus, using the data from fiscal year 2009, we estimate that we will receive a total of 15,140 reports of harm (11,534 by electronic means, 3,329 by telephone, and 277 by paper submissions). We had already estimated the time associated with the electronic and telephone submission of incident reports at 12 and 10 minutes respectively and so used those figures for present purposes as well. We estimate that the time associated with a paper form would be 20 minutes on average. Thus, we estimate the total burden hours associated with the submission of reports of harm to be 2,954 hours ((11,534 electronic report x 12 minutes per report) + (3,329 telephone reports x 10 minutes per report) + (277 paper reports x 20 minutes per report) = 177,238 minutes or approximately 2,954 hours)).

In 2008, manufacturers submitted comments to the CPSC in response to a consumer complaint forwarded to the manufacturer about 40% of the time. We estimate that the response rate will increase in the case of the public database; currently, neither the incident reports nor manufacturer comments are routinely public. We estimate that the manufacturer response rate will increase 25%, up to a 50% response rate. Therefore we expect to receive half as many total manufacturer comments as reports of harm

(15,140 reports of harm x 0.5 manufacturer comments per report of harm = 7,570 manufacturer comments). In terms of the manner of commenting, we do not currently keep track of how many manufacturer comments are submitted electronically versus in paper form. Because the public database will be online, we will assume that most manufacturers will utilize electronic options for participating in the database, especially when the public database (unlike the current incident reporting system) will not give manufacturers the option of submitting their comments by phone. However, to ensure that we avoid inadvertently underestimating the burden, we will assume that manufacturers would submit electronically at the same rate. That equates to an estimate of 5,753 manufacturer comments submitted electronically and 1,817 submitted on paper.

We also will assume that that there are two actions involved in a manufacturer comment: first, the research and preparation necessary to comment, and second, the act of providing the comment. To estimate how much time manufacturers will spend researching and preparing to comment, we contacted three manufacturers that have experience submitting comments in response to incident reports. The manufacturers each reported a range of time, because time required in preparing a comment can vary greatly. The three ranges were 15 minutes to 4 hours, 10 minutes to 5 hours, and 10 minutes to 3 hours. For purposes of estimating the burden, we used the average high end of these ranges, 4 hours, for that portion of the burden estimate. Based on our experience with the current manufacturing comment process, we estimate that manufacturers will spend between 5 and 30 minutes actually providing the comment, depending on the length and complexity of their comment. For the purposes of this estimate, we use the high end of that range for paper submissions (30 minutes) and the midpoint for electronic (15). Thus,

the estimated burden associated with manufacturer comments is approximately 32,607 hours (((5,753 electronic comments x 255 minutes per comment) + (1,817 paper comments x 270 minutes per comment) = 1,957,605 minutes or approximately 32,627 hours).

The total estimated burden, therefore, is 35,581 hours.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

VIII. Executive Order 12988

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. This regulation is issued under the authority of the CPSA, wherein preemption is discussed in section 26 of the CPSA. Section 26 of the CPSA only addresses the preemptive effect of consumer product safety standards under the CPSA. The current rule is not a consumer product safety standard under the CPSA. Accordingly, the Commission has determined that this rule does not contain requirements that impact the States.

IX. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the

proposed rule on small entities and identifying impact-reducing alternatives. 5 U.S.C. 603. Section 605(b) of the RFA, however, states that this requirement does not apply if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, and the agency provides an explanation for that conclusion.

The proposed rule will have little or no effect on small businesses. The rule would implement the statutory requirements set forth in section 6A of the CPSA for the establishment and maintenance of a publicly available database containing reports of harm involving the use of consumer products, as well as comments received by manufacturers regarding such reports of harm identifying their products. The agency anticipates that the new database will likely increase the number of consumer-generated reports over the number of incident reports currently filed with the Commission. However, because of their smaller sales volumes, small manufacturers are less likely to experience any impacts. Moreover, even if a small firm does choose to respond to an incident report, the amount of time to do so would not likely be more than a few hours, on average. Therefore, the Commission tentatively certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Commission invites comment on this analysis and preliminary certification statement.

X. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. § 553(d). The Commission intends that any final rule based on this proposal will become effective 30 days after the date of publication of a final rule in the Federal Register. However, as the

database is still being developed, and the requirements set forth in this rule will only be applicable once the public database is established, the Commission intends to state, in the final rule, when the database will become operational.

