



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically approved and signed.

Date: November 17, 2010

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM : Mary Kelsey James, EXIT
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SUBJECT : Publicly Available Consumer Product Safety Information Database Proposed Final Rule

Below are the staff’s responses to Commissioner Anne Northup’s follow-up questions after the staff Briefing on the Publicly Available Consumer Product Safety Information Database Proposed Final Rule. Commissioner Northup’s questions are included below.

Follow-up Question 1:

Could you list all “inputs” of consumer complaint information, and an estimate on how many complaints per year we receive from each of them? Which of these inputs are included in Phase I?

Staff Response

There are three major categories for incident reports received by the CPSC: The National Electronic Injury Surveillance System (NEISS), which collects information from hospital emergency rooms on product-related injuries; Death Certificates (DTHS), which the CPSC purchases from State governments; and the Injury or Potential Injury Incident (IPII) database, which includes Medical Examiners and Coroners Program (MECAP) reports, news clips, complaints filed through the CPSC’s website or hotline, email complaints, reports submitted by public safety entities, reports submitted by other government agencies, and manufacturer/retailer reports.

The number of reports received within these categories for FY 2009 was:

NEISS:	395,700
IPII Total:	51,400
Death Certificates:	3,600

Phase I of the Consumer Product Safety Risk Management System (CPSRMS) includes the Public Database and increasing efficiencies to CPSC's internal data collection process through modernization of CPSC's information technology infrastructure. The Public Database will contain only a subset of IPII, although all incident reports will be processed internally through the CPSRMS.

The subset in the Public Database will include only those incident reports currently collected through the Hotline, the CPSC's email, postal mail and incident reports submitted that are currently collected through the CPSC's website report forms. In 2009, this subset totaled approximately 16,000 incident reports. The Public Database will not include news clips, retailer reports, or Section 15 reports from manufacturers and will only contain those IPII reports that meet all the criteria for publication (i.e., submitter's contact information, product description, manufacturer identification, consent).

Follow-up Question 2:

Are these two statements correct: (1) we do In-depth investigations (IDIs) on approximately 20 percent of the Hotline complaints we receive; (2) overall, given the entire scope of our complaint data, we do IDI's on about 10 percent of the complaints we receive.

Staff Response

- (1) The 20 percent assignment rate applies to the 16,000 incident reports cited for Fiscal Year (FY) 2009 that were received through the CPSC's Hotline, email, and website form. This subset of 16,000 reports includes the types of reports we expect to collect through the new incident report form, but is not necessarily comparable to the reports that might be included in the Public Database because those reports must identify a manufacturer and have consent. In FY 2009 staff assigned approximately 14 percent of Hotline reports for follow-up investigations.
- (2) The 10 percent overall assignment rate for complaints investigated includes reports in IPII, but does not include NEISS or Death Certificates. The number of incidents assigned has remained relatively stable although the percentage has declined due to a steady increase in incident reports. For example, in FY 2005, we received 34,855 incident reports in IPII and assigned 4,759 follow-up investigations making the assignment rate almost 14 percent. In FY 2009, we received 51,541 incident reports in IPII and assigned 4,915 follow-up investigations making the assignment rate almost 10 percent.

Follow-up Question 3:

Have you estimated how many hours CPSC staff will have to spend to investigate a claim of inaccuracy by a manufacturer?

Staff Response

An analysis has not been conducted to estimate how much time will be spent by CPSC staff to investigate a claim of material inaccuracy.

Follow-up Question 4:

What does the data entry role currently entail (as performed by the Epidemiology Computer and Data Systems Support Branch, [EPDS]) with regards to raw data (incident reports) coming in to the Commission? Please describe any screening and/or QA/QC activity.

Staff Response

Currently, data entry generally includes:

1. Some process to make the full report available to CPSC staff as a PDF file. Depending upon how the report is received, this may involve reformatting spreadsheet data with a computer program, scanning a hardcopy report, or simply saving to the network a report received as a PDF file.
2. Coding and data entry – coders read each report; select and enter appropriate codes for product, hazard, and injury severity; key these codes into the database: important dates (date received, date of the incident, date of death), and other fielded information; and enter a brief narrative which synthesizes the incident or the consumer's concern. Reports that are considered out of scope are not entered into the database, nor are duplicates (reports of the same incident received from the same type of contact).

