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Quick Reference: Reviewing Deaths Related to Consumer Products

Introduction

Infant and child deaths can involve consumer products. Reporting incidents with hazardous products has life-saving implications, as it helps ensure that appropriate recalls and improved safety measures can be put in place.

This document provides guidance to fatality review teams on:



Identifying products that should be reported and to which agency



Completing important questions in the National Fatality Review-Case Reporting System (NFR-CRS)



Step 1: Reporting

Child Death Review (CDR) and Fetal and Infant Mortality Review (FIMR) teams have a unique opportunity to identify potentially hazardous products. Federal regulatory agencies rely on public reports to identify potentially hazardous products. Lives can be saved, and families served, by getting products removed from the market or improved for safer use. Many common products used for children, including toys, furniture, and infant care products, are regulated. The most common regulating agencies include the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the National Highway Traffic Safety Administration (NHTSA). While most consumer products are regulated, some are not. Fatality review teams are encouraged to use the following table, agency descriptions, and contact information to report fatalities related to consumer products to the appropriate federal agency as a primary prevention strategy.

Step 2: Data Collection

The NFR-CRS asks several questions about how consumer products may be related to fatalities and the status of the products in Section I3: Consumer Product. For the NFR-CRS, consumer products are defined as commercially available items.

See page 12 of this guidance for details on completing this section.

Table: Where to Report Issues with Various Products

	Consumer Product Safety Commission	National Highway Traffic Safety Commission	Food and Drug Administration
Products Regulated	Commercially produced furniture, electronics, batteries, toys, playground equipment, and other products including child safety packaging products	Cars, car seats, car parts, tires, street-legal motorcycles, and some mopeds	Cosmetics, pharmaceuticals, over- the-counter drugs, alcohol, veterinary medicines, medical devices, tobacco, and tobacco products
Examples of Consumer Product-related Deaths	Sleep-related infant deaths taking place in cribs, adult beds, infant swings, inclined sleepers, nursing pillows, etc. Poisoning from swallowing button batteries, as well as carbon monoxide poisonings from a generator or furnace Choking on toys or toy parts Burns from electrical devices or fireworks, or fires from lithium ion batteries Drownings when a gate or door failed, or involving inflatable devices, bathing, or swim aids	A death where a car, truck, or SUV had a defective gear mechanism, allowing it to be put into gear while parked Sleep-related infant death in an infant car seat Motor vehicle crash involving faulty or improperly installed seatbelts or car seats Crushing by a vehicle trunk or window Motor vehicle crash due to self-driving features, worn parts, or lack of vehicle maintenance	Death resulting from E. coli infections or other foodborne illness Allergic reaction to any food, supplement, herbal remedy, prescription, or overthe-counter drug Overdose death related to any pharmaceutical product Death as a result of ventilators, monitors, or other medical equipment failing or shutting off Death resulting from use of alcohol or tobacco

Table: Where to Report Issues with Various Products (continued)

	Consumer Product Safety Commission	National Highway Traffic Safety Commission	Food and Drug Administration
Reporting a Problem with a Consumer Product to a Regulatory Agency	Reports can be made by visiting the <u>Safer</u> <u>Products website</u> (URL: <u>https://saferproducts.gov</u>)	Reports of safety problems that could be a safety defect can be reported by calling: 1-888-327-4236 or by visiting the NHTSC Reporting webpage (URL: https://www.nhtsa.gov/report-a-safety-problem#index)	Reports are made to FDA in different ways depending on the product. Identify the appropriate reporting process by visiting the CFSAN Assistance webpage (URL: https://www.fda.gov/food/resources-you-food/industry-and-consumer-assistance-cfsan)

Table: Where to Report Issues with Various Products (continued)

Other Agencies

There are other regulatory agencies that monitor other types of commercial products.