List of Subjects in 16 CFR Part 1102

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

For the reasons stated above, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding a new Part 1102 to read as follows:

PART 1102—PUBLICLY AVAILABLE CONSUMER PRODUCT SAFETY INFORMATION DATABASE

The authority for part 1102 shall read as follows:

Authority: 15 U.S.C. 2051, 2051 note, 2052, 2055, 2055a, 2065, 2068, 2070, 2071, 2072, 2076, 2078, 2080, 2087;

* * * * *

Subpart A—Background and Definitions

Sec.

1102. 2 Purpose.

Subpart B—Content Requirements

Subpart C—Procedural Requirements

Subpart D—Notice and Disclosure Requirements

* * * * *

Subpart A—Background and Definitions

§ 1102.2 - Purpose.

This part sets forth the Commission's interpretation, policy, and procedures with regard to the creation and maintenance of a Consumer Product Safety Database on consumer products and other products or substances regulated by the Commission.

§ 1102.4 – Scope.

This part applies to the content, procedure, notice, and disclosure requirements of the Consumer Product Safety Database, including all information published therein.

§ 1102.6 – Definitions.

(a) Except as specified in paragraph (b) of this section, the definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part.

(b) For purposes of this part, the following definitions apply:

(1) *Additional information* means any information that the Commission determines is in the public interest to include in the Consumer Product Safety Database.

(2) *Commission or CPSC* means the Consumer Product Safety Commission.

(3) *Consumer product* means a consumer product as defined in section 3(a)(5) of the Consumer Product Safety Act and also includes any other products or substances regulated by the Commission.

(4) *Consumer Product Safety Database* means the database on the safety of consumer products created and maintained by the CPSC.

(5) *Harm means any injury,* illness, or death, or any risk of injury, illness, or death, as determined by the Commission.

(6) *Mandatory recall notice* means any notice to the public required of a firm pursuant to order issued by the Commission under section 15(c) of the Consumer Product Safety Act.

(7) *Manufacturer comment* means a comment made by a manufacturer or private labeler of a consumer product in response to a report of harm transmitted to such manufacturer or private labeler.

(8) *Report of harm* means any information submitted to the Commission regarding an injury, illness, or death, or any risk of injury illness, or death, as determined by the Commission, relating to the use of a consumer product.

(9) *Submitter of a report of harm* means any person or entity that submits information to the Commission through the public database regarding an injury, illness, or death, or any risk of injury, illness, or death relating to the use of a consumer product.

(10) *Voluntary recall notice* means any notice to the public by the Commission relating to a voluntary corrective action, including a voluntary recall of a consumer product, taken by a manufacturer in consultation with the Commission.

Subpart B—Content Requirements

§ 1102.10 - Reports of Harm.

(a) *Who may submit.* The following persons or entities may submit reports of harm:

(1) *Consumers* including, but not limited to, users of consumer products, family members, relatives, parents, guardians, friends, and observers of consumer product being used;

(2) *Local, State, or Federal government agencies* including, but not limited to, local government agencies, school systems, social services, child protective services, State attorneys general, State agencies, and all executive and independent federal agencies as defined in Title 5 of the United States Code ;

(3) *Health care professionals* including, but not limited to, medical examiners, coroners, physicians, nurses, physician's assistants, hospitals, chiropractors, acupuncturists;

*(4) Child service providers i*ncluding, but not limited to, day care centers, day care providers, child-care providers, pre-kindergarten school, and care providers;

(5) *Public safety entities* including, but not limited to, police, fire, ambulance, emergency medical services, federal law enforcement entities, and other public safety officials; and

(6) *Others* including, but not limited to, attorneys, professional engineers, investigators, non-governmental organizations, consumer advocates, consumer advocacy organizations, and trade associations.

(b) *Manner of submission.* Reports of harm must be submitted to the CPSC using one of the following methods:

(1) Internet submissions through the CPSC's Internet web site on an electronic incident report form specifically developed to collect such information. Reports of harm submitted electronically shall be complete upon final submission to the CPSC using the electronic incident report form.

(2) Telephonic submissions through a CPSC call center.

