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## 4 THINGS TO KNOW ABOUT NEW CPSC REGULATIONS THAT ESTABLISH THE PUBLICLY ACCESSIBLE DATABASE

On May 7, 2010, the Consumer Product Safety Commission (CPSC) gave notice of its proposed regulations establishing the publicly accessible and searchable database on the safety of consumer products, as required by Section 212 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).<sup>i</sup> Generally, these new regulations reflect the express statutory requirements of the CPSIA. They identify the information to be included in the database, the notice to be given to manufacturers, the publishing of Reports of Harm to the database, and the designation of confidential and materially inaccurate information to be protected.<sup>ii</sup> The CPSC database may be found at its new website, SaferProducts.gov.

Below are 4 essential things to know about the new database, including specific action manufacturers should take towards database Reports of Harm. In short, manufacturers must be prepared to manage in public the incoming data typically collected through its confidential customer service system.

### ***1. The new database differs from CPSC In-Depth Investigation (IDI) reports.***

Anyone can submit a Report of Harm.<sup>iii</sup> Manufacturers currently respond to CPSC In-Depth Investigation (IDI) reports, which originate with the CPSC and arise when a CPSC evaluation determines that a product may present a serious risk of harm. New regulations allow database Reports of Harm to be submitted by consumers,<sup>iv</sup> government agencies,<sup>v</sup> health care professionals,<sup>vi</sup> child service providers,<sup>vii</sup> public safety professionals,<sup>viii</sup> and “others.”<sup>ix</sup>

Reports of Harm must be published in the database within fifteen (15) days. IDIs are available via a Freedom of Information Act (FOIA) request. New regulations require the CPSC to transmit a Report of Harm to manufacturers within 5 business days after receiving a submission<sup>x</sup> and require the CPSC to publish the Report of Harm to the database within 10 business days after that transmittal.<sup>xi</sup> Manufacturers may comment, but comments may appear after the original Report of Harm is published to the database.

The new database is publicly available and searchable.<sup>xii</sup> None of the information from IDIs or its originating source was available online, was organized in a database, or was searchable. This change alone deepens the manufacturer’s responsibility to correct inaccuracies in Reports of Harm, report product risk under Section 15, be diligent about design change, and respond to claims from individual product users.

Finally, CPSC IDIs may still occur after a Report of Harm is submitted. The Commission may pursue an investigation about a product as a result of a Report of Harm. The Commission’s IDI does not change whether the Report is published in the database, but it may add information to the original Report.

### ***2. The content of a database report is tightly regulated.***

The new regulations establish minimum requirements for publication. A Report of Harm must meet

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threshold criteria to be published to the database, including a description of the consumer product, the manufacturer, the harm related to the product, and contact information, verification, and consent from the submitter.<sup>xiii</sup> Absent these minimum requirements, the Report is ineligible for publication to the database.<sup>xiv</sup>

Certain data from submitter's Report of Harm will not be published. This information includes the submitter's contact information and verification, a victim's identification and medical records without consent, inappropriate photographs, confidential business information, materially inaccurate data, or reports made by minors.<sup>xv</sup>

Manufacturers may request publication of its comment on the Report of Harm.<sup>xvi</sup> Likewise, any person, including a manufacturer, may request designation of materially inaccurate information to be excluded from or corrected in the database.<sup>xvii</sup> This request is decided by the Commission, and publication of a Report of Harm to the database may occur before the request is decided.<sup>xviii</sup> This category of information is intended to protect the product identified by the submitter and to protect the manufacturer from erroneously engaging in corrective action.<sup>xix</sup> Manufactures also may request designation of confidential business information to be excluded from a Report.<sup>xx</sup>

### **3. *Manufacturers can register to receive Reports of Harm.***

Manufacturers and private labelers may register to receive Reports of Harm. This is accomplished simply by selecting a method to receive Reports and by providing contact information to the CPSC.<sup>xxi</sup> If a manufacturer has not registered, Reports of Harm will be sent by U.S. Mail.<sup>xxii</sup> Even if registered, certain circumstances may make transmittal of the Report "impractical" within 5 days. These circumstances occur when the manufacturer is out of business, the submitter mistakenly identifies a manufacturer, the Report contains incorrect contact information, or when the CPSC cannot locate correct contact

information for a manufacturer.<sup>xxiii</sup> The transmission period is critical because the Report of Harm is typically published to the database 10 days after transmission by the CPSC.

