

UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

RECEIVED-OFFICE
OF THE SECRETARY

TO : The Commission

88 APR 28 A9:22 APR 25 1988

Through: Sadie E. Dunn, Secretary *S. Dunn*
Leonard DeFiore, Executive Counsel *LDF*
James V. Lacy, General Counsel *JVL*
Stephen Lemberg, Assistant General Counsel *SL*
Allen F. Brauninger, Attorney, OGC *AB*

SUBJECT: Small Parts Regulations - Advance Notice of Proposed
Rulemaking

BALLOT VOTE due MAY 5 1988

A memorandum from the Office of Program Management and Budget transmits a draft of an advance notice of proposed rulemaking (ANPR) which may lead to amendment of regulations banning certain toys and children's articles with small parts. On February 3, 1988, the Commission directed the staff to prepare this document after concluding that some change to the small parts regulations (16 C.F.R. § 1500.18(a)(9) and Part 1501) may be needed to reduce choking hazards associated with toys and other articles intended for children under three years of age.

As requested by the Commission, the draft ANPR solicits information relevant to the possible need for amendment of the small parts regulations and an appropriate modification of the test specified by Part 1501 to eliminate or reduce unreasonable risks of injury associated with toys and articles intended for children under three years of age which present choking hazards.

The attached draft also contains all other information required to be included in an ANPR by section 3(f) of the Federal Hazardous Substances Act (15 U.S.C. § 1262(f)).

Please indicate your vote:

I. Approve the draft ANPR for publication in the Federal Register without change.

Date

Signature

II. Approve the draft ANPR for publication in the Federal Register with the following changes (please specify): _____

Signature

Date

III. Do not approve the draft ANPR for publication in the Federal Register.

Signature

Date

IV. Abstain.

Signature

Date

UNITED STATES GOVERNMENT
Memorandum

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

APR 25 1988

TO : The Commission *SD un*
THROUGH : Sadye Dunn, Office of the Secretary *OMF*
THROUGH : James V. Lacy, Office of General Counsel *WJ*
THROUGH : Leonard DeFiore, Executive Director
THROUGH : Douglas L. Noble, Director, Office of Program Management
and Budget
THROUGH : Carl Blechschmidt, Program Manager, Office of Program
Management and Budget
FROM : *SD (for)* Elaine A. Tyrrell, Project Manager, Children's and *EATgrwell*
Recreational Products Program, Office of Program Management
and Budget
SUBJECT : Transmittal Memorandum for Draft Advance Notice of Proposed
Rulemaking - Small Parts Regulation

Attached for Commission approval is a draft Advance Notice of Proposed Rulemaking (ANPR) to solicit comments on amending the requirements of the Small Parts Regulations as codified at 16 C.F.R. 1500.18(a)(9) and Part 1501. During the Commission meeting on February 3, 1988, the staff was directed to prepare the draft ANPR and publish it within the next 90 days. The draft ANPR reflects the Commission's preliminary determination that an unreasonable risk of death and injury may be associated with some toys and articles intended for children under three years of age because of small parts and seeks information on the merits of amending the small parts regulations to change the test fixture.

The Directorates for Compliance and Administrative Litigation, Economic Analysis, Engineering Sciences, Epidemiology, Field Operations, and Health Sciences; and the Offices of Information and Public Affairs, Planning and Evaluation, and Program Management and Budget have reviewed the package and approved its contents.

Pursuant to Section 5 of the Commission General Policies of March 18, 1987, the Executive Director indicates that he is reasonably unaware of any relevant and significant minority or dissenting views on this issue except for those contained in this package, if any.

ATTACHMENT

CPRA 6 (4/1) Cleared

X 4/25/88
Red Aches/Privileges or

Products Identified

N Exempted by

Rules Modified

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1500 and 1501

Toys and Articles Intended for Children Under Three Years of Age Which Present Choking, Aspiration, Or Ingestion Hazards Because of Small Parts; Request for Comments and Information

AGENCY: Consumer Product Safety Commission

ACTION: Advance notice of proposed rulemaking

SUMMARY: On the basis of available information, the Commission has reason to believe that unreasonable risks of death and injury may be associated with some toys and articles intended for children under three years of age because of small parts. The toys and children's articles under consideration comply with all requirements enforced by the Commission but nevertheless have parts which may be small enough to present choking, aspiration, or ingestion hazards to children under three.

This advance notice of proposed rulemaking begins a rulemaking proceeding under the authority of the Federal Hazardous Substances Act. One outcome of the proceeding could be the amendment of existing requirements for toys and articles intended for children under three years of age to address risks of injury associated with small parts that present choking, aspiration, or ingestion hazards. Additionally, the Commission is considering the possibility that an existing voluntary standard might be modified or a new one developed to address the risks of injury described in this notice.