(3) Electronic mail directed to the [insert name of office], provided that the submitter completes the incident report form available for download on the CPSC's Internet web site specifically developed to collect such information. Reports of harm submitted by electronic mail shall be complete upon transmission to the CPSC; or

(4) Written submissions through the [insert office and address]. The Commission will accept only those written reports of harm that use the incident report form developed for the CPSC's Internet web site.

(c) *Minimum requirements for publication.* Subject to §§ 1102.23 and 1102.24, the Commission will publish in the Consumer Product Safety Database reports of harm containing all of the following information:

(1) *Description of the consumer product.* The description of the consumer product must, at a minimum, include a word or phrase sufficient to distinguish the product as a consumer product, a component part of a consumer product, or a product or substance regulated by the Commission. A description of a consumer product includes, but is not limited to, the name including the brand name of the consumer product, model, serial number, date of manufacture (if known) or date code, date of purchase, price paid, retailer, or any other descriptive information about the product.

(2) *Identity of the manufacturer or private labeler.* The name of one or more manufacturers or private labelers of the consumer product. Identification of a manufacturer or private labeler includes, but is not limited to, a mailing address, phone number, or electronic mail address.

(3) *Description of the harm.* A brief narrative description of an illness, injury, or death, or risk of illness, injury, or death related to use of the consumer product. Examples of a description of harm include but are not limited to: death, asphyxiation, laceration, abrasions, contusions, choking, suffocation, amputation, or any other narrative description relating a bodily harm or risk of bodily harm. Incident reports that relate solely to the cost or quality of a consumer product, with no discernable bodily harm or risk of bodily harm, do not constitute "harm" for purposes of this part. A description of harm may, but need not, include the date on which the harm occurred or manifested itself, and the severity of any injury and whether any medical treatment was received.

(4) *Contact information.* The submitter's first name, last name, and complete mailing address. Submitters also may, but are not required to, provide an electronic mail address and a phone number to allow for efficient and timely contact regarding a report of harm

when necessary. Although this information will not be published in the database it is required information for the report of harm.

(5) *Verification.* A submitter of a report of harm must affirmatively verify that he or she has reviewed the report of harm and that the information contained therein is true and accurate to the best of the submitter's knowledge, information and belief. Verification procedures for each method of submission will be specified. Although this information will not be published in the database it is required information for the report of harm

(6) *Consent.* A submitter of a report of harm must consent to publication of the report of harm in the Consumer Product Safety Database if he or she wants the information to be included in the Consumer Product Safety Database.

(d) *Information not published.* The Commission will exclude the following information provided on report of harm from publication in the Consumer Product Safety Database:

(1) Name and contact information of the submitter of a report of harm;

(2) Victim's name, if the victim has not provided consent, and contact information;

(3) Photographs which, in the determination of the Commission, are not in the public interest including photographs that depict a person or injury or constitute an invasion or personal privacy;

(4) Medical records;

(5) Confidential information as set forth in § 1102.23;

(6) Materially inaccurate information as set forth in § 1102.24; and/or

(7) Any other information submitted on or with a report of harm whose inclusion in the Consumer Product Safety Database the Commission determines is not in the public interest to publish. The Commission's determination shall consider whether the information is related to a product safety purpose served by the Consumer Product Safety Database, including whether or not the information helps Consumer Product Safety Database users to:

(i) identify a consumer product;

(ii) identify a manufacturer or private labeler of a consumer product;

(iii) understand a harm or risk of harm related to the use of a consumer product; or

(iv) understand the relationship between a submitter of a report of harm and the victim.

(e) *Reports of harm from persons under the age of 18.* The Commission will not accept any report of harm when the report of harm is or was submitted by anyone under the age of 18 without consent of the parent or guardian of that person.

(f) *Commission maintenance and use.* Any information received by the Commission related to a report of harm that does not meet the requirements for submission or publication will not be published but will be maintained for internal use.

§ 1102.12 - Manufacturer Comments

(a) Who may submit. A manufacturer or private labeler may submit a comment related to a report of harm if the report of harm identifies the manufacturer or private labeler and the CPSC transmits such report of harm to the manufacturer or private labeler.

(b) How to submit. A manufacturer or private labeler may submit comments to the CPSC using one of the following methods:

(1) A manufacturer or private labeler who registers with the Commission as described in § 1102.20 (e) may submit comments through a manufacturer portal maintained on the CPSC's Internet website;

(2) A manufacturer or private labeler may submit comments by electronic mail, directed to the Office of the Secretary at (insert email address); or

(3) A manufacturer or private labeler may submit written comments directed to the Office of the Secretary at 4330 East West Highway, Bethesda, MD 20814-4408.

