if registered as a futures commission merchant, 7% of the funds required to be segregated pursuant to the Commodity Exchange Act and the regulations thereunder, if greater, or less than 120% of the minimum dollar amount required by paragraph (f) of this section, or (iii) the amount of its then outstanding subordination agreements exceeds the limits specified in paragraph (d) of 17 CFR 240.15c3–1. Such temporary subordination agreement shall be subject to all the other provisions of this Appendix.

* * * * *

Subordination Agreements in Effect Prior to Adoption

(7) Any subordination agreement which has been entered into prior to December 20, 1978 and which has been deemed to be satisfactorily subordinated pursuant to 17 CFR 240.15c3–1 as in effect prior to December 20, 1978, shall continue to be deemed a satisfactory subordination agreement until the maturity of such agreement. *Provided,* That no renewal of an agreement which provides for automatic or optional renewal by the broker or dealer or lender shall be deemed to be a satisfactory subordination agreement unless such renewed agreement meets the requirements of this Appendix within 6 months from December 20, 1978. *Provided, further,* That all subordination agreements must meet the requirements of this Appendix within 5 years of December 20, 1978.

By the Commission.

George A. Fitzsimmons,

Secretary.

June 5, 1979.

[FR Doc. 79–18641 Filed 6–14–79; 8:45 am]

BILLING CODE 8010–01–M

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17 CFR Part 249

[Release No. 34–15899]

Forms, Securities Exchange Act of 1934

Focus Reporting System; Requirements for Financial Reporting

AGENCY: Securities and Exchange Commission.

ACTION: Rule amendment.

SUMMARY: The Commission today announced amendments to the financial and operational reporting requirements collectively known as the FOCUS reporting system by adopting the previously proposed Schedule of Segregation Requirements and Funds on Deposit in Segregation currently being used by the Commodity Futures Trading Commission for its registered futures commission merchants. This schedule will apply only to those brokers or dealers that are also futures commission merchants.

EFFECTIVE DATE: July 23, 1979.

FOR FURTHER INFORMATION CONTACT: James G. Moody, Attorney Advisor, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549, (202) 376–8135.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission today announced the adoption of certain amendments to Part II of Form X–17A–5, a financial and operational combined uniform single report under the Securities Exchange Act of 1934. The amendments will revise the form so as to incorporate the Schedule of Segregation Requirements and Funds on Deposit in Segregation currently being used by the Commodity Futures Trading Commission.

Discussion

On December 17, 1975 the Commission adopted Form X–17A–5 (§ 249.617), the Financial and Operational Combined Uniform Single ("FOCUS") Report, to become effective on January 1, 1976.[1] Part II of Form X–17A–5 is a general purpose financial and operational report designed to obtain essential regulatory information on a quarterly basis and to develop financial statements in a format consistent with generally accepted accounting principles.

On September 1, 1978, the Commodity Futures Trading Commission (the "CFTC") amended its rules pertaining to the minimum financial and related reporting requirements imposed upon futures commission merchants.[2] Although the CFTC amendments apply only to futures commission merchants, about half of all commodity customer business in the futures industry is done by futures commission merchants that are also registered with the Commission as securities broker-dealers and are therefore subject to the FOCUS reporting requirements. Accordingly, the amendments adopted herein are designed to incorporate the Schedule of Segregation Requirements and Funds on Deposit in Segregation currently being used by the CFTC. This will enable brokers and dealers that are also futures commission merchants to satisfy the CFTC's reporting requirements by filing the amended Part II [3] of the FOCUS Report on a quarterly basis, thereby eliminating the need to make burdensome duplicate reports.

Statutory Basis and Competitive Considerations

Pursuant to the Securities Exchange Act of 1934 and particularly sections 15(c)(3), 17 and 23 thereof, 15 U.S.C. 78*o*(c)(3), 78q and 78w, the Commission hereby amends 17 CFR 249.617 of Chapter II of Title 17 of the Code of Federal Regulations in the manner set forth below. The Commission believes that any burden imposed upon competition by the amendments is necessary and appropriate in furtherance of the purposes of the Act, and particularly to implement the Commission's continuing mandate under section 15(c)(3) thereof, 15 U.S.C. 78*o*(c)(3), to provide minimum safeguards with respect to the financial responsibility of brokers and dealers.

§ 249.617 [Amended]

Text of Schedule

The Commission amends Part II of Form X–17A–5, a financial and operational combined uniform single report under the Securities Exchange Act of 1934, by adding the following schedule.

Financial and Operational Combined Uniform Single Report

Broker or Dealer—as of ————.

Schedule of Segregation Requirements and Funds in Segregation

Customers' regulated commodity futures accounts[**]

Segregation requirements

1. Net ledger balance:
   a. Cash.....$————
   b. Securities (at market).....————
2. Net unrealized profit (loss) in open futures contracts.....————
3. Net equity (deficit) [Total of 1—plus or minus 2.....————
4. Add: accounts liquidating to a deficit and accounts with debit balances with no open trades .....————
5. Amount required to be segregated [Total of 3 & 4) .....$————

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[1] Securities Exchange Act Release No. 11935, December 17, 1975; 40 FR 59706, December 30, 1975. Part IIA is an abbreviated version of Part II which is filed on a quarterly basis by brokers and dealers which neither clear transactions nor carry customer accounts. As these amendments were originally proposed, Part IIA would also have been amended to incorporate the CFTC's Schedule. However, since Part IIA is filed only by brokers and dealers which neither clear nor carry customer accounts, this additional information is unnecessary.

[2] 43 FR 39956 (September 8, 1978).

[3] The new Schedule will become page 10 of Part II. The current page 10 will become page 11 of Part II.

[**] The term "customer" shall mean "customer" as defined in 17 CFR 1.17(b)(2).