NOTE: This document has not been reviewed or accepted by the Commission.
Initial Date 4/25/88

The Commission solicits written comments from all interested persons on the risks of injury and regulatory alternatives discussed in this notice, and other possible means to address those risks of injury. The Commission particularly desires to receive technical and medical data and other information relevant to (1) the possible need for amendment of the small parts regulations; (2) an appropriate modification of the present test for determining if toys or articles intended for children less than three years of age are banned because of small parts; and (3) the economic impact of amending the small parts regulations. Additionally, the Commission invites all interested persons to submit an existing standard or a statement of intent to modify or develop a voluntary standard to address the risks of injury described in this notice.

DATE: Written comments and submissions in response to this notice must be received by the Commission by [insert date 60 days after publication in the Federal Register].

ADDRESS: Comments should be mailed, preferably in five (5) copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 528, 5401 Westbard Avenue, Bethesda, Maryland; telephone (301) 492-6800.

FOR FURTHER INFORMATION CONTACT: Elaine A. Tyrrell, Project Manager, Office of Program Management and Budget, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 492-6554.

SUPPLEMENTARY INFORMATION:

A. Background

At the age of about four months, most infants acquire the ability to bring objects to their mouths and to suck on them. At about the same age, infants begin to explore their surroundings by putting objects in their mouths, and gum objects in an attempt to relieve teething pains. Many infants and young children continue to put objects in their mouths indiscriminately until they are about three years old. Infants gradually develop skills which enable them to prevent objects from entering and remaining in their throats, but until children are about three years old many are not able to remove or expel an object from their own throat or mouth. For this reason, children under the age of three are particularly susceptible to injuries which result when objects are swallowed or become lodged in the mouth or throat.

In 1979, the Commission issued regulations under provisions of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. § 1261 et seq.) to ban certain toys and other articles intended for children under three years of age which present unreasonable risks of injury because of small parts. Those regulations are codified at 16 C.F.R. § 1500.18(a)(9) and Part 1501, and are intended to address the following risks of death and injury:

- (1) Asphyxiation from lodgment of an object in the throat resulting in blockage of air to the lungs;

- (2) Asphyxiation from obstruction of the airway by a foreign object or vomit;
- (3) Aspiration of an object into a bronchus or a lung; and
- (4) Cuts or penetration wounds to internal organs from sharp or pointed objects which have been swallowed.

The regulation codified at 16 C.F.R. § 1500.18(a)(9) bans any toy or other article intended for children under three years of age which presents a choking, aspiration, or ingestion hazard because of small parts, and which is introduced into interstate commerce after January 1, 1980. The regulation codified at 16 C.F.R. Part 1501 describes certain types of products which are subject to the banning rule codified at section 1500.18(a)(9); lists certain other types of products which are specifically exempted; and provides a test method for determining whether an article presents a choking, aspiration, or ingestion hazard because the article itself, or any part which could be detached or broken off during normal or reasonably foreseeable use, is too small.

Section 1501.2(a) of the regulation contains a list of products which the Commission considers to be intended for children under three years of age. This list is illustrative, but not all-inclusive. Among the products listed in section 1501.2 are squeeze toys, teethers, crib exercisers, crib mobiles, pull and push toys, pounding toys, blocks and stacking sets, stuffed animals and other figures, dolls intended for children under

three such as baby dolls, rag dolls, and bean bag dolls, and infant and juvenile furniture intended for children under three such as cribs, playpens, strollers, and carriages.

In addition to the product types listed in section 1502.2(a), the banning rule codified at section 1500.18(a)(9) is also applicable to any other toys or articles which are intended to be entrusted to or used by children under three years of age. Section 1501.2(b) lists the factors which are relevant when deciding whether a particular product not listed in section 1501.2(a) is subject to the banning rule. Those factors include the manufacturer's stated intent on labeling and elsewhere, if reasonable; advertising, promotion, and marketing of the product; and whether the product is commonly recognized as one intended for children under three years of age.

Section 1501.3 of the regulation exempts ten categories of products from the banning rule. Two of the exempted products are rattles and pacifiers which are subject to other FHSA regulations containing requirements to address risks of injury presented by small parts. Rattles are subject to regulations codified at 16 C.F.R. § 1500.18(a)(15) and Part 1510; pacifiers are subject to regulations codified at 16 C.F.R. § 1500.18(a)(8) and Part 1511.

Other categories of exempt products include books and articles made from paper; writing materials such as crayons, chalk, pencils, and pens; children's clothing and accessories,

such as shoe lace holders and buttons; grooming, feeding, and hygiene products such as diaper pins, barrettes, toothbrushes, drinking glasses, dishes and eating utensils; and phonograph records. These products were exempted because the Commission determined that their functional, educational, or other value outweighed any possible hazard from small parts.

Modeling clay and similar products, and finger paints, water colors, and other paint sets were exempted because they cannot be manufactured so that small bits will never separate from these items. Finally, balloons were exempted from the products subject to the banning rule because the Commission concluded that balloons cannot be subject to this regulation without being banned entirely.

