The Consumer Product Safety Commission Database

By Bradley C. Nahrstadt

What Every Manufacturer Needs to Know (and Think About)

In 2008, Congress passed the Consumer Product Safety Improvement Act of 2008 (CPSIA). Section 212 of the CPSIA amended the Consumer Product Safety Act and required the Consumer Product Safety Commission to establish and maintain a searchable product safety information database that was available to the public. On May 7, 2010, the CPSC gave notice of its proposed regulations establishing a publicly accessible and searchable database. On December 9, 2010, the CPSC published in the Federal Register its Final Rule establishing the Publicly Available Consumer Product Safety Information Database (the Database). This Database went live on March 11, 2011 (although, according to the Database, reports of harm will not be available for public review until the beginning of April). The database can be found at http://www.saferproducts.gov/Default.aspx.

Some have suggested that the Database is long overdue and will serve to inform the public fully of problems associated with consumer products. Others have voiced their concern that such a "crowd-sourced" website will be bloated with bogus, inaccurate, and misleading reports. Still others have argued that the Database will be used by consumer advocate groups and plaintiffs' attorneys to manufacture evidence to be used in class action lawsuits. All of these claims may be true—but one thing is certain: product manufacturers and labelers must be intimately familiar with the Database and take certain steps to make sure that they are prepared to respond to reports of harm that are submitted to the CPSC for inclusion in the Database.

What Is the Database?

The Database allows individuals to submit reports of harm for all types of consumer products, as well as other products or substances regulated by the CPSC (reports regarding food, drugs, cosmetics, cars, and firearms will not be posted in the Database). Not only are individuals allowed to submit reports of harm, they are able to conduct searches: for categories of products, for products produced in a particular state, or for specific products and manufacturers. The Database will collect reports on manufacturers of consumer products, importers of consumer products, and owners of a brand or trademark of a consumer product that bears a private label.

The Database consists of two separate portals: the consumer portal and the industry portal. The consumer portal contains two main tools: one that allows users to post details of a product safety-related incident quickly and easily, and one that allows users to search previous incidents easily and quickly. The industry portal allows authorized and registered manufacturers and labelers to comment on incident reports submitted via the consumer portal. According to the CPSC, appropriate security and user-interface components will be used to isolate companies and segregate internal data. Manufacturers and labelers will be authorized to use only sites and data that are necessary for their contributions and will be restricted from viewing other firms' data.

What Is the Report of Harm?

The Database is intended to serve as a repository of reports of harm relating to the use of consumer products. Reports of harm can be submitted by any consumer, including the user of the product, as well as any family member, guardian, friend, or observer of the use of the product. In addition, reports of harm can be filed by "others," including:

- local, state, or federal government agencies
- health care professionals
- child service providers
- public safety professionals
- attorneys
- consumer advocates.

The individual who submits the report of harm does not need to have firsthand knowledge of the alleged harm caused by the product; no evidence or proof of injury, illness, or death is required to be submitted. Reports of harm can include not only actual injury, illness, or death, but also what the consumer or submitter perceives to be a "risk" of injury, illness, or death (about the only thing that cannot be included in a report of harm are complaints about the quality of the product or the price of the product). Users of the Database may enter reports of harm regardless of when the incident occurred. As a result, some submitters may file reports of incidents that occurred long before the Database was created and years after any opportunity to investigate the incident has passed. To make matters even worse, users are allowed to submit reports of harm for products that they bought new or used.

Reports of Harm can be submitted online, via e-mail, by written submission, or via telephone. Internet, e-mail, and written submissions must use the incident report form available at http://www.saferproducts.gov/. Telephone submissions will utilize a CPSC call center that enters information

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taken over the phone into the electronic incident form.

A report of harm must meet certain threshold criteria in order to be published in the database. All publishable reports of harm must contain:

- the incident date
- the category of submitter
- a description of the consumer product (according to the regulations the description can be as short as "a word or phrase sufficient to distinguish the product")
- the identity of the manufacturer of the product
- a description of the harm related to use of the product
- contact information for the person submitting the report (at a minimum the submitter's name and address)
- verification by the submitter of the truth and accuracy of the information submitted
- the submitter's consent for inclusion of the report in the Database.