These include:

- The Federal Aviation Administration regulates aircraft. Reports can be made on the <u>FAA Reporting webpage</u> (URL: https://www.faa.gov/aircraft/safety/report)
- The National Association of State Boating Law Administrators fields reports on problems with boats. To identify state-level contacts, visit the <u>NASBLA Boating Contacts</u> webpage (URL: https://www.nasbla.org/about-nasbla/boating-contacts)
- The U.S. Chemical Safety and Hazard Investigation Board regulates commercial chemical accidents. Learn how to make reports by visiting the <u>CBS Incident Reporting webpage</u> (URL: http://www.csb.gov/news/incident-report-rule-form-/)
- The Environmental Protection Agency regulates pesticides and fungicides. Reports can be made on the <u>EPA Violation Reporting webpage</u> (URL: https://epa.gov/report-violation)
- The Occupational Safety and Health Administration (OSHA) regulates industrial, commercial, and farm equipment. Reports can be made on the <u>OSHA Complaint</u> <u>Form webpage</u> (URL: https://www.osha.gov/form/osha7)

What is a CPSC-regulated consumer product?

For purposes of the NFR-CRS, CPSC-regulated consumer products are commercially available items including toys, sleep-related products, pools, bicycles, electrical devices, and others. Deaths attributed to CPSC-regulated consumer products may involve products used according to manufacturer's guidelines or used incorrectly.

Deaths that occur because of CPSC-regulated consumer products can include, but are not limited to:

- Sleep-related deaths occurring in cribs, adult beds, swings or rocking-inclined sleepers, with nursing pillows, or other baby products
- Poisoning from swallowing batteries
- Injuries from playground equipment, tipping furniture, non-commercial lawn mowers and yard equipment, bicycles, non-"street-legal" vehicles (e.g., golf carts, ATVs, "quads"), non-vehicular wheeled devices (e.g., bicycles, scooters, strollers, hoverboards), helmets, and booster seats (but not car seats)
- Choking from toys, especially if small parts broke off
- Strangulation from belts, clothing, blind cords, or cargo nets
- Burns from electrical devices or fireworks, or fires caused by a lithium ion battery
- Poisonings from generators, carbon monoxide, or a furnace
- Drownings, including when a gate or door failure led to water access; drownings in hot tubs or above-ground or inflatable backyard pools; and drownings in infant bath seats or bathing devices
- Falls from a window with a screen

To report a death or injury related to a CPSC product, visit the <u>CPSC Reporting</u> webpage (URL: https://saferproducts.gov/IncidentReporting).

What are FDA or NHTSA-regulated products?

Some products and devices have a separate governing agency tracking reports and issues, such as the Food and Drug Administration (FDA) or National Highway Traffic Safety Administration (NHTSA).

Deaths because of FDA-regulated consumer products can include, but are not limited to:

- Foodborne illness, such as E. coli
- Ventilators, monitors, or other medical equipment failing or shutting off
- Deaths from alcohol or tobacco products
- Prescription drugs, over-the-counter drugs, supplements, herbal remedies, and veterinary drugs
- Allergic reactions to foods, cosmetics, or drugs
- Choking on a food
- Sleep-related issues from a product advertising itself as preventing Sudden Infant Death Syndrome (SIDS)

To report an issue related to an FDA-regulated product, visit the <u>CFSAN Assistance</u> webpage (URL: https://www.fda.gov/food/resources-you-food/industry-and-consumer-assistance-cfsan).

To report an issue with an FDA-regulated medical device, visit the <u>Medical Device Reporting webpage</u> (URL: https://www.fda.gov/medical-devices/medical-device-medical-device-problems).

To report an issue with FRA-regulated food, supplements, or cosmetics, visit the <u>CFSAN Assistance webpage</u> (URL: https://www.fda.gov/food/resources-you-food/industry-and-consumer-assistance-cfsan).

For all other FDA-regulated products, visit the <u>FDA Problem Reporting webpage</u> (URL: https://www.fda.gov/safety/report-problem-fda).