(c) What must be submitted. Subject to § 1102.24, the Commission will publish manufacturer comments related to a report of harm transmitted to a manufacturer or private labeler in the Consumer Product Safety Database if such manufacturer comment meets the following requirements:

(1) Manufacturer comment relates to report of harm. The manufacturer or private labeler's comment must relate to information contained in a specific report of harm that: identifies such manufacturer or private labeler and that is received in the database and transmitted to the manufacturer or private labeler by the CPSC.

(2) *Unique identifier.* A manufacturer comment must state the unique identifier provided by the CPSC when transmitted to the manufacturer for the report of harm to which the comment pertains.

(3) Verification. A manufacturer or private labeler must verify that it has reviewed the report of harm and the comment related to the report of harm and that the

information contained in the comment is true and accurate to the best of the firm's knowledge, information, and belief.

(4) *Request for publication.* When a manufacturer or private labeler submits a comment regarding a report of harm, it may request that the Commission publish such comment in the Consumer Product Safety Database. A manufacturer or private labeler must affirmatively request publication of the comment, and consent to such publication in the Consumer Product Safety Database, for each comment submitted to the CPSC.

(d) Information published. Subject to § 1102.24, the Commission will publish a manufacturer comment and the date of its submission to the CPSC in the Consumer Product Safety Database if the comment meets the minimum requirements for publication as described in section (c).

(e) Information not published. The Commission will not publish in the Consumer Product Safety Database consents and verifications associated with a manufacturer comment.

§ 1102.14 - Recall Notices.

All information presented in a voluntary or mandatory recall notice that has been made available to the public shall be accessible and searchable in the Consumer Product Safety Database.

§ 1102.16 - Additional Information.

(a) *Additional information which shall be published.* In addition to reports of harm, manufacturer comments, and recall notices, the CPSC may include in the Consumer Product Safety Database any additional information it determines to be in the public interest, consistent with the requirements of section 6(a) and (b) of the CPSA. To determine whether it is in the public interest to publish additional information, the Commission shall consider whether the information helps Consumer Product Safety Database users to:

(1) identify a consumer product;

(2) identify a manufacturer or private labeler; or

(3) understand a harm or risk of harm related to the use of a consumer product.

Subpart C—Procedural Requirements

§ 1102.20 - Transmission of reports of harm to the identified manufacturer or private labeler.

(a) *Information transmitted.* Except as provided in paragraphs (a)(1) through (a)(3) of this section, the Commission will transmit all information provided in a report of harm which meets the minimum requirements for publication in the Consumer Product Safety Database to the manufacturer or private labeler identified in a report of harm. The following information will not be transmitted to a manufacturer or private labeler:

(1) Name and contact information for the submitter of the report of harm , unless such submitter provides express written consent to provide such information to the manufacturer or private labeler;

(2) Photographs which depict a person or an injury, unless the submitter of the report of harm consents, in writing, to provide such photograph(s) to the manufacturer or private labeler;

(3) Medical records, unless the person about whom such records pertain, or his or her parent, guardian, or appropriate legally authorized representative, consents to providing such records to the manufacturer or private labeler.

(b) *Limitation on use of contact information.* A manufacturer or private labeler who receives name and contact information for the submitter of a report of harm and/or a victim must not use or disseminate such information to any other party for any other purpose other than verification of information contained in a report of harm. Verification of information contained in a report of harm must not include activities such as sales, promotion, marketing, warranty, or any other commercial purpose. Verification of information contained in a report of harm is limited to verification of the:

(1) identity of the submitter and/or the victim, including name, location, age and gender;

(2) consumer product, including serial or model number, date code, color, or size;

(3) harm or risk of harm related to the use of the consumer product; and/or

(4) description of the incident related to use of the consumer product.