16 C.F.R. §1102.10(d). If this information is not included in the report of harm, the report is ineligible for publication in the Database. Indeed, the pertinent regulations require that "[a]ny information received by the Commission…that does not meet the requirements for submission or publication will not be published." 16 C.F.R. §1102.10(h).

The submitter is not required to submit the name of the "victim." Although the submitter's contact information will not be published, it is a requirement of submission—anonymous reports will not be included in the Database.

Submitters may also include a variety of optional information as part of the report of harm. That optional information may include the name of the product, the product brand name, the model number, the serial number, where the product was purchased, the date of manufacture, the location of the incident, a description of the severity of the injuries, and an indication of whether the submitter has contacted the manufacturer about the alleged incident. The submitter may also upload photographs or videos of the product or the injuries sustained, as well as copies of the injured party's medical records. The CPSC requests, but does not require, that the submitter retain the product for 30 days in order to allow a CPSC investigator the chance to inspect the product.

What Does the CPSC Do Once a Report of Harm Is Filed?

Within five days of receiving a report of harm, the CPSC must, "to the extent practicable," provide the report of harm to the manufacturer or private labeler identified in the report. A report likely will not be transmitted in a timely fashion when the manufacturer is out of business, the submitter mistakenly identifies a manufacturer, the report contains incorrect contact information, or the CPSC cannot locate the correct contact information for a manufacturer.

Although the submitter's contact information will not be published, it is a requirement of submission—anonymous reports will not be included in the Database.

If a manufacturer or labeler is registered to receive reports of harm, the CPSC will send notice of reports of harm to the registered account user and any other designated recipients (notification can even be made via text message if the manufacturer selects that method to receive reports). If a manufacturer or labeler is not registered with the CPSC, reports of harm will be sent via U.S. mail to the principal place of business.

The notification sent to manufacturers and labelers will contain all information provided in the report of harm, except for the name and contact information of the submitter, photographs, and medical records. The submitter can consent to the release of this information to the manufacturer. If express written consent is provided, this consumer information may not be used or disseminated to any other party for any purpose other than verifying the details of a report submitted to the Database (identity of the subscriber, identity of the product, a description of the incident and a description of the harm or risk of harm).

What Can the Manufacturer Do Once It Receives Notice of a Report of Harm?

A manufacturer or labeler who receives a report of harm from the CPSC has 10 business days from the date on which the CPSC transmitted the report to submit comments about the report of harm. It should be noted that the CPSC is required to publish a report of harm that includes the minimum required information set forth above no later than 10 business days after the date on which the CPSC transmits the report of harm to the manufacturer—whether the manufacturer comments on the report or not. 16 C.F.R. §1102.28.

Manufacturer comments can be submitted via regular mail, electronic mail or online through the business portal. Comments that are submitted within the 10-day window will be published in the Database at the same time as the report of harm, provided that certain minimum requirements are met. In order to meet the minimum requirements set forth in the regulations, the comment must specifically relate to the report of harm, contain a unique identifier assigned to the report, been verified by the manufacturer or labeler, and affirmatively request and consent to publication. Companies may submit comments about reports of harm at any time; however, comments received more than a year after notification of a report of harm may be excluded from publication if the CPSC determines that it is not in the public interest to publish the comments. Leta E. Gorman and Lisa Grimm, "The CPSC's Consumer Database Officially Launches in March 2011: Are Your Clients Ready?" IADC Product Liability Committee Newsletter, p. 3 (February 2011), http://www.iadclaw.org/default.aspx.

In a nutshell, if a manufacturer wants the CPSC to review its comments (including any assertions that the report of harm contains confidential or materially inaccurate information), and publish those comments at the same time the report of

harm is posted, the manufacturer has a maximum of 10 business days to accomplish all of the following:

- Investigate the report
- Decide whether to respond with comments
- Draft the comments, including any assertions that the report contains materially inaccurate or confidential information
- Receive any required approval of comments from upper management, in-house counsel, or outside counsel
- Submit the comments to the CPSC
- Request that the CPSC publish the comments.

How Can Confidential Information Be Protected?