Section 1501.4 sets forth the test used to determine if a toy or article intended for children under three is banned because of small parts. The apparatus used in this test is a hollow truncated cylinder having an interior diameter of 1.25 inches, a minimum interior depth of 1.0 inches, and maximum interior depth of 2.25 inches. See Figure 1.

The product to be tested is placed in the test cylinder and must be large enough not to fit entirely within the cylinder. Any detachable component is tested in the same manner. If neither the product nor any detachable component fits entirely within the test cylinder, the product is subjected to the applicable "use and abuse" procedure codified at 16 C.F.R. §§ 1500.51 and 1500.52, with the exception of the bite tests

specified at §§ 1500.51(c) and 1500.52(c). Any component or piece that becomes separated from the product during use and abuse testing is tested individually by placing it in the cylinder. (Paper and pieces of fabric, yarn, fuzz, elastic, or string that separate during use and abuse testing are not tested in the cylinder; this aspect of the test is clarified in a statement of enforcement policy published in the Federal Register of _____, 1988, 53 F.R. _____.) If the entire product, any detachable component, or any component or any piece which separates during use and abuse testing fits entirely within the cylinder, the product is banned if it is intended for use by children under three years of age.

The Commission issued the small parts regulation to reduce unreasonable risks of injury to children under three years of age from choking on, aspirating, or ingesting toys or articles intended for their use. The Commission recognized, however, that by restricting the scope of the regulation to items intended for children under three, it would not eliminate all choking, aspiration, or ingestion hazards to children associated with small objects. See the Federal Register notice of June 15, 1979; 44 F.R. 34892.

In 1983, the Commission's Directorate for Epidemiology published a human factors analysis of 195 incidents in which children ranging in age from one month to four years old choked on toys or children's products. Thirty-seven of these incidents resulted in deaths of children. All of the incidents considered

in this study were selected because they involved items which were too large to fit entirely within the test cylinder specified by Part 1501.

The incidents occurred from 1973 through 1983. More than half of these incidents involved products in two categories exempted from the small parts regulations: rattles and pacifiers. Rattles were involved in 97 of the choking incidents, including 14 which resulted in death. Pacifiers were involved in nine incidents, including three fatalities.

One purpose of the 1983 analysis was to identify common characteristics, such as size and shape, of the items involved in the selected choking incidents. Another purpose of the analysis was to determine the interaction of the anatomy and behavior of the children with the characteristics of the products involved in an attempt to determine why choking incidents resulted. This analysis also examined the requirements of the Commission's regulations applicable to rattles, pacifiers, and toys and articles intended for children under three years of age in an attempt to determine if a single test apparatus and procedure could be developed to identify a choking hazard presented by any type of toy or product intended for children younger than three.

The 1983 report outlined proposals for such a test. One approach proposed by the 1983 report was to prohibit all toys or articles intended for children less than three years of age which could enter a child's mouth and extend far enough to block passage of air to the lungs. This approach proposed a test fixture

having an opening 1.68 inches in diameter, and a depth of 1.18 inches. See Figure 2. The report stated that mandatory requirements based on this approach would have prohibited the sale of all but five of the items involved in the 195 choking incidents selected for analysis. The report observed, however, that mandatory requirements based on such an approach would require substantial modifications of many toys then on the market.

Since 1983, the Commission's Directorate for Epidemiology has collected additional information about injuries to children which have resulted from choking on, aspirating, or ingesting toys and other children's products with small parts. This information has been obtained through the National Electronic Injury Information Surveillance System (NEISS), in-depth investigations, death certificates, consumer complaints, newspaper and magazine articles, and reports from coroners and medical examiners.

During fiscal year 1988 (October 1, 1987 through September 30, 1988), the Commission staff is conducting a special study of choking incidents involving toys and children's products which are treated at emergency rooms of NEISS participating hospitals. Follow-up investigations of selected incidents treated at NEISS participating hospitals will obtain detailed information about the children and products involved, and the accident scenarios. The special study will yield data which can be used to make statistically valid estimates of the total number of children in the United States who sustain injuries from choking incidents which require emergency room treatment during a specific time period. The staff will also obtain anecdotal information about choking

incidents associated with toys and children's products from death certificates, consumer complaints, periodicals, reports from coroners and medical examiners, and investigations of some accidents reported by these sources. During fiscal year 1989, the staff will prepare an analysis of the information obtained from the special study and other sources in an effort to define more precisely the nature and scope of choking, aspiration, and ingestion hazards associated with toys and children's products.

