



Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary **DATE:** April 10, 2024

THROUGH: Jessica L. Rich, General Counsel
Austin C. Schlick, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs

SUBJECT: Notice of Availability: Data Regarding Incidents Associated with Infant Support Cushions

BALLOT VOTE DUE: Tuesday, April 16, 2024

The Office of the General Counsel is providing for the Commission’s consideration the attached draft notice of availability (NOA) for Data Regarding Incidents Associated with Infant Support Cushions. The draft NOA announces the availability of, and seeks comments from the public on, this information related to the Notice of Proposed Rulemaking, Safety Standard for Infant Support Cushions, 89 FR 2530 (Jan. 16, 2024).

Please indicate your vote on the following options:

- I. Approve publication of the attached notice in the *Federal Register*, as drafted.

(Signature)

(Date)

- II. Approve publication of the attached notice in the *Federal Register*, with the following changes:

(Signature)

(Date)

III. Do not approve publication of the attached notice in the *Federal Register*.

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft *Federal Register* notice: Notice of Availability: Data Regarding Incidents Associated with Infant Support Cushions

CONSUMER PRODUCT SAFETY COMMISSION**16 CFR Parts 1112, 1130, and 1243****[Docket No. CPSC-2023-0047]****Notice of Availability and Request for Comment: Data Regarding Incidents Associated with Infant Support Cushions****AGENCY:** Consumer Product Safety Commission.**ACTION:** Proposed rule; availability of supplemental information; request for comment.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) published a notice of proposed rulemaking (NPR) in January 2024 regarding a rulemaking to address suffocation, entrapment, fall, and other hazards associated with infant support cushions. CPSC is announcing the availability of, and seeking comment on, details about incident data relevant to the rulemaking that are associated with infants and the use of infant support cushions.

DATES: Submit comments by [**30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit comments, identified by Docket No. CPSC-2023-0047, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC does not accept comments submitted by e-mail, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. If you wish to submit

confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may e-mail them to cpSC-os@cpSC.gov.

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: To read background documents or comments regarding this proposed rulemaking, go to: <https://www.regulations.gov>, insert Docket No. CPSC-2023-0047 in the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Ashley Johnson, Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 504-7872 e-mail: aajohnson@cpSC.gov.

SUPPLEMENTARY INFORMATION:

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, in January 2024 the Commission published an NPR, Safety Standard for Infant Support Cushions, to reduce the risk of death and injury associated with infant support cushions. 89 FR 2530 (Jan. 16, 2024).

An infant support cushion is defined in the NPR as “an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a

gel, liquid, or gas, and which is marketed, designed, or intended to support an infant’s weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.” 89 FR 2544. This definition includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as “tummy time,” and other similar products. 89 FR 2530.

The Commission is now making available incident reports underlying the data discussed in the NPR, as described below.¹ These reports have been redacted to protect personal information, confidential medical information, and other information protected from disclosure by section 6 of the Consumer Product Safety Act. 15 U.S.C. 2055.

The NPR discussed information about incidents from two databases: the Consumer Product Safety Risk Management System (CPSRMS)² and the National Electronic Injury Surveillance System (NEISS).³ CPSC staff searched these databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010, and December 31, 2022. The data for this timeframe pertained to at least 79 fatal and 124 nonfatal incidents reported to CPSC.⁴ The NPR included information about the hazard patterns of fatal and nonfatal incidents such as infants’

¹ The Commission voted X-X on April XX, 2024, to publish this document.

² CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports. A large portion of CPSRMS data consists of incident reports from consumer complaints, media reports, medical examiner or coroner reports, retailer or manufacturer reports (incident reports received from a retailer or manufacturer involving a product they sell or make), safety advocacy groups, law firms, and federal, state, or local authorities, among others. It also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes (ICD-10). The third major component of CPSRMS is the collection of in-depth follow-up investigation reports. Based on the incident reports, death certificates, or NEISS injury reports, CPSC Field staff conduct IDIs (on-site, via telephone, or online) of incidents, deaths, and injuries, which are then stored in CPSRMS.

³ NEISS is the source of the injury estimates; it is a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of about 100 hospitals, with 24-hour emergency departments and at least six beds, selected as a probability sample of all U.S. hospitals. The surveillance data gathered from the sample hospitals enable CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

⁴ The NPR listed 125 nonfatal incidents, but one of those incidents was a duplicate.

ages, hazard scenarios, infant support cushion/infant placement, and product-specific concerns. 89 FR 2532-34.

Relevant data from CPSRMS include incident reports from medical examiners, consumers, death certificates, and manufacturers. Some of the incident data relied on for the rulemaking were obtained from 83 in-depth investigations (IDIs) conducted by CPSC. Among these IDIs, 73 were fatal incidents and 10 were nonfatal incidents. The Commission also obtained information from reports submitted by consumers, medical examiners, and the Food and Drug Administration concerning five other fatal incidents and 58 nonfatal incidents involving falls (29 incidents), threatened asphyxiation (26 incidents), and one incident report each of limb entrapment, choking and near strangulation. 89 FR 2533.⁵ Incident data has been redacted for personally identifiable information or confidential information, as required by law and any applicable confidentiality agreements.

The Commission also relied on data from NEISS that contains incidents and injuries treated in U.S. hospital emergency departments. One of these incidents resulted in a fatality. The Commission relied on 26 NEISS records associated with infant support cushions, as summarized in a spreadsheet of these NEISS incidents.

The Commission invites comments on the incident data and analysis of this data in the NPR. CPSC is making available for review and comment the incident reports relied upon and discussed in the NPR, to the extent allowed by applicable law, along with the associated IDIs. To obtain access to the data, submit a request to: <https://forms.office.com/g/AJ1JCDNuKD>. You will then receive a website link to access the data for this rulemaking at the email address you provide. Information on how to submit comments and contact information for CPSC's Office of the Secretary are in the **ADDRESSES** section of this notice.

⁵ As stated above, one incident reported in the NPR (a threatened asphyxiation) has been removed as a duplicate.

Alberta E. Mills, Secretary
Consumer Product Safety Commission.