Deaths because of NHTSA-regulated products can include, but are not limited to:

- A defective gear mechanism causing a car, truck, or SUV to be put into gear while parked
- Defective, damaged, or worn tires on a car, truck, or SUV
- Sleep-related deaths from an infant sleeping in a car seat, even if the seat was not in a vehicle at the time of death
- Motor vehicle crash deaths, including faulty or improperly installed/used seatbelts or car seats
- Motor vehicle crashes attributed to worn parts or lack of maintenance
- Crushing by vehicle trunk or window
- Vehicle fires

To report an issue related to an NHTSA-regulated product, visit the <u>NHTSA Reporting</u> webpage (URL: https://nhtsa.gov/report-a-safety-problem#index).

Not all consumer products are regulated by the above three agencies. Below are examples of other products and the corresponding regulation agency:

- Aviation and aircraft (Federal Aviation Administration)
- Boats (U.S. Coast Guard)
- Chemicals (U.S. Chemical Safety and Hazard Investigation Board)
- Pesticides, fertilizer, fungicides (Environmental Protection Agency)
- Industrial, commercial, and farm equipment or machinery (Occupational Safety & Health Administration)
- Marijuana produced, processed, and distributed in a state with legalized retail marijuana and cannabis products (varies by jurisdiction)
- Amusement park rides (varies by jurisdiction)



Some products are not regulated. These products include:

- Firearms
- Products like Kratom, spice
- Illicit drugs (e.g., heroin, cocaine)

Why should I report a death related to a consumer product?

The responsible regulatory agencies track issues relating to their consumer products from confidential reports. Reports about unsafe or hazardous products could lead to that product being recalled, preventing further injuries and deaths, and with the consumer often getting a refund or replacement. Reports can also be used to develop standards for products. See pages 6-7 of this guidance for direction on where to report issues with various products that may have been involved in the infant or child death. If in doubt of if or where to report, report to CPSC.

- Visit the <u>CPSC Incident Reporting webpage</u> (URL: https://saferproducts.gov/
 IncidentReporting
 to submit a report to the CPSC electronically or learn how to submit one by phone or email.
- Each state has a representative from CPSC. To see your state's representative, visit the <u>Product Safety State Contacts webpage</u> (URL: https://cpsc.gov/About-CPSC/Contact-Information/Product-Safety-State-Contacts-faq).

NFR-CRS Data Entry Tips

The NFR-CRS' Section I3: Consumer Products asks for details about deaths as a consequence of a consumer product. The questions appear as follows:

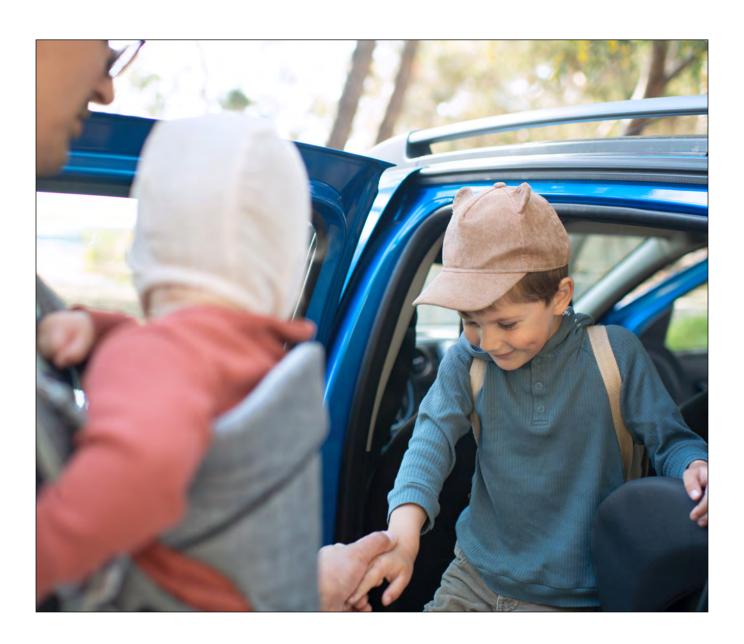


- If "yes" is selected for I3, please briefly describe the product, and the circumstances of use leading to death. For instance, "placed in a rocking inclined chair to sleep" or "vehicle had airbags known to be defective."
- Determining if the product was used properly can be subjective at times.