B. Petition

By letter dated April 20, 1987, the Consumer Federation of America and the New York State Attorney General's Office petitioned the Commission to amend the small parts regulation by modifying the test apparatus specified by 16 C.F.R. Part 1501. The petition (HP 87-1) requested the Commission to amend Part 1501 to prescribe a test which would ban any toy or article intended for children under three years of age having a diameter less than 1.68 inches. The petition asserted that the requested amendment of Part 1501 was needed to prevent choking incidents involving toys and articles intended for children under three years of age which had resulted in deaths and injuries. The petition cited the 195 incidents discussed in the 1983 human factors analysis issued by the Commission's Directorate for Epidemiology, and other information obtained from the Commission about deaths and injuries to children from choking incidents involving toys and children's products.

The Commission staff prepared briefing materials for consideration by the Commission when deciding whether to grant or deny the petition. The briefing materials included information about current activities to address choking hazards presented by toys and children's products and comments on the injury information cited in the petition. The staff observed that of the 195 choking incidents considered in the 1983 analysis, 71 were associated with products which are not currently subject to either mandatory requirements or provisions of a voluntary standard for toy safety to address choking hazards. The briefing materials also contained information about the various types of toys and children's products intended for children under three years of age, the annual volume of sales of such products, and possible costs to manufacturers and importers of such products if the Commission amended the small parts regulations.

After consideration of the petition and supporting information provided by the petitioners, the briefing materials and an oral briefing by the Commission staff, and other information, the Commission voted on February 3, 1988, to deny the petition. The Commission took this action after deciding that available information does not support the specific modification of the test in Part 1501 requested by the petitioners.

Nevertheless, the Commission concluded that some change to the small parts regulations may be needed to reduce choking hazards associated with toys and articles intended for children

under three years of age. The Commission voted to publish an advance notice of proposed rulemaking to begin a proceeding which may result in the amendment of the small parts regulations, and to solicit information relevant to such a proceeding. The Commission particularly desires to obtain technical and medical data and other information relevant to:

- (1) the possible need for amendment of the small parts regulations;
- (2) an appropriate modification of the test specified by Part 1501 to eliminate or reduce unreasonable risks of death and injury associated with toys and articles intended for children under three years of age which present choking, aspiration, or ingestion hazards;
- (3) the economic impact of amending the small parts regulations, including information about the various types of toys and children's products which may be affected by an amendment of those regulations, the annual volume of sales of those products and the number of units affected, and the costs of such an amendment to manufacturers and importers.

C. Statutory Authority

This proceeding is conducted under provisions of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. § 1261 et seq.). Section 2(f)1(D) of the FHSA (15 U.S.C. § 1261(f)1(D)) defines the term "hazardous substance" to include "[a]ny toy or other article intended for use by children" which the Commission determines by regulation to present "an electrical, mechanical, or

thermal hazard." Section 2(s) of the FHSA provides that an article may be determined to present a "mechanical hazard" if in normal use or reasonably foreseeable use or abuse it presents an unreasonable risk of personal injury or illness because the article or any of its parts may be aspirated or ingested. The Commission may make its determination that a toy or children's article presents a mechanical hazard by issuance of a regulation in accordance with provisions of sections 3(e) through (i) of the FHSA (15 U.S.C. §§ 1262(e) through (i)). A toy or children's article which has been determined by regulation to present a mechanical hazard is a "banned hazardous substance" as that term is defined by section 2(q)(1)(A) of the FHSA (15 U.S.C. §1261(q)(1)(A)) and may not be imported into or sold in the United States. See section 4(a) of the FHSA (15 U.S.C. § 1263(a)).

The first step in a proceeding under provisions of section 3(e) through (i) of the FHSA to issue a rule declaring that a toy or children's article presents a mechanical hazard is the publication of an advance notice of proposed rulemaking (ANPR) in accordance with section 3(f). If after considering comments received in response to the ANPR the Commission decides to continue the proceeding, section 3(h) of the FHSA requires publication of the text of the proposed rule and a preliminary regulatory analysis of the proposal including a description of potential benefits and potential costs of the proposal. If the Commission issues a final rule, it must publish a third notice which sets forth the text of the final rule, a summary of significant issues raised by comments on the proposal, a final regula-

tory analysis including a description of potential benefits and potential costs, as well as specified findings about voluntary standards and the relationship of the costs and the benefits of the rule.

D. The Products and Risks of Injury

This proceeding is concerned with all toys and other articles intended for children under three years of age which present choking, aspiration, or ingestion hazards because of small parts. All such toys and children's products, including those specifically exempted from the small parts regulations by 16 C.F.R. § 1501.3, and those complying with all requirements of 16 C.F.R. §§ 1500.18(a)(8), (9), and (15), and Parts 1501, 1510, and 1511 to address hazards from small parts are within the scope of this proceeding.

This proceeding is concerned with unreasonable risks of death and injury which may occur when a child under three years of age asphyxiates or is otherwise injured from the aspiration or ingestion of a toy or children's article, or any part thereof, intended to be entrusted to or used by children in that age group. These risks of injury are discussed in detail under the heading "Background" in this notice.