Funds on Deposit in Segregation

	bank
6. Deposited in segregated funds accounts:	
a. Cash	———
b. Securities representing investments of customers' funds (at market)	———
c. Securities held for customers in lieu of cash margins (at market)	———
7. Margins on deposit with clearing organizations of contract markets:	
a. Cash	———
b. Securities representing investments of customers' funds (at market)	———
c. Securities held for customers in lieu of cash margins (at market)	———
8. Settlement due from (to) contract market clearing organization	———
9. Net equities with other FCMs	———
10. Segregated funds on hand:	
a. Cash	———
b. Securities representing investments of customers' funds (at market)	———
c. Securities held for customers in lieu of cash margins (at market)	———
11. Total amount in segregation (Total of 6 through 10)	$———
12. Excess funds (insufficiency) in segregation (11 minus 5)	$———

By the Commission.

George A. Fitzsimmons,

Secretary.

June 5, 1979.

[FR Doc. 79-18642 Filed 6-14-79; 8:45 am]

BILLING CODE 8010-01-M

federal register

Friday
June 15, 1979

Part IX

Consumer Product Safety Commission

Method For Identifying Toys And Other Articles Intended For Use By Children Under 3 Years Of Age Which Present Choking, Aspiration, Or Ingestion Hazards Because Of Small Parts

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1500 and 1501

Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts

AGENCY: Consumer Product Safety Commission.

ACTION: Final regulation.

SUMMARY: The Commission is issuing a regulation that classifies as banned hazardous substances certain toys and other articles intended for use by children under 3 years of age. It covers products that the Commission believes present a choking, aspiration or ingestion hazard, based on their failure to comply with specified size criteria. By banning these products, the regulation is expected to reduce the risks to children under 3 from choking, aspirating, or ingesting small parts.

DATES: Products introduced into interstate commerce after January 1, 1980 are subject to the regulation.

FOR FURTHER INFORMATION CONTACT: Elaine Besson, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, telephone: 301–492–6453.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Consumer Product Safety Commission believes that toys and other articles intended for use by children under 3 that contain parts small enough to be aspirated or ingested present an unreasonable risk of injury. The Commission is issuing a regulation that would classify such articles as banned hazardous substances.

The regulation requires that toys and other articles intended for very young children be tested in a specially designed device. The design of this device is based both on anthropometric measurements and on actual injury data. The device is intended to screen out items which are small enough to be ingested or aspirated by very young children. The test method in the regulation incorporates the Commission's "use and abuse" test methods; use and abuse testing will permit identification of small parts that may separate from a covered product during its lifetime.

The scope of the regulation is limited to toys and other articles intended for use by children under 3. The Commission believes that these very young children are particularly susceptible to small parts-related injuries because they are relatively unaware of risks and because they tend to place objects indiscriminately in their mouths. Frequently, too, adults believe that items intended for use by this age group are designed for unsupervised play.

The Commission is taking this action under its Federal Hazardous Substances Act authority to ban children's products which present an unreasonable risk of injury. The Commission's belief that an unreasonable risk of injury exists is supported by injury information which indicates that a substantial number of injuries related to small parts involves children in this age group and items intended for their use. The Commission recognizes that by limiting the scope of the regulation to only those items intended for very young children, it will not eliminate all small parts incidents. However, the regulation will eliminate some of these frequently unanticipated and potentially life-threatening injuries.

Certain items have been exempted from the regulation. These include articles which have functional, educational, or other value which outweighs the risk they present, and articles already covered under other Commission regulations. In addition to these specific exemptions, the Commission notes that articles intended only for use by older children are not within the scope of the regulation; examples of such products are discussed below.

The regulation includes a list of articles which the Commission believes are intended for children under 3 and thus within the scope of the regulation. In addition, the regulation contains a list of factors which the staff will consider before determining whether products not specifically listed are covered. The Commission recognizes, however, that in some cases questions may arise. Therefore, the regulation references a procedure which firms may use to provide information on the intended use of the product before the Commission staff takes enforcement action.

II. Background

The Commission regulates the safety of toys and other children's articles under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261 *et seq.*). Before the Commission began operating in May 1973, the Food and Drug Administration (FDA) regulated toy safety under FHSA authority.

In 1970 the FDA issued two toy safety regulations which addressed the aspiration, ingestion, and choking hazards presented by particular small parts in toys, such as noisemaking components in rattles (these regulations are now codified with the Commission's regulations at 16 CFR 1500.18(a)(1) and (2)). Under the authority of these regulations, the FDA and later the Commission took many actions against particular toys which contained loose, small objects that could injure children.

In January 1973 the FDA proposed for public comment a comprehensive regulation designed to (1) identify toys and other articles intended for use by children under 3 years of age which present a mechanical hazard from small parts, (2) identify mouth-actuated toys intended for use by children under 8 years of age which present a mechanical hazard from small parts, and (3) classify all such products as "banned hazardous substances" under the FHSA (38 FR 2179–80, Jan. 22, 1973).

The January 1973 proposed regulation used a truncated, hollow cylinder of specified dimensions to determine which products were too small (or had components that were too small). In addition, the proposal referenced "use and abuse" test procedures to simulate the "normal use" and "reasonably foreseeable damage or abuse" which are part of the statutory definition of a mechanical hazard (section 2(s) of FHSA, 15 U.S.C. 1261(s)).

Some products which are normally intended by the manufacturer for children over 3 years of age may not be readily recognized by the purchaser as potentially unsuitable for younger children due to the presence of small parts. The FDA proposal therefore provided an exemption for those products only if they had the "negative" label "Caution: Not Recommended for Children Under 3 Years Old." A similar exemption based on cautionary negative labeling was proposed for mouth-actuated toys "not generally recognized as being suitable for use only by children 8 years of age or older." The proposal contained additional exemptions for chalk, crayons, and books made entirely from paper because the FDA believed the developmental benefits that children derive from the use of these products outweigh the potential danger of their being aspirated or ingested.

In response to its proposal, the FDA received over 90 comments from manufacturers, distributors, trade associations, the American Academy of Pediatrics, and individual consumers. Many of these comments were extensive and extremely critical. They addressed: the very broad and undefined scope of

the regulation; the lack of documentation for establishing the size and configuration of the test device; the vagueness of the labeling provisions and the exaggerated size requirements of lettering; the adverse effect of negative labeling; and the adequacy of lead time for compliance. In addition, the comments included requests for 20 different product class exemptions.