If a manufacturer or labeler believes that a report of harm contains confidential business or trade secret information, it may, "in a timely manner" before the expiration of the 10-day window for submission of comments, request a confidential designation of such information. 16 C.F.R. §1102.24(d). Such requests must be conspicuously marked. The burden of proof with regard to confidentiality rests with the manufacturer or labeler. A request for confidential designation must include (1) the specific information claimed to be confidential; (2) whether that information has ever been released to anyone who is not an employee or in a confidential relationship with the manufacturer; (3) whether the information is commonly known in the industry or readily ascertainable by outside persons with a minimum of effort; (4) the relationship (if known) between the manufacturer and the person submitting or the subject of the report of harm and how that person came to be in possession of the information; (5) how the release of the information would cause substantial harm to the manufacturer and (6) whether the person submitting the request for confidential treatment is authorized to make such a claim. 16 C.F.R. §1102.24(b).

If the CPSC agrees with the manufacturer that the identified information is indeed confidential, it must redact the information before publishing the report in the Database. 16 C.F.R. §1102.24(f). If additional time is needed to make a determination as to the confidentiality of the designated information, the CPSC will redact the information and continue with publication of the report of harm until a final determination can be made. If the CPSC does not agree with the confidential designation, it must notify the manufacturer of its decision to include the information in the report to be published in the Database. 16 C.F.R. §1102.24(g). The manufacturer may, if it chooses, 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, to seek removal of the information from the database." 16 C.F.R. §1102.24(h).

> A manufacturer or labeler who receives a report of harm from the CPSC has 10 business days from the date on which the CPSC transmitted the report to submit comments about the report of harm.

Identifying "Materially Inaccurate Information"

Anyone reviewing a report of harm or a manufacturer's comment may notify the CPSC of his or her belief that the report or comment contains "materially inaccurate information." 16 C.F.R. §1102.26(b). "Materially inaccurate information" is defined as "information that is false and misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product…." 16 C.F.R. §1102.26(a). With respect to a claim of materially inaccurate information in a report of harm, the information must relate to (1) the identification of the consumer product; (2) the identification of the manufacturer; (3) the harm or risk of harm related to the use of the product; or (4) the date or approximate date on which the incident occurred. 16 C.F.R. §1102.26(a)(1). With respect to a manufacturer's comment, the claimed materially inaccurate information must pertain to (1) the description of the product; (2) the identity of the entity responsible for importing, manufacturing, distributing, or selling the product; (3) the harm or risk of harm related to the use of the product; (4) the status of a CPSC or manufacturer investigation; (5) whether the manufacturer is engaging in any corrective action and whether such action has been approved by the CPSC; or (6) whether the manufacturer has taken, or promised to take, any other action with regard to the product. 16 C.F.R. §1102.26(a)(2).

Requests for removal of materially inaccurate information can be made either before or after publication of a report of harm. The requester bears the burden of proof. Requests for expedited review can be made if the request is less than five pages long. Although expedited review is available, the CPSC has discretion to withhold a report from publication or to publish it before making a final decision about the claimed material inaccuracy. In short, a manufacturer cannot be sure that a claim of material inaccuracy will be resolved prior to publication of a report of harm; accordingly, information considered by the manufacturer to be materially inaccurate may be available for public viewing for some time prior to its ultimate removal.

Any person making a request that the CPSC correct or exclude materially inaccurate information must provide the CPSC with the following information:

- the unique identifier assigned to the report of harm or manufacturer's comment
- the exact portion or portions of the report or comment claimed to be materially inaccurate
- the basis of the claim of material inaccuracy
- evidence to support the claim of material inaccuracy
- whether the requester seeks exclusion of the entire report or comment, redaction of specific information or addition of corrective information
- whether and how the alleged material inaccuracy may be corrected without excluding the entire report or comment

- whether the requester is authorized to make the claim of material inaccuracy.

16 C.F.R. §1102.26(b).

If the CPSC determines, after conducting an investigation, that the report of harm or manufacturer's comment does contain materially inaccurate information, then, within seven business days of making that determination, the CPSC must do one of the following three things: (1) decline to publish the report in the Database or, if already published, remove the report from the Database; (2) correct the information and publish a corrected report of harm or manufacturer's comment, or (3) add information to the report of harm or comment in order to correct it. 16 C.F.R. §1102.26(b).