E. Voluntary Standard

The Commission is aware of only one voluntary standard applicable to the products and risks of injury with which this proceeding is concerned. That standard is published by the American Society for Testing and Materials and is designated F 963-86, Standard Consumer Safety Specification on Toy Safety.

This voluntary standard has provisions intended to address a variety of hazards presented by a wide range of toys and children's products, some of which are intended for children as old as 14 years of age. However, this standard does include provisions intended to address choking, aspiration, and ingestion hazards from small parts of toys and articles intended for children under three years of age.

The voluntary standard includes the same small parts requirements for toys and products intended for children under three years of age as those codified at 16 C.F.R. Part 1501. The voluntary standard also includes the same requirements for rattles as those codified at Part 1510, and the same requirements for pacifiers as those at Part 1511. Moreover, the voluntary standard imposes the following additional requirements:

(1) All teethers and squeeze toys are tested in accordance with the test for rattles set forth in Part 1510; and

(2) All rattles, teethers, and squeeze toys with nearly spherical, hemispherical, or circular flared ends are subjected to a supplementary test to identify those articles which could penetrate far enough into an infant's mouth to block passage of air to the lungs. This supplementary test uses a test fixture similar to the apparatus illustrated in Figure 2 of this notice.

F. Regulatory Alternatives Under Consideration

The Commission decided to begin this proceeding after it denied a petition requesting amendment of Part 1501 to prescribe a test which would ban any toy or product intended for children

under three years of age having a diameter less than 1.68 inches. The Commission concluded that available information did not support the specific change requested by the petition.

In this proceeding, the Commission is considering any modification of the provisions of 16 C.F.R. § 1500.18(a)(9) and Part 1501 which can be supported by information currently available or developed during the course of this proceeding. The Commission may reconsider the specific change requested by the petition if information becomes available to support that particular modification of the test in Part 1501.

The Commission is also considering the possibility that the voluntary standard for toy safety, ASTM F 968-86, could be revised to reduce even further the hazards to children under three years of age from choking on, aspirating, or ingesting toys or products intended for children of that age group, or that a new voluntary standard to address those hazards might be developed.

G. Solicitation of Information and Comments

This advance notice of proposed rulemaking is the first step of a proceeding which could result in amendment of existing regulations prescribing requirements for toys and articles intended for children under three years of age to address risks of injury from choking on, aspirating, or ingesting small parts. All interested persons are invited to submit to the Commission:

(1) written comments concerning the risk of injury discussed in this notice; the regulatory alternatives being considered by the Commission to address those risks; and other

possible alternatives to address those risks.

(2) any existing standard or portion of an existing standard which could be published as a proposed amendment of the small parts regulations.

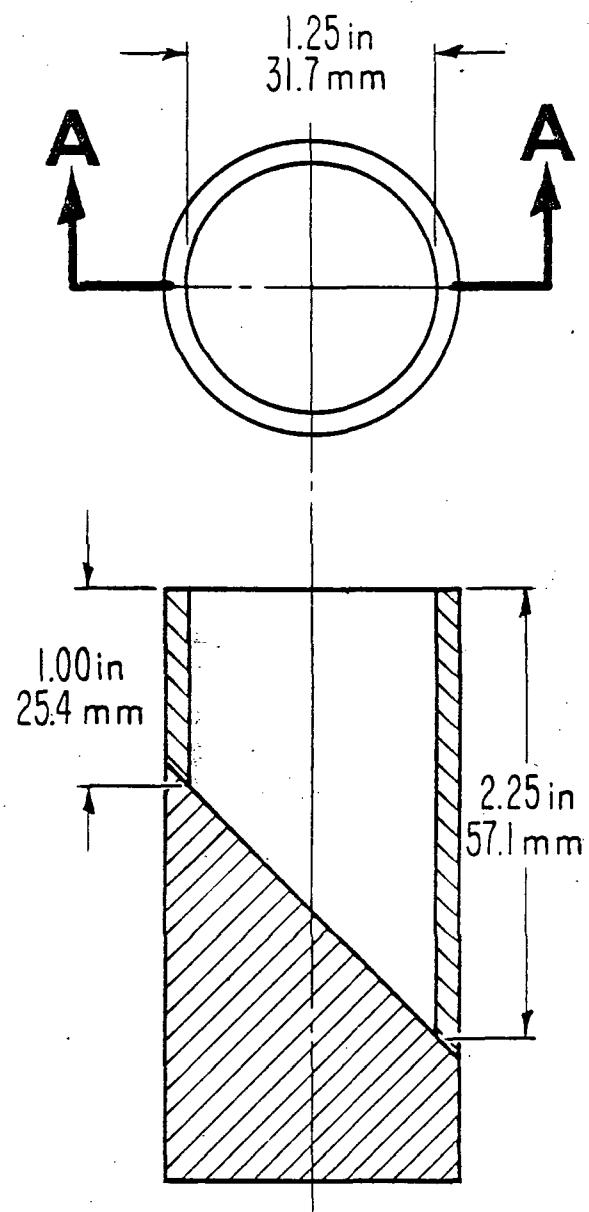
(3) a statement of intent to modify or develop a voluntary standard to address the risks of injury discussed in this notice, together with a description of the plan for modification or development of that standard.