On October 16, 1978 the Commission proposed for public comment a revised small parts banning regulation (43 FR 47684–88). In this revised proposal, the Commission took into account the comments received in response to the FDA's January 1973 proposal.

III. Proposed Regulation

The October 1978 revised proposed small parts regulation was based on current injury data. It used the same cylindrical test device that the January 1973 proposal used, but it defined the scope of the regulation more clearly. The following is a discussion of the October 1978 proposal:

A. Injury Data

The government and industry toy safety efforts directed at small parts have been effective in reducing the risk of injury presented by small parts on toys and other articles intended for use by children under 3 years of age.[1] Nevertheless, the Commission published the October 1978 proposal because of its preliminary finding that an unreasonable risk still exists which should be addressed by a mandatory and comprehensive regulation. In particular, the fact that many of the injuries are fatal to children supported the Commission's belief about the unreasonableness of the risk from small parts.

During calendar year 1976, more than 7,000 children under 10 years of age were treated in U.S. hospital emergency rooms for injuries related to small parts in toys. This is a Commission estimate which is based on data from a statistical sample of 119 hospitals comprising the National Electronic Injury Surveillance System (NEISS). A number of Commission efforts have led to additional injury information that focuses on the hazard which small parts present to children under 3:

(1) *Special study.* Between December 24, 1976 and February 9, 1977 the Commission's epidemiological staff conducted a special study of small parts injuries reported through NEISS. The staff investigated and analyzed the injuries and found 153, representing an estimated 3,800 nationwide injuries for that period. These were verified to be ingestions, throat lodgments, or foreign body lodgments in ears or noses. Forty-six percent of these injuries were to children under 3 years of age, and 79 percent of all choking incidents were to children under three. (The complete study, "Injuries Associated with Small Objects," is available from the Office of the Secretary.)

(2) *Bendix study.* In 1976 the Commission contracted with the Bendix Company to conduct an investigation into the size of toys/small parts which have caused choking deaths or incidents in children under the age of 6 years. Bendix solicited information from the membership of the National Association of Medical Examiners.

Death certificates and injury reports obtained by Bendix indicated that toys, toy parts, and other objects ranging in size from 9/16 inch to 1¾ inches in greatest diameter can produce fatal obstruction of the air passage. (Copies of this Bendix report are available from the Office of the Secretary.)

(3) *Data on deaths associated with small parts.* The staff has compiled data, from its own files and from those of the Bendix Company, on deaths associated with small parts. Between March 1973 and March 1977 the Commission received 113 death certificates in which the cause of death was related to small parts. Forty-five deaths were associated with 14 different types of children's toys and nursery products.

The following causes of death were among those revealed by the certificates: (1) lodgment of an object in the pharynx or larynx area of the throat which blocked the air passage and resulted in suffocation; (2) asphyxiation due to partial or total blockage of air to the lungs, resulting from either direct obstruction of the trachea (windpipe) by a foreign object or indirect obstruction by vomitus; (3) swallowed sharp or pointed objects which cut or pierced internal organs; (4) aspiration of an object into a bronchus or lung.

Approximately half of the victims in the Commission's death certificate file on small parts were under 3 years of age. In the Bendix Company data on deaths associated with choking, more than two-thirds of those who died were children under 3 years of age.

(4) *Other data bases.* The Commission also reviewed over 200 indepth investigations and consumer complaints in its files which involved injuries from small parts. These involved foreign body throat lodgments, ingestions, and aspirations, as well as foreign body ear and nose lodgments. The throat lodgments cut off the breathing of many of the victims, and some children survived only because an adult was present to remove the object. Other victims died of suffocation. All of the victims who aspirated objects required hospital in-patient treatment.

B. Statutory Framework

Under section 2(f)(1)(D) of the FHSA, the definition of "hazardous substance" includes "[a]ny toy or other article intended for use by children which the [Commission] by regulation determines * * * presents an electrical, mechanical, or thermal hazard." Under section 2(s) of the FHSA, "[a]n article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness * * * because the article (or any part or accessory thereof) may be aspirated or ingested * * * or * * * because of any other aspect of the article's design or manufacture."

The Commission proposed to define as hazardous substances certain toys and other articles intended for use by children under 3 years of age, based on the small parts hazard they present. Following issuance of a final regulation defining them as "hazardous substances," toys that contain small parts, as defined in the regulation are automatically "banned hazardous substances" under section 2(q)(1)(A) of the FHSA, because they would be "toy[s] or other article[s] intended for use by children which [are] hazardous substance[s]."

Under section 3(e) of the FHSA, the Commission must follow the informal notice and comment rulemaking procedures of 5 U.S.C. 553 to determine that a toy presents a mechanical hazard, unless it elects alternative procedures. In this small parts proceeding the Commission has followed the 5 U.S.C. 553 procedures.

C. Scope

As proposed, the small parts regulation applied to nearly all toys and other articles intended for children under 3 years of age. All children and adults are potential victims of the hazard presented by small parts, but children under 3 are particularly susceptible.

Children under 3 indiscriminately put things into their mouths and do not have the knowledge of cause and effect relating to protecting themselves from potential hazards as does an older child

[1] In an effort to simplify the preamble discussion, the term toy(s) will be used inclusively for both toys and other articles intended for use by children.

or adult. (This is discussed fully in an April 17, 1978 staff report, entitled "Normal Developmental Behavior in Young Children and Their Relationship to Potential Hazards," which is available from the Office of the Secretary.) In addition, very small parts on toys that are intended for use by children under 3 usually serve a limited or no functional purpose.

Finally, it is easier to control the products to which children under 3 have access than to control the products to which older children have access. Children under 3 could, of course, encounter and choke on a coin, hairpin, or other adult item or on toys intended for use by their older brothers and sisters. However, the Commission's proposal was based on its belief that a regulation directed at toys intended to be used by children under 3 will have a positive impact in reducing injuries.