Efforts to Delay Implementation of the Database

Earlier this year, Representative Mike Pompeo, Republican of Kansas, introduced a bill that would block the CPSC from spending any money to operate the Database. In an interview, Pompeo said the Database needs to be revised so that the Commission—and manufacturers—can better vet reports before they are posted to ensure accuracy. Pompeo believes that the current version of the Database allows for the easy posting of bogus reports that can lead consumers astray. Although the House approved Pompeo's legislation on February 18, 2011, Senate Democrats are seeking to remove the provision from the House-approved budget package. On March 4, 2011, Democrats on the Senate Appropriations Committee released their own version of the budget that specifically called for restoring funding of the CPSC Database.

The National Association of Manufacturers has also been involved in efforts to delay the implementation of the Database. Rosario Palmieri, Vice President, Infrastructure, Legal and Regulatory Policy for the NAM, recently sent a letter to the CPSC requesting at least a three-month continuance in the "soft launch" of the Database. In his letter, Mr. Palmieri identified numerous problems with the Database discovered by those manufacturers who have been participating in the soft launch phase of the Database rollout, including the following:

- Manufacturers with different divisions and brands among different product lines have indicated an inability on the part of CPSC staff to timely register multiple parties within such corporations. According to Palmieri, the difficulty in registering by brand/product line/division and the slow or incomplete response by the CPSC to registration raises troubling questions about the promised flow of information between the CPSC and registered companies.
- A number of manufacturers, importers and private labelers have reported that reports not directly involving "harm" have been posted to the Database. Some manufacturers have reported that as many as 30 percent of the complaints forwarded were not adequately scrubbed to assure that they involve "harm" as defined by the regulations.
- Licensors have indicated that they have received reports that are materially inaccurate since they involve products for which they are not the manufacturer, importer or private labeler.
- Manufacturers, importers or private labelers have indicated that they have received reports of harm identifying an incident involving their product that did not in fact involve their product and they advised CPSC of that fact. These entities have not received return affirmative confirmation that the CPSC will not publish such false claims in the Database.
- Registrant businesses have reported that the completed complaint form they received often omitted data necessary to identify the products alleged to have been involved in the harmful incident. That absence of such data, such as the model, serial number, date of manufacture or date/tracking codes (required by law to be contained on many products) makes the reports almost impossible to verify.
- The CPSC's decision to define the term "consumer" very broadly appears contrary to the intent of Congress and will result in the potential for multiple reports of harm involving the identical incident.

As noted above, despite the perceived flaws announced in Mr. Palmieri's letter, and a request that the launch of the Database be postponed, the Database went live on March 11, 2011.

Manufacturers Must Be Proactive Towards Database Reports About Their Products

Proactive planning is the key to responding quickly and effectively when trying to balance the ability to meet the tight deadlines imposed under the CPSIA with protecting both the company and consumer safety. While it will be difficult to prepare procedures for dealing with reports of harm that might be so varied as to content, source, reliability, or seriousness of complaint, planning for how one reacts to them is probably time well spent versus simply reacting to them upon receipt.

Manufacturers cannot control certain things about the database: whether the consumer identifies the correct manufacturer and the correct product; whether the consumer omits important facts or misunderstands what caused the alleged injury; whether CPSC satisfactorily verifies the accuracy of the report prior to posting it; what others will do with the publicly available information. However, advanced planning can help manufacturers control what can be controlled: receiving notice of an incident report as quickly as possible by registering contact information with CPSC; responding within the deadline; providing the CPSC with additional information that identifies material inaccuracies or confidential information in the incident report; making the company's position regarding the incident publicly viewable along with the incident report.

Register

One of the first things all manufacturers and labelers must do is select a Database incident report coordinator or team. The company must make sure that these individuals are registered with the CPSC to receive notice of reports of harm. More than one person from the company should be registered (although steps must be taken to ensure that there is a clear delineation of who is responsible for responding to the report of harm and in what order—in order to avoid a report falling through the cracks). The CPSC should be provided with e-mail addresses and text message addresses in order to facilitate prompt delivery of reports of harm.