Any plan submitted with a statement of intent to modify or develop a voluntary standard should include, to the extent possible, a description of how interested groups and persons will be notified that a proceeding to modify or develop a voluntary standard is under way; a description of how the views of interested groups and persons will be addressed in the development of the standard; a detailed discussion of how the modification or development of the standard will proceed; a realistic estimate of the length of time that will be required to modify or develop the standard; a list of persons expected to participate in the modification or development of the standard, together with information about their backgrounds and experience; and a description of any facilities or equipment that will be used during the project.

All comments and submissions should be addressed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, and received not later than [insert date 60 days after publication in the Federal Register].

Dated: _____

Sadye E. Dunn, Secretary
Consumer Product Safety Commission



Section A-A

FIG 1—SMALL PARTS CYLINDER

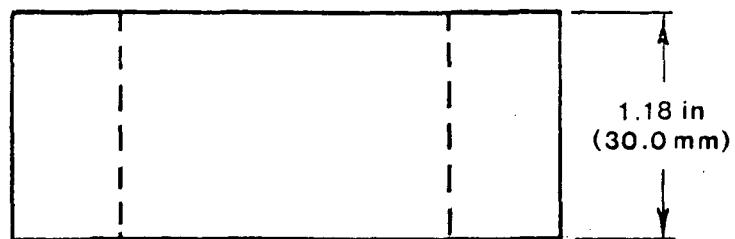
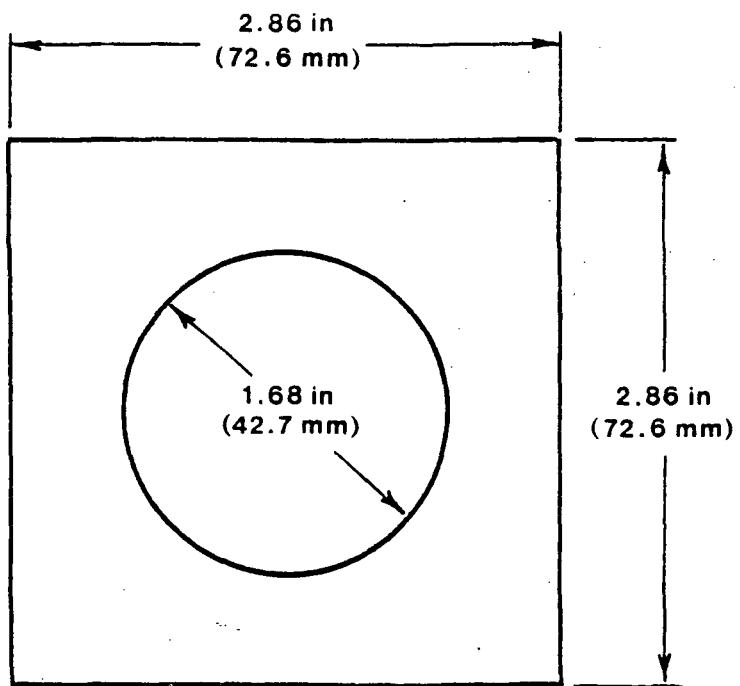


FIG. 2 - TEST FIXTURE

REFERENCE DOCUMENTS

The following documents contain information relevant to this rulemaking proceeding and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Room 528, 5401 Westbard Avenue, Bethesda, Maryland:

1. Federal Register notice of June 15, 1979 (44 F.R. 34892) entitled Method for Identifying Toys or Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards.
2. Briefing materials on Petition HP 87-2 for amendment of the small parts regulation, dated December 7, 1987. The TABS are listed separately below.
3. TAB A - (1) Memorandum from James V. Lacy, General Counsel, and Stephen Lemberg, Assistant General Counsel, dated May 6, 1987, entitled Petition to Amend Small Parts Regulation; (2) Petition from the New York Attorney General and Consumer Federation of America to amend the small parts test, and attachments: Letter from Bernard P. Dreyer, M.D., Associate Professor of Clinical Pediatrics, New York School of Medicine, to Phyllis Spaeth, New York State Department of Law, dated January 15, 1987; Human Factors Analysis -Choking Incidents in Children, by Shelley Waters Deppa, Directorate for Epidemiology, Consumer Product Safety Commission.