In determining which toys and other articles are intended for children under 3, the Commission proposed to consider such factors as the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the toy; and whether the toy is commonly recognized as being intended for children under 3. As proposed, none of these factors would necessarily be determinative. (It should be noted that products which are intended both for children under 3 and for older children would fall within the scope of the regulation.)

The proposed regulation covered all toys and other articles intended for use by children under 3 that were included in a long list of product categories. The list was developed from a number of sources including the Toy Manufacturers of America classification system, published commercial promotional materials, and a retail store survey conducted by the Commission staff. While this list was not intended to be exhaustive, the Commission believed that the vast majority of toys covered by the regulation would fall within at least one of these categories. Because of the very broad scope of the proposed regulation, the Commission expected the list of product categories to help industry representatives and consumers focus on the products being regulated. The Commission emphasized that, even if a toy did not fall within a category on the list, it would be covered by the regulation as long as it is intended for use by children under 3 and is not specifically excluded from coverage.

The Commission proposed exemptions for a number of products whose functional, educational, or other value outweigh any possible hazard from small parts. In some cases, compliance with the small parts regulation would mean drastic redesign of useful everyday products at substantial cost to the consumer. In other cases, compliance would be physically impossible because the product could not perform its function if redesigned.

As examples, books made of paper and writing materials are educational. Children's clothing and accessories, such as shoe lace holders and buttons, are functional. Modeling clay and fingerpaints cannot practicably be manufactured so that small bits of these substances will never break off. (Under the FHSA, any such products which are harmful to children because of their toxicity, as an example, are automatically banned.)

The Commission also proposed to exempt marbles and balloons from the small parts regulation. If the regulation covered marbles and balloons, these entire product types would be effectively banned. The Commission believed that the negative effect of removing traditional toys such as these from the selections available to consumers would outweigh the net safety gain. In any case, the Commission expressed its belief that marbles, when used in the game of "marbles," are generally intended for children over 3. However, the proposed regulation did cover any marbles which are part of a toy that is intended for children under 3.

Finally, the Commission proposed to exempt pacifiers and rattles from the small parts regulation. The Commission's existing regulations for these products both contain requirements which specifically address the risk of injury presented by small parts (see 16 CFR Part 1510 for the rattle regulation and 16 CFR Part 1511 for the pacifier regulation).

A comment to the January 1973 proposal had requested an exemption for vending machine products. This was based on the claim that these products are not intended for children under 3 because such children cannot activate the machines. The Commission expressed its belief that some vending machine products are nevertheless intended for children under 3, and the proposed regulation did not exempt vending machine products as a broad category. Instead, the Commission proposed to evaluate them individually as to whether they are intended for use by children under 3.

D. Regulatory Criteria

The Commission's October 1978 proposed regulation centered on a measuring device—a truncated, hollow cylinder—which separates toys and their components into two classes, according to their size and shape. The Commission proposed that a toy or component which fits entirely within the cylinder is to small for children under 3 and should be banned.

The same cylinder has been used as the basis of voluntary toy safety efforts by the FDA and by Commission staff members. In addition, the Toy Manufacturers of America (TMA) incorporated the cylinder into its Toy Safety Voluntary Product Standard PS 72–76 (1976).

The dimensions of the cylinder, as proposed, were identical to those proposed by FDA in January 1973. Data obtained by the Commission and analyses performed since 1973 confirmed that a cylinder with those dimensions is the most meaningful, effective, and practical way to identify toys and components that present unreasonable risks of choking, aspiration, or ingestion to children under 3 years of age.

The Commission staff first evaluated the relevant medical data found in the existing literature. These data on the actual dimensions of air and food passages in humans are sparse and alone are probably insufficient to support the determination that objects of a particular size are hazardous. However, the data proved useful in establishing certain approximate size boundaries.

The staff then evaluated the sizes and shapes of the objects known to be involved in choking, aspiration, or ingestion incidents in children under 3. Many of these objects were identified in the Bendix contract report. The staff found that the cylinder would "screen out" the vast majority of such objects.

The staff also evaluated a test device with dimensions used by the Commission (43 FR 22002, May 23, 1978) and the Canadian government to define hazardous rattles. This device also screened out many objects which were involved in actual choking, aspiration, or ingestion incidents. However, the rattle test device additionally screened out a large number of products not so involved and not otherwise believed by the staff to be hazardous. Based on this analysis, the Commission decided to incorporate the test cylinder into its proposed regulation.

A June 5, 1978 Commission staff report, entitled "Human Factors

Analysis of Ingestion, Aspiration, and Choking Injuries," discusses in some detail the link between the cylinder and the risks of injury it addresses. In particular, the report (which is available from the Office of the Secretary) traces the evolution of the cylinder and its dimensions.

Briefly, the design of the cylinder is derived from two screening devices originally proposed by the Toy Manufacturers of America. These devices consisted of a hollow sphere with an inside diameter of 1¼ inches and a long narrow cylinder having an inside diameter of ⅛ inch and a length of 2¼ inches. The purpose of the sphere and the cylinder was to eliminate objects which had been involved in ingestions, aspirations, and airway obstructions, such as small balls and slender pins. However, use of the two devices incorrectly implied that two separate and distinct problems existed. therefore, FDA combined the concepts of the two TMA devices into a single measuring tool, a truncated cylinder, which incorporated the dimensions of each.

The diameter of the cylinder is based upon a set of recommendations made by the Accident Prevention Committee of the American Academy of Pediatrics. As stated in this committee's correspondence, "an item having a 1¼ inch minimum width is not likely to . . . suddenly and completely obstruct the airway." The depth of the cylinder is based upon data and medical literature available to the Commission which indicate that the vast majority of objects involved in injuries to children under 3 years of age were less than 2¼ inches in length.

The regulation, as proposed, also referenced certain "use and abuse" test procedures which the Commission published in final form in the **Federal Register** on January 7, 1975 (40 FR 1484–85) and which appear at 16 CFR 1500.51 and 1500.52 (excluding the bite test procedure—section (c) of both provisions). These procedures are intended to simulate the normal use and reasonably foreseeable damage or abuse to which a toy for children under 3 would be subjected. As mentioned in the Background section above, this concept is contained in the statutory definition of a mechanical hazard.