A manufacturer receives all information provided in the Report of Harm, except for the name and contact information for the submitter, photographs, and medical records of the victim, unless consent has been given.<sup>xxiv</sup> If a manufacturer receives this additional information by consent, its use is limited to the submitter directly and to the product at issue.<sup>xxv</sup>

### **4. *Manufacturers must be proactive towards database reports about their product.***

The public database is new and its launch date is March 11, 2011. Nothing can be known about the practical application of these new regulations to Reports that a manufacturer will receive when this new system begins. In the interim, manufacturers should continue to follow the existing rule—*protect the user, protect the brand*. This means that incoming data from Reports of Harm must be examined to determine whether the product caused an injury, illness, or death to a user and, if so, whether other users can be protected, and whether it triggers Section 15 reporting duties. Likewise, incoming data must be examined for accuracy about the product, the manufacturer, and whether the harm had a genuine, casual connection to the product or its function.

Because publication of these Reports of Harm can occur 10 days after transmission, manufacturers must act swiftly. Traditionally, these assessments unfolded over weeks, if not months. Now, manufacturers must act quickly if they intend to assert a first line of defense against inaccuracies in reports that may otherwise lead to unnecessary regulatory action, ill-advised product recalls, and misinformed tort suits.



Under the new regulations, manufacturers should take the following actions: Upon receipt, a speedy, first assessment must be made to decide if the Report:

- (a) identified the correct product;
- (b) identified the correct manufacturer;
- (c) stated a casual connection between the product and a harm that is implausible if not impossible;
- (d) 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;
- (e) requires an immediate designation of confidential information to protect company trade secrets and proprietary data in the Report before it is published to the database;
- (f) requires comment on the submitter's data about the product or the related incident;

- (g) requires Section 15 reporting, particularly given that the CPSC has already seen and processed the incident; and
- (h) presents an opportunity to provide a remedy to the reporting product user.

Even after these first assessments, the manufacturer must consider whether information from the Report informs its design team about hazards that presented during use and whether the company's foreseeable use of the product captured the incident described. This information may change the design and manufacturing of the product, which will now be public knowledge, and which the CPSC will want to know, should the product become the subject of an IDI or a field investigation. In short, the manufacturer must be prepared to manage in public the data typically collected in private during its customer service system.

OF NOTE: *Mark A. Kinzie* has been counsel to product manufacturers in regulatory actions, product recalls, and mass tort litigation. He frequently counsels manufacturers about warnings, product safety, litigation control, and the risk management required to reduce and prevent product liability.

*Averture* is a law firm dedicated exclusively to the practice of product safety and its lawyers represent manufacturers of children's products, consumer products, chemical goods, industrial equipment, medical devices, and product components.

<sup>i</sup> Publicly Available Consumer Product Safety Information Database, 16 CFR Part 1102, Docket CPSC-2010-0041, *Notice of Proposed Rulemaking* (May 7, 2010) (collectively, "Notice"); see also 15 U.S.C. § 2055(a), *Publicly Available Consumer Product Safety Information Database* (Sec. 212, 122 Stat. 3048, Public Law 110-314 (August 14, 2008)). As of May 17, 2010, these proposed regulations had not yet been published in the Federal Register.

<sup>ii</sup> See Notice at 117-150, proposing regulations at 16 C.F.R. §§ 1102.2—1102.44 in four (4) subparts: (A) Background and Definitions; (B) Content Requirements; (C) Procedural Requirements; and (D) Notice and Disclosure Requirements.