(c) *Timing.* To the extent practicable, the Commission will transmit a report of harm to the manufacturer or private labeler within five business days of submission of the completed report of harm. Examples of circumstances that may arise which may make transmission of the report of harm impracticable within five business days include, but are not limited to:

(1) The manufacturer or private labeler is out of business with no identifiable successor;

(2) The submitter misidentified a manufacturer or private labeler; or

(3) The report of harm contained inaccurate or insufficient contact information for a manufacturer or private labeler; or

(4) when the Commission cannot locate valid contact information at all for a manufacturer or private labeler

(d) *Method of transmission.* The Commission will transmit reports of harm to a manufacturer or private labeler who has registered with the Commission as described in paragraph (e) of this section. The Commission will use the method of transmission and contact information provided by the manufacturer or private labeler. If a manufacturer or private labeler has not registered with the Commission, the Commission will send reports of harm through the United States mail to the firm's principal place of business.

(e) *Manufacturer Registration.* Manufacturers and private labelers may register with the Commission to select a preferred method for receiving reports of harm which identify such firm as the manufacturer or private labeler. Manufacturers and private labelers that chose to register with the Commission must:

(1) Register with the Commission through a process identified for such registration;

(2) provide and maintain updated contact information for the firm, including the name of the firm, title of a person to whom reports of harm should be directed, complete mailing address, telephone number, electronic mail address, and web site address (if any); and

(3) select a specified method to receive reports of harm that identify the firm as the manufacturer or private labeler of a consumer product.

§ 1102.22 – Manufacturer or private labeler comment.

A manufacturer or private labeler who receives a report of harm from the CPSC may comment on the information contained in such report of harm. The Commission, in its discretion, may choose not to publish a manufacturer comment to the database if such comment is received more than one year after transmission of the report of harm to the manufacturer or private labeler where it determines it is in the public interest to do so. The Commission may, in its discretion, limit the data size of comments, which may include attachments submitted, where such comments and attachments may negatively impact the technology performance of the system.

§ 1102.24 – Designation of confidential information.

(a) For purposes of this section, "confidential information" is considered to be information that contains or relates to a trade secret or other matter referred to in 18 U.S.C. 1905 or that is subject to 5 U.S.C. 552(b)(4).

(b) A manufacturer or private labeler identified in a report of harm and who receives a report of harm from the CPSC may review such report of harm for confidential information and request that portions of the report of harm be designated as confidential information. Each such request for a designation of confidential information, must:

(1) Specifically identify the exact portion(s) of the report of harm claimed to be confidential;

(2) State whether the information claimed to be confidential has ever been released in any manner to a person who was not an employee or in a confidential relationship with the company;

(3) State whether the information so specified is commonly known within the industry or is readily ascertainable by outside persons with a minimum of time and effort;

(4) State the company's relationship with the victim and/or submitter of the report of harm and how the victim and/or submitter of the report of harm came to be in possession of such allegedly confidential information;

(5) State how the release of the information would be likely to cause substantial harm to the company's competitive position; and

(6) State whether the person submitting the request for treatment as confidential information is authorized to make claims of confidentiality on behalf of the person or organization concerned.

(c) *Manner of submission.* Requests for designation of confidential information may be submitted in the same manner as manufacturer comments as described in § 1102.12(b). A request for designation of confidential treatment must be conspicuously marked.

(d) *Timing of submission.* A request for designation of confidential information must be received by the Commission in a timely manner. If a request for confidential treatment is submitted in a timely fashion, the Commission may,

in its discretion, withhold a report of harm from publication in the Consumer Product Safety Database until it makes a determination regarding confidential treatment.

(e) *Assistance with defense.* No request to redact confidential information from a report of harm pursuant to 5 U.S.C. 552(b)(4) should be made by any person who does not intend in good faith to assist the Commission in the defense of any judicial proceeding that might thereafter be brought to compel the disclosure of information which the Commission has determined to be a trade secret or privileged or confidential commercial or financial information.

(f) *Commission determination of confidentiality.* If the Commission determines that information in a report of harm is confidential, the Commission shall:

(1) notify the manufacturer or private labeler;

(2) redact such confidential information in the report of harm; and

(3) publish the report of harm in the Consumer Product Safety Database.

(g) *Commission determination of no confidentiality.* If the Commission determines that a report of harm does not contain confidential information, the Commission shall:

(1) notify the manufacturer or private labeler; and

(2) publish the report of harm in the Consumer Product Safety Database.

(h) *Removal of confidential information* - To seek removal of alleged confidential information that has been published in the Consumer Product Safety Database, a manufacturer or private labeler may bring an action in the district

court of the United States in the district in which the complainant resides, or has its principal place of business, or in the United States District Court for the District of Columbia.