Under the proposed regulation, toys (and detachable components) would be tested as potential small parts by being placed in the cylinder. They must be large enough so that they do not fit entirely within the cylinder. If a toy does not fit entirely within the cylinder, it would then be subjected to the referenced "use and abuse" procedures. The toy is again tested by being placed in the cylinder. In addition, any components or pieces that have become detached from the toy during the "use and abuse" procedures are separately tested in the cylinder. If any toy or any component or piece of a toy fails the test criteria (by being small enough to fit entirely within the cylinder), the toy is a banned hazardous substance.

E. Labeling

The regulation, as proposed in October 1978, did not contain any labeling requirements. The Commission considered and rejected the "negative" labeling approach that FDA used in its 1973 proposal. Because there was no attempt in the FDA proposal to define specific categories of toys to be covered, any toy not intended for children under 3, which contained small parts, had to be labeled with the warning "Caution: Not Recommended for Children Under 3 Years Old."

The 1973 labeling proposal, although never issued by the FDA or the Commission, prompted many manufacturers and importers to apply this label to many of their products. Such labeling was apparently designed to exempt products automatically from coverage of any final small parts regulation that might be applied to toys intended for children under 3.

As part of its October 1978 proposal, the Commission expressed its belief that the label has been used indiscriminately and without regard for the intentions of the original proposal. For example, certain items, such as squeeze toys and stuffed animals which are clearly intended for infants, have been distributed in commerce bearing the label.

In its proposal, the Commission strongly discouraged improper use of age labeling on children's products. The Commission proposed to disregard any label on a toy clearly intended for children under 3 that states otherwise. However, the Commission encouraged the use of proper age labeling, and proposed that such labeling be one factor it would consider before determining whether a particular toy is intended for use by children under 3 years of age (as discussed in the Scope section above). The Commission decided that a negative labeling requirement was not needed because the proposal clearly stated the intended scope of the regulation.

F. Effective Date

The Commission proposed that the final small parts regulation become effective six months after its issuance. This was based on the Commission's desire to make the regulation effective sooner than one year after its final issuance. The proposal was supported by the fact that the test cylinder has been available since 1973 to toy companies, most of which already produce complying products. The Commission sought comment especially on this proposal that the small parts regulation become effective six months after its publication in final form.

G. Economic Considerations

In its discussion of the October 1978 proposal, the Commission stated its expectation that the industry-wide economic impact of the small parts regulation would be small. The results of a standardized retail store survey suggested that the vast majority of toys and children's articles already meet the requirements of the proposed regulation. In part because of the existing voluntary standard and the specific exemptions of certain toys, only a small fraction of toys would be affected by the small parts regulation, as proposed.

Of those firms whose products did not then meet the requirements, the majority were expected to need only minor changes to bring their products into compliance. Frequently, the necessary adjustments would simply involve removal from the products of a small part which does not change the basic nature or function of the product. Alternatively, the manufacturer could redesign the product so that the small part is larger and thus complies with the regulation.

In some cases the regulation was expected to pose problems for manufacturers of products which contain small parts that a child can easily detach from a toy. The Commission expressed its belief that existing technology could solve such problems because nearly identical products exists which do not have such easily-detached small parts. More glue, rivets, or other similar solutions may be sufficient to bring a product into compliance, with only minor cost increases.

The Commission did not expect small businesses to face undue hardship in meeting the requirements of the regulation, as proposed. The economic considerations concerning the small parts proposal were fully discussed in the May 1978 staff report, entitled "Economic Assessment of the Proposed Small Parts Regulation," which is available from the Office of the Secretary.

H. Environmental Considerations

The Commission assessed the potential environmental impact of the small parts regulation, as proposed, and concluded that no potentially significant environmental impacts are associated with it. Therefore, the Commission decided that no environmental impact statement was necessary. (Copies of the environmental assessment are available from the Office of the Secretary.)

IV. Discussion of Public Comments

The Commission received 46 comments from the public on its October 1978 small parts proposed regulation. Eighteen of these came from industry and 17 came from individuals unaffiliated with any groups or organizations. Included among the 11 other comments were submissions from representatives of the medical profession and of state and local governments. All comments received are available for inspection in the Office of the Secretary.

The following discussion of the comments is categorized by subject. It does not correspond exactly with the discussion of the proposed regulation in section III, but it covers most of the same subjects.

A. Risk of Injury

1. *Injury data.* A number of commenters have asserted that the injury data cited by the Commission do not justify issuance of the small parts regulation. The most common comment was that many of the small products and components causing the deaths and injuries that were cited by the Commission would not be addressed by the regulation.

Based on the injury data which supported the proposed regulation, the Commission continues to believe that small parts present a serious hazard to children under 3 years of age. All of the available injury data, taken together, support the finding that the risk which small parts present to children under 3 is an unreasonable one.

For example, the NEISS data show the scope of the problem. Of the estimated 3,800 incidents uncovered during the 6-week special study of NEISS data on small parts injuries, 46 percent were to children under 3 and 79 percent of all life-threatening choking incidents were to children under 3. In addition, 68 percent of the NEISS injuries in the special study involving children's products involved products for children under 3 (if products exempted from the regulation are not counted, it is 64 percent).

The Commission's regulation will not eliminate all aspiration, choking and ingestion incidents. Some reported injuries were caused by household articles that are not intended for use by children under 3, including toys intended for use by older children. Other injuries may have resulted from misuse of the products that was not reasonably foreseeable.

By the same token, the NEISS data are not intended to pinpoint every injury which a proposed regulation might address. NEISS merely provides injury statistics which identify the broad categories of products and victims that are associated with injuries treated in hospital emergency rooms. The NEISS data relevant to the small parts regulation indicate that children under 3 bear a disproportionate share of the choking and other injuries caused by small parts. In conjunction with other injury data, the NEISS data support the finding that the risk which small parts present to children is an unreasonable one.