Screening: Currently, screening may happen at several points: in the field where many news clips are received; during an initial review of reports received via the CPSC's website; during an initial review of death certificates and MECAP reports received by EPDS program analysts; and during data entry. Data entry staff screen all reports before entering them into our database to make sure that the subject product is within the CPSC's jurisdiction, that the incident appears to have been accidental and not a deliberate act to injure or cause damage (with the exception of incidents where the individual involved is a child aged 12 or under), and that there is either an incident with the product or the report expresses a concern about the safety of the product. EPDS staff does not attempt to make any judgments on the validity of concerns expressed by the submitter. Additional screening occurs after data entry, as part of the quality control process, or in response to questions raised by the CPSC's technical staff.

Quality Control: Quality control is performed both by the data entry contractor and by EPDS staff. Either the contract supervisor or the coder reviews a printed listing of all coded incident reports and checks for consistency between the coded fields and the synopsis. In addition, EPDS runs a program identifying records that appear to have inconsistencies, and then the contractor reviews the output to determine if any corrections are required. Once the contractor indicates that they have completed work on a set of records, EPDS performs quality control on the records. EPDS staff runs the same quality control program that identifies records that have possible coding errors and validates that all required corrections have been made. Staff reviews approximately 60 percent of the records (the percentage varies according to the experience and reliability of the coder) to check for consistency between the coded fields and the narrative, and verifies that the reports are in-scope. In addition, 10 percent of the listed records are selected randomly for a check of the database record against the original incident report. Staff also runs programs to check that there is a PDF file for each incident report and to identify possible duplicates.

Follow-up Question 5:

Please provide an estimate of the number of incident reports (or percentage of total) that are not entered into the database as a result of any screening and/or QA/QC activity? What are the most common reasons for a report to be excluded?

Staff Response

We estimate that about 4 percent of IPII incident reports received in EPDS are not entered into the database. About 40 percent of the rejected incident reports are duplicates. The remainder are considered out of scope, usually because the product is not within the CPSC's jurisdiction or because no product type is identified.

Note that death certificates are a special case and are not included in the above calculation. Death certificates are purchased based on the International Classification of Diseases (ICD) cause of death codes assigned to each death certificate. Certificates are reviewed by EPDS staff and divided into two groups: DTHS (those that identify a product and are accidental), which are entered into the database for further analysis, and ABDT (those with no product or are out of scope for some other reason), which are used only to monitor the completeness of reporting from the states. About 40 percent of death certificates are screened and placed into ABDT.

Follow-up Question 6:

Will the screening and/or QA/QC activity change in any way when the new Public Database is launched?

Staff Response

In regard to quality control, we will be capturing much more detailed data in the database fields, so staff anticipates developing even more effective quality control programs. In addition, EPDS staff plans to perform a second review (in addition to that of the contractor) of 100% of the records that are eligible for the Public Database.

In regard to screening, staff will be conducting two types of screening. Staff will use the same criteria used now to review each incident report to decide if it is acceptable for inclusion in the CPSC's internal database, which is used to support analytical and compliance activities. However, staff will also review each incident to determine if it meets the criteria for inclusion in the Public Database.

Follow-up Questions 7 through 10:

Could you answer the following questions regarding the National Highway Traffic Safety Administration's (NHTSA) database, Safercar.gov?

Follow-up Question 7:

Our understanding is that in the case of an investigation, NHTSA gives manufacturers the opportunity to contact the submitter of the report. Does the submitter have to consent to have their contact information released to the manufacturer?

Staff Response

NHTSA has a Routine Use provision that allows the agency to share the incident report with the named manufacturer, including personally identifiable information. It should be noted, however, that the CPSIA specifically addresses the question of the availability of contact information so the NHTSA example may not comport to our statutory requirements. The statute unequivocally states that the Commission may not disclose the name, address or other contact information of a submitter of a report of harm to the manufacturer without the submitter's express written consent.

Follow-up Question 8:

Other than the case of an investigation, does NHTSA provide the manufacturer submitter's contact information if the submitter has consented to release their contact information?

Staff Response

We do not have any information regarding the above question.

Follow-up Question 9:

What percentage of NHTSA's complaints in their database come with a VIN number?

Staff Response

We do not have any information regarding the above question.

Follow-up Question 10:

Can a person's Personally Identifiable Information (PII) be accessed through a VIN number?

Staff Response

We do not have any information regarding the above question.