<sup>iii</sup> A Report of Harm is an information submitted through proposed 16 C.F.R. § 1102.10(b) about an actual or potential risk of an injury, illness or death from the use of a consumer product. See Notice proposing 16 C.F.R. § 1102.6(b) (8), *Definitions, Report of Harm*.

<sup>iv</sup> Proposed 16 C.F.R. § 1102.10(a), identifying product users, family members, relatives, friends, observers, *et al.*

<sup>v</sup> Proposed 16 C.F.R. § 1102.10(a)(2) identifying local government, schools, social services, state attorney generals, *et al.*

<sup>vi</sup> Proposed 16 C.F.R. § 1102.10(a) (3) identifying medical examiners, coroners, physicians, nurses, hospitals, chiropractors, acupuncturists, *et al.*



<sup>vii</sup> Proposed 16 C.F.R. § 1102.10(a) (4) identifying child care providers, pre-kindergarten schools, *et al.*

<sup>viii</sup> Proposed 16 C.F.R. § 1102.10(a) (5) identifying police, fire, EMT, public safety officials, *et al.*

<sup>ix</sup> Proposed 16 C.F.R. § 1102.10(a) (6) identifying attorneys, engineers, consumer advocates, trade associations, *et al.*

<sup>x</sup> Proposed 16 C.F.R. § 1102.20(c), *Timing*. The Commission transmits Reports of Harm to the manufacturer within five (5) days after its original submittal to the CPSC.

<sup>xi</sup> Proposed 16 C.F.R. § 1102.28 (a), *Timing*. The Commission must publish Reports of Harm no later than the 10<sup>th</sup> day after it was submitted to the manufacturer for comment.

<sup>xii</sup> See 15 U.S.C. §2055(a) (1), *Database Required* (the CPSC “shall . . . establish and maintain a database on the safety of consumer products . . . that is (A) publicly available; (B) searchable; and (C) accessible through the Internet”).

<sup>xiii</sup> Proposed 16 C.F.R. §1102.10(d) (1)-(6), *Minimum requirements for publication*.

<sup>xiv</sup> Proposed 16 C.F.R. §1102.10(h), *Incomplete reports of harm* (“Any information received by the Commission . . . that does not meet the requirements for submission or publication will not be published”); and proposed 16 C.F.R. § 1102.28(a) (the CPSC “will publish reports of harm that meet the requirements for publication in the Database.”).

<sup>xv</sup> Proposed 16 C.F.R. §1102.10(f) and (g), *Information not published and Reports of harm from persons under the age of 18*, respectively.

<sup>xvi</sup> Proposed 16 C.F.R. §1102.12(c) (4), *Request for publication* (“A manufacturer or private labeler must affirmatively request publication of the comment and consent to such publication in the Database”). Like the Report of Harm, a manufacturer’s comment has minimum requirements for publication. *Id. at (c) (1)-(4)*.

<sup>xvii</sup> Proposed 16 C.F.R. §1102.26(b), (h).

<sup>xviii</sup> Although an expedited review is available, the Commission has discretion to withhold a report from publication or to publish it before a final decision about the material inaccuracy. Proposed 16 C.F.R. §1102.26(c), (d).

<sup>xix</sup> A requester must submit seven (7) data points about the inaccuracy to the Commission. *Id. at §1102.26(b) (1)-(7)*.

<sup>xx</sup> Proposed 16 C.F.R. §1102.24. (“[C]onfidential 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 . . . 5 U.S.C. §552(b)(4).”) These requests are decided before publication. *Id. at §1102.24(d), Timing of submission*.

<sup>xxi</sup> Proposed 16 C.F.R. §1102.20(f).

<sup>xxii</sup> *Id. at §1102.20(d)*.

<sup>xxiii</sup> *Id. at §1102.20(c) (1)-(4)*.

<sup>xxiv</sup> *Id. at §1102.20(a) (1)-(3)*.

<sup>xxv</sup> *Id. at §1102.20(b) (1)-(4)*.