An example of other injury data which support the unreasonable risk finding is the significant number of deaths that small parts have caused to children under 3. The Commission's files contain 113 certificates on deaths caused by small parts. Of these, 45 were associated with various children's toys and nursery products, and approximately half of the victims in the 113 cases were under 3 years of age. A recent check of the Commission's death certificate data base reveals that at least 25 deaths from small parts involved products that are not exempt from the regulation.

Again, the Commission's regulation would not have prevented all of the deaths of children under 3 that were caused by small parts. Because products not intended for children caused some of the deaths, even a ban of all children's products involved in fatal incidents could not eliminate all risk. Nevertheless, the death certificate data support the existence of a serious risk from small parts. The Commission's regulation addresses a substantial portion of this risk in a fair, practical and effective way.

Injury statistics understate the risk of injury addressed by the small parts regulation. Even if every injury and death could be recorded and analyzed, incidents in which children under 3 barely escaped death and serious injury are unlikely to appear in statistical studies.

A parent who finds an infant choking on a teething ring and not breathing will immediately dislodge the ring. The infant may be fine in a few moments. Although death was nearly the tragic result, this incident would probably not show up in hospital emergency room records and would not be reported on a death certificate.

Such "close calls" are important indicators that a risk of injury from small parts exists. Although "close calls" are not routinely reported to the Commission, two mothers did describe such incidents in their official comments on the proposed small parts regulation. Both reports involved babies under six months and both involved crib toys. Although neither baby was injured, one or both could have choked to death on the small parts that came off the toys involved.

The Commission believes that it should not wait for deaths, injuries, or even "close calls" to occur before determining that a children's product presents an unreasonable risk of injury under the FHSA. As the Chairman of the National Commission on Product Safety said at a Senate subcommittee hearing in 1969, in testimony concerning toy safety amendments to the FHSA, "[w]hen your intelligence tells you that something will create an injury and it seems conceptually clear that an injury will occur, it is primitive to wait until a number of people have lost their lives or sacrificed their limbs before we attempt to prevent those accidents" (Hearing before the Consumer Subcommittee of the Committee on Commerce, April 16, 1969, pp. 31–32).

The Commission does know that small parts have caused the deaths of children under 3. By size and intended use, the Commission has categorized the products which present the greatest risk and which can be effectively regulated. Especially because deaths are involved, the Commission will not delay acting against the risk until every item in the category has been involved in a specific incident.

A trade association of firms associated with bulk vending products, the National Bulk Vendors Association (NBVA), has questioned whether such products present an unreasonable risk of injury to children under 3. NBVA has claimed that bulk vending products are not associated with particular small parts injury incidents.

The Commission believes that potential future incidents should be prevented, for the reasons discussed in this section. In addition, NBVA has stated that only two injury incidents in the Commission's data base might have involved bulk vending products. However, these two incidents were found in a 6-week special survey of

incidents in a sample of hospital emergency rooms. Therefore, each statistically represents many more emergency room incidents and many other incidents which would never show up in emergency room statistics. More importantly, products are generally categorized by type, not by method of distribution, for injury reporting purposes. The injuries associated with "bulk vending products" cannot therefore be accurately quantified using existing data.

2. *Legislative history of FHSA.* NBVA has made an additional argument, based on the legislative history of the FHSA, that vending machine products do not present an unreasonable risk of injury. As discussed under Statutory Framework (section III, B, above), the Commission is regulating small parts by classifying as "mechanical hazards" toys which are or which contain small parts. This classification must be based on a Commission finding that such toys present "an unreasonable risk of personal injury or illness."

NBVA's argument, based on its interpretation of the FHSA, is that "in contrast to electrical or thermal risks, mechanical risks are to be judged quantitatively before being classified as unreasonable risks." More specifically, NBVA has asserted that the Commission cannot classify a toy as a mechanical hazard merely because it is small. Rather, the Commission must also consider factors other than size.

The Commission agrees with all but a minor portion of MBVA's analysis of the legislative history. It is true that the definition of "electrical hazard" in the FHSA does not contain the "unreasonable risk" phrase. (Presumbly, any electrical risk is a serious one and a separate "unreasonable risk" finding is unnecessary.) However, the definition of "thermal hazard" does contain the same language about "unreasonable risk" that the definition of "mechanical hazard" contains.

The crucial point is that the Commission has not proposed to classify any toy as a mechanical hazard merely because of its size. As explained under Proposed Regulation (section III, above), the Commission has considered a number of factors. First, the Commission has identified the most vulnerable population at risk, children under 3. Because of the relative helplessness of these children and because of their propensity to place things in their mouths (as discussed in section III, C, above), the Commission's regulation is limited to toys and other articles intended for children under 3. If size were the only factor, the Commission would have banned all small toys intended for use by children of any age.

Another factor which the Commission has considered is the educational and functional value of the products potentially covered by the regulation. Some educational and functional products cannot be redesigned to comply with the regulation. Modeling clay is not modeling clay unless bits can break off. Buttons must be relatively small and are extremely useful on children's clothing. Therefore, the Commission granted exemptions for these and other products. If size were the Commission's only consideration, the regulation would have the practical effect of banning clay, paints, diaper pins, hair barrettes, and a host of other products.

Finally, the Commission has considered the severity of the injuries caused by the small toys. If a risk less severe than possible death were involved, the Commission may not have found it necessary to issue any small parts banning regulation at all.

NBVA's argument based on the FHSA legislative history might be convincing if the Commission had limited its consideration of factors to the size of the toys involved. However, the Commission has not done this. Instead, as required by the provisions of the FHSA, the Commission evaluated whether the toys it has regulated present an unreasonable risk of injury. The determination that they do is based on a careful consideration of such factors as the age of the children involved, the educational and functional value of the toys, the severity of the injuries involved, and the size of the toys.

B. Scope

1. *Products covered by regulation.* Many commenters have expressed views about the scope of the small parts regulation. A recurring comment from the toy industry was that the regulation does not clarify which toys and other articles are "intended for use by children under 3 years of age."