4. TAB B - Memorandum from Deborah Tinsworth, EPHA, to Elaine A. Tyrrell, EXPM, dated November 12, 1987, entitled FY 88 Choking Hazards Project.
5. TAB C - Memorandum from Deborah Tinsworth, EPHA, to Elaine A. Tyrrell, EXPM, dated November 12, 1987, entitled Small Parts Petition HP 87-2.
6. TAB D - Memorandum from Shelley Waters Deppa, EPHF, to Elaine A. Tyrrell, EX-PB, dated November 19, 1987, entitled Human Factors Input to Small Parts Petition Briefing Package.
7. TAB E - Memorandum from Terrance R. Karels, ECSS to Elaine A. Tyrrell, EX-P, dated November 10, 1987, entitled Small Parts Petition - HP 87-2.
8. TAB F - (1) Memorandum from Alfred L. Roma, AEDFO, to Elaine A. Tyrrell, OPMB, dated November 30, 1987, entitled Briefing Package on Petition HP 87-2 -- Amend the Small Parts Regulation. (2) Memorandum from Robert D. Verhalen, AEDEP, to Elaine A. Tyrrell, OPMB, dated November 30, 1987, entitled Epidemiology Position on Petition HP 87-2 Amend the Small Parts Regulation. (3) Memorandum from Warren J. Prunella, AEDEC, to Douglas L. Noble, OPMB, dated November 30, 1987, entitled Petition HP 87-2 to Amend the Small Parts Regulation. (4) Memorandum from Andrew G. Ulsamer, AEDHS, to Elaine A. Tyrrell, dated December 1, 1987, entitled Small Parts Petition. (5) Memorandum from

David Shiflett, OIPA, to Elaine A. Tyrrell, OPMB, dated November 30, 1987, entitled Petition HP 87-2 to Amend the Small Parts Regulation. (6) Memorandum from Walter Hobby, OPE, to Elaine A. Tyrrell, OPMB, dated November 30, 1987, entitled Petition HP 87-2 to Amend the Small Parts Regulation. (7) Memorandum from William W. Walton, AEDES, to Elaine A. Tyrrell, EX-PB, dated November 30, 1987, entitled Petition HP 87-2 to Amend the Small Parts Regulation. (8) Memorandum from David Schmeltzer, AEDCA, to Elaine A. Tyrrell, OPMB, dated December 4, 1987, entitled Small Parts Petition - AEDCA Recommendation. (9) Memorandum to the File from Douglas Noble, OPMB, dated December 4, 1987, entitled Petition HP 87-2 to Amend 16 C.F.R. Section 1501.4.

9. Standard Consumer Safety Specification on Toy Safety, ASTM F 963-86, published by the American Society for Testing and Materials.

APR 26 1988
TS-2

UNITED STATES GOVERNMENT

MEMORANDUM

RECEIVED-OFFICE
OF THE SECRETARY

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

TO : The Commission *APR 25 1988*

Through: Sadye E. Dunn, Secretary *S. Dunn*
Leonard DeFiore, Executive Counsel *LF*

FROM : James V. Lacy, General Counsel
Stephen Lemberg, Assistant General Counsel *SL*
Allen F. Brauninger, Attorney, OGC *AB*

SUBJECT: Small Parts Regulations - Advance Notice of Proposed
Rulemaking

MAY 5 1988
BALLOT VOTE due _____

A memorandum from the Office of Program Management and Budget transmits a draft of an advance notice of proposed rulemaking (ANPR) which may lead to amendment of regulations banning certain toys and children's articles with small parts. On February 3, 1988, the Commission directed the staff to prepare this document after concluding that some change to the small parts regulations (16 C.F.R. § 1500.18(a)(9) and Part 1501) may be needed to reduce choking hazards associated with toys and other articles intended for children under three years of age.

As requested by the Commission, the draft ANPR solicits information relevant to the possible need for amendment of the small parts regulations and an appropriate modification of the test specified by Part 1501 to eliminate or reduce unreasonable risks of injury associated with toys and articles intended for children under three years of age which present choking hazards.

The attached draft also contains all other information required to be included in an ANPR by section 3(f) of the Federal Hazardous Substances Act (15 U.S.C. § 1262(f)).

Please indicate your vote:

I. Approve the draft ANPR for publication in the Federal Register without change.

Date

Signature

II. Approve the draft ANPR for publication in the Federal Register with the following changes (please specify): See attached.



James Scanlon
Signature

5/13/88
Date

III. Do not approve the draft ANPR for publication in the Federal Register.

Signature

Date

IV. Abstain.

Signature

Date

CHANGES IN DRAFT ANPR ON SMALL PARTS

Page 7, lines 6-7, strike "a statement of enforcement policy" and insert in lieu thereof "a Commission statement of interpretation".

Page 11, line 6, after the word "that" insert ", while three".

Page 11, line 7, strike "analysis, 71 were" and insert in lieu thereof "analysis took place outside the United States and 49 involved products that complied with the current 1.25" diameter requirement, 71 (including 14 that resulted in death) were".

Page 12, line 9, strike "test specified by" and insert in lieu thereof "provisions of".