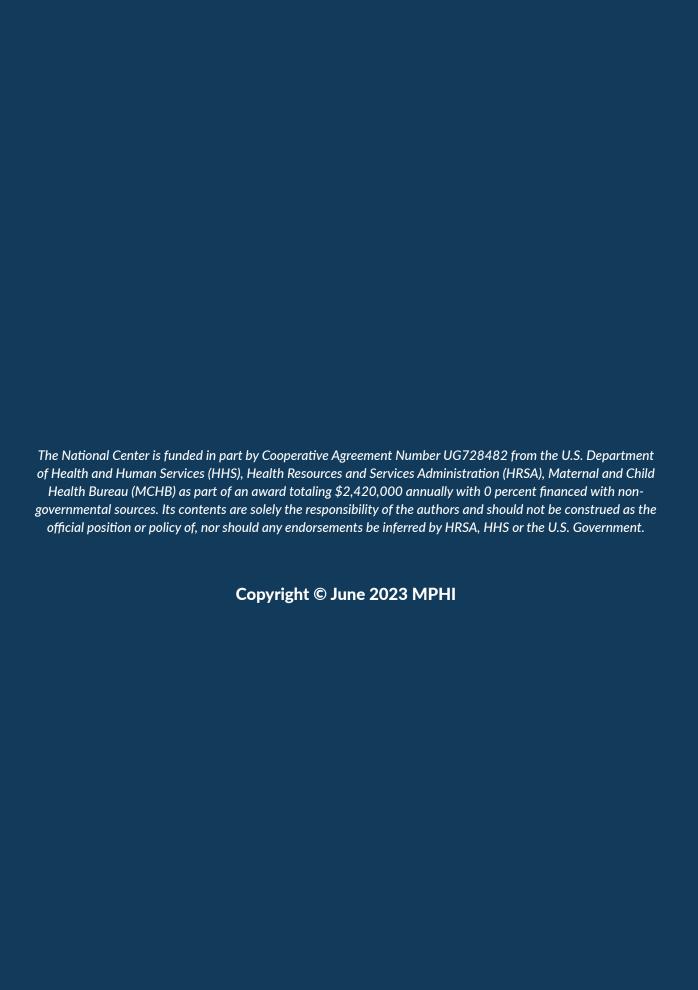
 Some obvious examples of "no" would be placing an infant in an unsafe sleep environment or having a gas generator indoors during a storm. "Yes" would be appropriate if a child had an allergic reaction to a medication after the recommended dose had been administered.
- This can be answered "yes" if a recall was in place at the time of death, but not followed. To learn more if a recall for the product is in place, visit the CPSC Recalls webpage (URL: https://cpsc.gov/Recalls).
- Products might have safety labels on them or on the packaging they came with. For instance, a toy with small parts might say on the box, "WARNING: Choking Hazard. Small parts. Not for children under 3 years."
- Select if a member of the child death review team (such as a coroner or medical examiner) reported the product to the appropriate governing agency. If not reported yet, please consider having an appropriate member of the team report the product as this can have life-saving benefits to prevent further injuries or deaths.

Public reports of fatal incidents related to consumer products are an important part of ensuring that hazardous products are recalled and no longer available. Fatality review teams are uniquely positioned to identify and understand the ways in which consumer products may be related to deaths of infants, children, and youth.

The National Center for Fatality Review and Prevention provides this resource to support effective and accurate reporting of hazardous consumer products to the appropriate federal regulatory agency. Please reach out to the National Center for Fatality Review and Prevention at info@ncfrp.org if there is difficulty answering section I3, Consumer Product, or if there are additional questions.









www.ncfrp.org