When proposing the small parts regulation in October 1978 the Commission provided a specific list of the toys which are covered. The Commission also listed the factors it would consider before determining which other toys might be intended for children under 3. As summarized above in the Scope section under Proposed Regulation (section III, C), these factors include the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the toy; and whether the toy is commonly recognized as being intended for children under 3.

Since none of the factors is determinative, many toy manufacturers expressed the concern that they will not know for certain whether their toys are covered by the regulation. Therefore, many suggested that the manufacturer's labeling should be conclusive on the question of whether a toy is intended for children under 3.

The Commission made a special effort to define clearly the scope of the small parts proposed regulation. The scope section (1501.2) included a lengthy list of the types of products that are definitely covered. This list was based on the Commission staff's retail survey of toys and children's articles. The Commission believes that this list covered most products which might reasonably be intended for children under 3.

The nature of any broad, generic regulation is that a few products will not be conclusively included in or excluded from the defined class. Therefore, the Commission has indicated factors to help determine fairly which "borderline" products might be covered by the regulation.

No single factor can determine conclusively whether a borderline toy is intended for children under 3. The manufacturer's labeling is undoubtedly one factor. If a toy's carton recommends "For children ages 2–5," it is likely that purchasers of that toy will give it to children of those ages. However, it is also likely that some purchasers will buy the toy for precocious children who are only one-and-one-half years old. Thus, despite the labeling, such a toy will actually be used by children for whom the manufacturer apparently does not intend it.

Similarly, the ways in which toys are packaged, promoted, and otherwise marketed will be factors in determining the age group for which they are intended. As an example, an exclusive import shop might be selling an expensive collector's item for adults or older children. A toy store might be selling inexpensive imitations of this item as toys for young children. In this example, place of sale and price would be important factors. The type and manner of advertising might also be factors.

Most marketing factors cannot be conclusive in determining whether a toy is intended for children under 3. Using the collector's item example, what would be the price cut-off and what would be the definitive description of what is an import shop and what is a toy store? In order to write a rule in which specific marketing factors clearly

separated toys intended for children under 3 from all other products, the Commission would have to disregard many subtle but relevant factors.

If the manufacturer's intent as stated on a label were solely determinative, hazardous toys that are genuinely intended for children under 3 could be intentionally or unintentionally mislabeled to fall outside of the Commission's small parts regulation.

Another deficieny with making labeling the sole and conclusive factor is that there are no industry-wide guidelines on age labeling. Consumers must contend with the differing practices of individual manufacturers. The Commission has observed at least one extreme example of how much these practices differ. On one page of a newspaper advertising supplement, a major toy retailer pictured and described a number of "baby dolls". In essence, these were the same dolls but were made by different companies. The manufacturers' age recommendations, which were also noted, were 3–8, 3–9, 2–up, 3–10, 3–up, 2–7, 1–7, and 2–9. Nevertheless, the Commission has every reason to believe that these baby dolls are all appropriate for use by children in the same age group.

The Commission believes that many factors are relevant to the determination of whether particular toys are intended for children under 3 and that none of these factors can be conclusive in isolation. In addition, manufacturers are not powerless to affect the marketing of their toys and are not ignorant of the way their toys are actually marketed.

Because of the importance of the factors, the Commission has decided to incorporate them into the small parts regulation. (They were discussed in the preamble to the small parts proposal.) Section 1501.2(b) of the final regulation below reflects this change.

The factors are most meaningful when they are carefully applied to the particular toys involved. Under a recently-amended procedure, the Commission's compliance and enforcement staff will be required to do this in every case, before initiating any enforcement action under the small parts regulation. The Commission believes that the scope of its small parts regulation is sufficiently clear. However, many commenters from the industry disagree. The procedure, along with the Commission's willingness to entertain requests for advice about the coverage of specific toys, addresses the strongly-stated industry comments that some toys are not clearly included in or excluded from the regulation.

Specifically, people and firms will have an opportunity to present written and/or oral evidence and arguments that enforcement action against their products would be unjustified. The longstanding practice of the Commission staff, which the Commission believes is a reasonable and important practice, has been to provide such an opportunity. Therefore, this procedure is now contained in staff enforcement guidelines.[2] The procedure (as contained in the guidelines, which are available from the Office of the Secretary), is summarized in the small parts regulation at § 1501.5 below.

Under the procedure, affected persons and firms will have the opportunity to present their arguments and evidence that a particular toy does not violate the regulation or that enforcement action is unwarranted. This opportunity is available anytime within 10 days of the time the staff sends them a "Letter of Advice" that their toys are noncomplying and that enforcement action might be necessary. The contentions will be addressed to the Area Office which sent the Letter of Advice. If the Area Office staff remains convinced that the toy is in violation of the regulation, its recommendation to initiate enforcement action (seizure, prosecution, or injunction), along with the firm's response to the Letter of Advice, must be made to the Commission or to a delegated staff member. The Commission has delegated this function to the Associate Executive Director for Compliance and Enforcement.[3]

This timely opportunity for submissions addresses the industry's concern that the regulation will be enforced against toys that are not intended for children under 3. At the same time, the ten-day period will not unduly delay necessary enforcement actions. (When required to protect the public safety in an emergency situation, the Commission may utilize more expeditious alternatives.) Especially because of the need for prompt consideration of the submissions, those that discuss the § 1501.2(b) factors will be particularly helpful.

2. *Expansion of scope.* One commenter—Edward M. Swartz, a Boston attorney who has been active in toy safety matters—has suggested that the Commission expand the scope of the small parts regulation to include toys foreseeably used by children up to age 5. Although this suggested change would almost surely result in some additional protection from hazardous toys, the Commission must reject it for the present time.

If the small parts regulation were broadened at this time, the scope of products covered would become uncertain. While most products intended for use by children under 3 are easily categorized as such, this may not be true for products intended for children between 3 and 5 years of age. In addition, although children 3 and older have been injured and endangered by small parts, a broadening of the regulation would require follow-up economic and injury data analyses to support an unreasonable risk of injury finding. Rather than delaying the present regulation, the Commission may consider as a separate regulatory possibility the protection of children 3 and older from the small parts hazard.