§ 1102.26 – Designation of materially inaccurate information.

(a) For purposes of this section, the following definitions apply:

(1) Materially inaccurate information in a report of harm means information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial confusion among Consumer Product Safety Database users regarding:

(i) the identification of a consumer product;

(ii) the identification of a manufacturer or private labeler; or

(iii) the harm or risk of harm related to use of the consumer product.

(2) Materially inaccurate information in a manufacturer comment means information that is inaccurate or misleading in any relevant and sufficiently significant way such that it creates, or has the potential to create, substantial confusion among Consumer Product Safety Database users regarding:

(i) the nature, scope, liability, or cause of a harm or risk of harm related to the use of a consumer product;

(ii) the status of a Commission, manufacturer, or private labeler investigation;

(iii) the identity of the firm or firms responsible for the importation, manufacture, distribution, sale, or holding for sale a consumer product;

(iv) whether the manufacturer or private labeler is engaging in a corrective action (when such action has not been approved by the Commission); or

(v) whether the manufacturer has taken, or promised to take, any other action with regard to the product.

(b) Request for designation of materially inaccurate information. Any person or entity reviewing a report of harm or manufacturer comment, either before or after publication in the Consumer Product Safety Database, may request that the report of harm or manufacturer comment, or portions of such report of harm or manufacturer comment, be excluded from the Consumer Product Safety Database or corrected by the Commission because it contains materially inaccurate information. A request for exclusion or correction must:

(1) State the unique identifier of the report of harm or manufacturer comment to which the request for a determination of materially inaccurate information pertains;

(2) Specifically identify the exact portion(s) of the report of harm or the manufacturer comment claimed to be materially inaccurate;

(3) State the basis for the allegation that such information is materially inaccurate;

(4) Provide evidence, which may include documents, statements, electronic mail, internet links, photographs, or any other evidence, sufficient for the Commission to make a determination that the designated information is materially inaccurate;

(5) State what relief the requester is seeking exclusion of the entire report of harm or manufacturer comment; redaction of specific information; correction of specific information; or the addition of information to correct the material inaccuracy;

(6) State whether and how an alleged material inaccuracy may be corrected without removing or excluding an entire report of harm or manufacturer comment; and/or

(7) State whether the person submitting the allegation of material inaccuracy is authorized to make claims of material inaccuracy on behalf of the person or organization concerned.

(c) *Manner of submission.*

(1) *Manufacturers and private labelers.* A manufacturer or private labeler may requests a Commission determination of materially inaccurate information related to a report of harm in the same manner as described in § 1102.12(b). Such requests should be conspicuously marked.

(2) *All other requests.* All other requests for a Commission determination of materially inaccurate information contained in a report of harm or manufacturer comment made by any other person or firm must be submitted to the CPSC using one of the methods listed below. The requests for a Commission determination of materially inaccurate information may be made through:

(i) *Electronic mail.* By electronic mail directed to the Office of the Secretary at (insert email address); or

(ii) *Paper- Based. W*ritten submission directed to the Office of the Secretary at (insert mailing address).

(d) *Timing of submission.* A request for a Commission determination regarding materially inaccurate information may be submitted at any time. If a request for determination of materially inaccurate information is submitted prior to publication in the database, the Commission shall withhold a report of harm from publication in the Consumer Product Safety Database until it makes a determination.

(e) *Assistance with defense.* No request for a determination of materially inaccurate information should be made by any person who does not intend in good faith to assist the Commission in the defense of any judicial proceeding that might thereafter be brought to compel the disclosure of information which the Commission has determined to be materially inaccurate information.

(f) *Notice.* The Commission shall notify the person or firm requesting a determination regarding materially inaccurate information of its determinatio*n and* method of resolution after resolving such request.

(g) *Commission determination of material inaccuracy before publication.* If the Commission determines that the requested information in a report of harm or manufacturer comment is materially inaccurate information before it is published in the Consumer Product Safety Database, the Commission may:

(1) decline to add the materially inaccurate report of harm or manufacturer comment to the Consumer Product Safety Database;

(2) correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in §§ 1102.10(c) and 1102.12(c) are met, publish the report of harm or manufacturer comment in the Consumer Product Safety Database; or

(3) add information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in d §§ 1102.10(c) and 1102.12(c) are met, publish the report of harm or manufacturer comment in the Consumer Product Safety Database.