Develop Procedures for Handling Incident Reports

It is imperative that every manufacturer and labeler determine a protocol for thoroughly investigating any report of harm posted to the Database. Although the protocol will vary depending on the manufacturer, the type of product manufactured, the sophistication of personnel, the geographic reach of the company, and other factors, any proposed protocol should include an initial assessment to decide if the report:

- identified the correct product;
- identified the correct manufacturer;
- stated a causal connection between the product and a harm that is implausible if not impossible;
- requires an immediate designation of material inaccuracy filed in time to accompany any publication of the report of harm to the Database before the CPSC decides the designation;
- requires an immediate designation of confidential information to protect company trade secrets and proprietary data in the report before it is published;
- requires comment on the submitter's data about the product or the related incident;
- requires reporting under Section 15, particularly given that the CPSC has already seen and processed a report concerning the incident (the CPSC has made it very clear that the report of harm, either alone or when added to pre-existing data, needs to be assessed for 15(b) reporting obligations and it cannot be assumed that an event that the agency already knows about through the Database need not be subjected to reporting obligations within the CPSA, including Section 15(b));
- presents an opportunity to provide a remedy to the reporting product user.

Mark A. Kinzie, "The Publicly Accessible Database: Four Things to Know About New CPSC Regulations," *In-House Defense Quarterly*, p. 41 (Fall 2010). In addition to the foregoing, every manufacturer or private labeler must implement a calendaring and notice system to track the 10-day deadline and make sure key employees are aware of the deadlines associated with database reports and comments.

Develop a Policy for Submitting Comments

There are several factors that companies will want to consider when developing a policy for submitting comments:

- Will the company respond to every incident report or only certain kinds of reports?
- What will determine whether the company will respond, *e.g.*, the type of product, seriousness of the injury, number of related or similar reported incidents?
- Will the company draft a unique response every time or use form responses?
- What level of investigation must be completed, if any, prior to commenting?
- What will trigger the need for involvement of upper-level management, in-house counsel, or outside counsel?
- Will the company always have comments published or will it sometimes submit them without seeking publication in the database?
- Will other manufacturers' comments regarding similar incidents or products affect how your company comments?
- Who must approve comments prior to submission to the CPSC?
- What safeguards are in place to make sure that the company considers previously submitted comments when drafting new comments?

Other Important Considerations

In addition to developing procedures for handling incident reports and developing a policy for submitting comments, companies should give careful consideration to some other important considerations. Some early thinking needs be given to the following:

- Does the company undertake to investigate a report of harm that has attribution for the reporter and who should conduct that task and under what circumstances?
- Are reports of harm filed by third parties (law enforcement personnel, lawyers, social services providers, "witnesses" to incidents, etc.) to be investigated and if so, to what extent?
- Are reports of harm to be integrated with general field experience records, which may be considered to be producible during the discovery process?
- Should outside counsel be utilized to develop the methods of investigation and follow-up (including comments of a manufacturer)?
- What role should outside attorneys play in advising manufacturers on the subject of whether receipt of reports of harm need to be considered to be "notice" and worthy of investigative effort by the subject company and how that might be best approached within the limitations of anonymity for "reporters" and restrictions on manufacturer contacts with consumers?
- Is this a system of outsider review and reporting that has similarity to consumer reviews on general websites such as Amazon.com, Wal-Mart, etc. that bring such new volume, content and consequence that they should be dealt with collectively for their importance in a marketplace whose activities are increasingly driven by electronic communications and data storage?

Barring a complete about-face on the perceived need for a "consumer" driven database, or the death of all funding to operate it, the Consumer Product Safety Commission Database is here to stay. As a result, product manufacturers and labelers need to become intimately familiar with the Database requirements, the timeframes applicable to reporting and commenting, and the ways to protect confidential information from disclosure and to identify materially inaccurate information. In addition, manufacturers must be proactive in their efforts to deal with Database reports. Proactively determining and implementing procedures needed to handle reportable incidents and consumer-reported incidents in the Database is a necessary step toward effectively addressing such incidents in a way that protects both the company and consumer safety.