Page 12, line 10, after "1501" insert the phrase "including the test procedures as well as test apparatus and the products excluded from the small parts rule".

Page 14, line 25, after the word "standard" insert "was revised in 1986 (following the 1983 CPSC study),".

Page 16, line 12, strike "ASTM F 968-86" and insert in lieu thereof "ASTM F 963-86".

2/24/88

5/24/88

CHANGES IN DRAFT ANPR ON SMALL PARTS

Page 7, lines 6-7, strike "a statement of enforcement policy" and insert in lieu thereof "a Commission statement of interpretation".

~~Page 11, line 6, after the word "that" insert "while three".~~

~~Page 11, line 7, strike "analysis, 71 were" and insert in lieu thereof "analysis took place outside the United States and 49 involved products that complied with the current 1.25" diameter requirement, 71 (including 14 that resulted in death) were".~~

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Page 11, substitute the following language for the sentence which begins on line 6:

The staff observed that, of the 195 choking incidents considered in the 1983 analysis, 49 involved products with ~~1.25~~ diameters smaller than the 1.25 inch ~~1.25~~ interior diameter currently specified for the test cylinder but which passed the small parts test, and 71 were associated with products which are not currently prohibited by either mandatory requirements or provisions of a voluntary standard for toy safety to address choking hazards. The latter 71 choking incidents included 14 fatalities, three of which occurred outside the United States.

Am. Thurs
5/24/88

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UNITED STATES GOVERNMENT

MEMORANDUM

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
RECEIVED
OF THE SECRETARY
WASHINGTON, D.C. 20207

CB/SD-3

TO : The Commission

Through: Sadye E. Dunn, Secretary *Dunn*
Leonard DeFiore, Executive Counsel *JLF*

FROM : James V. Lacy, General Counsel *JVL*
Stephen Lemberg, Assistant General Counsel *SL*
Allen F. Braunerger, Attorney, OGC *AB*

SUBJECT: Small Parts Regulations - Advance Notice of Proposed
Rulemaking

BALLOT VOTE due MAY 5 1988

A memorandum from the Office of Program Management and Budget transmits a draft of an advance notice of proposed rulemaking (ANPR) which may lead to amendment of regulations banning certain toys and children's articles with small parts. On February 3, 1988, the Commission directed the staff to prepare this document after concluding that some change to the small parts regulations (16 C.F.R. § 1500.18(a)(9) and Part 1501) may be needed to reduce choking hazards associated with toys and other articles intended for children under three years of age.

As requested by the Commission, the draft ANPR solicits information relevant to the possible need for amendment of the small parts regulations and an appropriate modification of the test specified by Part 1501 to eliminate or reduce unreasonable risks of injury associated with toys and articles intended for children under three years of age which present choking hazards.

The attached draft also contains all other information required to be included in an ANPR by section 3(f) of the Federal Hazardous Substances Act (15 U.S.C. § 1262(f)).

Please indicate your vote:

- I. Approve the draft ANPR for publication in the Federal Register without change.

Date

Signature

II. Approve the draft ANPR for publication in the Federal Register with the following changes (please specify): _____

see attached changes

Carol G. Danene
Signature

5/20/88

5/13/88
Date

III. Do not approve the draft ANPR for publication in the Federal Register.

Signature

Date

IV. Abstain.

Signature

Date

CHANGES IN DRAFT ANPR ON SMALL PARTS

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UNITED STATES GOVERNMENT

MEMORANDUM

RECEIVED-OFFICE
OF THE SECRETARY

U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

TO : The Commission *2/22/88*

Through: Sadie E. Dunn, Secretary *S. Dunn*
Leonard DeFiore, Executive Counsel *LDF*

FROM : James V. Lacy, General Counsel
Stephen Lemberg, Assistant General Counsel *SL*
Allen F. Braunerger, Attorney, OGC *AB*

SUBJECT: Small Parts Regulations - Advance Notice of Proposed
Rulemaking

APR 25 1988

BALLOT VOTE due MAY 5 1988

Extended to 5/10/88

A memorandum from the Office of Program Management and Budget transmits a draft of an advance notice of proposed rulemaking (ANPR) which may lead to amendment of regulations banning certain toys and children's articles with small parts. On February 3, 1988, the Commission directed the staff to prepare this document after concluding that some change to the small parts regulations (16 C.F.R. § 1500.18(a)(9) and Part 1501) may be needed to reduce choking hazards associated with toys and other articles intended for children under three years of age.

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Please indicate your vote:

I. Approve the draft ANPR for publication in the Federal Register without change.

Date

Signature

II. Approve the draft ANPR for publication in the Federal Register with the following changes (please specify): _____

See attached

W. Orchan
Signature

5.20.88
Date

III. Do not approve the draft ANPR for publication in the Federal Register.

Signature

Date

IV. Abstain.

Signature

Date

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