(h) *Commission determination of material inaccuracy after publication.* If the Commission determines, after an investigation, that the requested designated information in a report of harm or manufacturer comment contains materially inaccurate information after the report of harm or manufacturer comment has been published in the Consumer Product Safety Database, the Commission may, within seven business days after such determination:

(1) remove the report of harm or manufacturer comment from the Consumer Product Safety Database, including any associated documents, photographs, or comments;

(2) correct the information, and, if the minimum requirements for publication as set forth in §§ 1102.10(c) and 1102.12(c) are met, maintain the report of harm or manufacturer comment in the Consumer Product Safety Database; or

(3) add information to the report of harm or the manufacturer comment to correct the materially inaccurate information, and, if the minimum requirements for publication as set forth in §§ 1102.10(c) and 1102.12(c) are met, maintain the report of harm or manufacturer comment in the Consumer Product Safety Database

(i) *Commission discretion.* In exercising its discretion to remove, correct or add information to correct materially inaccurate information contained in a report of harm or manufacturer comment, the Commission shall preserve the integrity of information received for publication in the Consumer Product Safety Database whenever possible. Subject to §§ 1102.10(c) and 1102.12(c), the Commission shall favor correction and addition to correction over exclusion of entire reports of harm and manufacturer comments where possible.

(j) *Commission determination of no material inaccuracy.* If the Commission determines that the requested information in a report of harm does not contain materially inaccurate information, the Commission will:

(1) notify the requester of its determination;

(2) publish the report of harm or manufacturer comment in the Consumer Product Safety Database if it meets the minimum requirements set forth in sections 1102.10, 1102.12 and 24.

(k) The Commission may review a report of harm or manufacturer comment for materially inaccurate information on its own initiative, following the same notice and procedural requirements set forth in sections (g) through (j).

§ 1102.28 - Publication of reports of harm.

(a) *Timing.* Subject to §§ 1102.10, 1102.24 and 1102.26, the Commission will publish reports of harm that meet the requirements for publication in the Consumer Product Safety Database. The Commission will publish reports of harm as soon as practicable but no later than 10 days after such report of harm is transmitted to the manufacturer or private labeler by the CPSC.

(b) *Exceptions.* The Commission may publish a report of harm that meets the requirements of § 1102.10(c) in the Consumer Product Safety Database beyond the 10 business day time frame set forth in paragraph (a) of this section if the Commission determines a report of harm misidentifies or fails to identify all manufacturers or private labelers, such information must be corrected through the procedures set forth in § 1102.26 for materially inaccurate information in a report of harm. Once a manufacturer or a private labeler has been identified correctly, the time frame set forth in paragraph (a) of this section shall apply.

§ 1102.30 - Publication of manufacturer comments.

(a) *Timing.* Subject to §§ 1102.12 and 1102.26, the Commission will publish in the Consumer Product Safety Database manufacturer comments submitted in response to a report of harm which meet the minimum requirements set forth in §1102.12(c). This publication will occur at the same time as the report of harm is published or as soon as practicable thereafter. Examples of circumstances which may make it impracticable to publish a manufacturer comment at the same time as a report of harm include, but are not limited to:

(1) the Commission did not receive the comment until on or after the publication date of the report of harm; or

(2) the Commission is resolving a claim that the manufacturer comment contains materially inaccurate information.

Subpart D—Notice and Disclosure Requirements

§ 1102.42 - Disclaimers.

The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the Consumer Product Safety Database, particularly with respect to the accuracy, completeness, or adequacy of information submitted by persons outside of the CPSC. The Consumer Product Safety Database will contain a notice to this effect that will be prominently and conspicuously displayed on the database and on any documents that are printed from the database.

§ 1102.44 - Applicability of section 6(a) and (b) of the CPSA.

(a) *Generally.* Section 6(a) and 6(b) of the CPSA shall not apply to the submission, disclosure and publication of information provided in a report of harm that meets the minimum requirements for publication in § 1102.10(c), in the Consumer Product Safety Database.

(b) *Limitation on Construction.* Section 1102.42(a) shall not be construed to exempt from the requirements of sections 6(a) and 6(b) of the CPSA information received by the Commission pursuant to:

(i) section 15(b) of the CPSA; or

(c) any other mandatory or voluntary reporting program established between a retailer, manufacturer, or private labeler and the Commission.

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