Other commenters suggested that polyurethane pellets, nut shells, and other toy stuffing materials be added to the scope of the small parts regulation. Since the integrity of covering materials will be tested under the use and abuse procedures, any stuffing materials that could pose a risk to children under 3 are already covered by the regulation. Neither the pellets nor shells nor any other stuffings need to be specifically or separately mentioned.

3. *Exemptions.* The Commission received numerous comments stating that particular products should or should not be exempted from the small parts regulation. As proposed, the following products were exempted: balloons; most marbles; books and other articles made of paper; writing materials; children's clothing and accessories; grooming, feeding, and hygiene products; records; modeling clay and similar products; paints; rattles; and pacifiers.

A few commenters suggested that marbles and balloons should be covered by the small parts regulation. As discussed in the Scope section under Proposed Regulation (section III, C), the Commission believes that marbles are not intended for use by children under 3 unless they are incorporated in a toy that is intended for such children. Therefore, the listing of marbles under exemptions was merely for clarification. They are not covered by the regulation (when sold on their own) and technically need not be exempted. In the final regulation they have been deleted from the list of exemptions.

Balloons represent a special situation. They cannot be regulated by the criteria in this regulation to address the small parts risk without being completely

[2] Enforcement guidelines were filed as a part of the original document.

[3] Copies of the authority delegation were filed as a part of the original document.

banned. The Commission has therefore decided not to include balloons in the final banning regulation below, and may consider a separate regulatory action for them. If so, the Commission will consider the possibility of requiring cautionary labeling, as two commenters suggested. (One of these commenters singled out balloons shorter than six inches, but the Commission knows of no safety-related basis for this distinction.)

Aside from the specific exemptions, the Commission's proposed regulation excluded from coverage certain substances that could become exposed as a result of the use and abuse testing. These were bits of fabric, yarn, paper, and fuzz. The reason for these exclusions was that these fibrous-type materials cannot be meaningfully tested with the truncated cylinder when they are pulled off or out of a toy. For example, the bits of fuzz that can be "picked-off" a teddy bear and the clumps of yarn hair that can be plucked from a doll's head cannot be tested in the cylinder with any precision. The Commission does not expect these minor exclusions to affect the overall effectiveness of the regulation.

A number of commenters have named other substances that they believe should be similarly excluded from coverage if exposed during use and abuse testing. The Commission agrees that some of the additional fibrous-type substances named in the comments should be added because they present the same testing limitations as fabric, yarn, paper, and fuzz. Therefore, the parenthetical exclusion in the final regulation (§ 1501.4(b)(2)) has been modified to include elastic and string. Because cotton and wool are fabrics, and therefore already covered by the parenthetical exclusion, the requests to add them to the list are denied as unnecessary.

There are a number of other substances and products which commenters specifically discussed:

(a) *Foam and other porous materials, such as sponge.* These products break off in distinct "chunks" and can be tested. In addition, the Commission believes that they are particularly hazardous because they can lodge in a child's throat and then expand to make it difficult to dislodge them. The Commission has numerous reports of choking incidents associated with foam from playpen rails and playpen pads. In fact, one of the comments to the small parts regulation discusses just such a "close call" involving foam from a playpen. The Commission has not added to the regulation any exemption for foam or similar products.

(b) *Doll clothing and other accessories.* While accessories on children's clothing are functional, the same accessories on doll's clothing are not. A child may play with the button on his or her sweater, but this is different from playing with a button on a doll's sweater which is specifically and solely designed for play purposes. Therefore, doll's accessories are not exempt from the small parts regulation. Toy dishes are similarly not exempt.

(c) *Teddy bears.* One commenter seems to imply that a teddy bear should be exempt from the regulation because its psychological value is as great as the educational value of balloons or crayons. Since it would be virtually impossible to design crayons (which break into pieces) or balloons that comply with the regulation, they have been exempted. However, it is possible to design teddy bears that comply with the regulation. Therefore, the Commission has not banned teddy bears by issuing this regulation, and no exemption for them is needed.

(d) *Ohajikes.* A Japanese trade association has asked whether Ohajikes are covered by the regulation. The Commission has learned that these are the Japanese equivalent of marbles and are not intended for use by children under 3. Therefore, they are not included within the scope of the regulation, unless they are incorporated in a toy intended for this age group.

(e) *Craft items.* Because craft items are not intended for use by children under 3, no exemption from the regulations is necessary.

(f) *Bulk vending products.* At the time it proposed the small parts regulation, the Commission specifically solicited comments on the question of whether these products should be exempt. The American Academy of Pediatrics has commented that they should not be. The National Bulk Vendors Association (NBVA) has submitted an extensive set of comments arguing that they should be.

NBVA has asserted that many bulk vending products are not intended for children under 3. To the extent that this is true, the small parts regulation does not apply and the issue of an exemption does not arise. However, NVBA's comments have assumed that some bulk vending products do fall within the scope of the regulation. The comments include a request for an exemption for the category of bulk vending products, a category which is defined by methods of distribution rather than by nature of the product.

The regulation contains exemptions for certain specific products, such as balloons. After considering the products in the category and balancing numerous factors, the Commission has determined that an exemption for balloons is appropriate. Similarly, the Commission has exempted some broader categories of products, such as those made of paper. Because all such products have a common characteristic, the Commission can determine whether an exemption based on that characteristic is appropriate.

However, NBVA seeks an entirely different kind of exemption. The category of bulk vending products includes many different types of products and products made of many different substances. The only link is that they are sold in vending machines. Only if this link were a factor which related significantly to the risk presented would an exemption be appropriate. NBVA has submitted no data establishing such a link. The Commission does not see any such link and has therefore declined to grant the exemption.

The NBVA has asserted that children under 3 cannot operate vending machines, but his is not a relevant consideration. Even if children under 3 could not obtain bulk vending toys directly from the machines without assistance from an adult or older child, it is still possible that the toys are intended for use by children under 3. The crucial point is that children under 3 are unlikely to go into stores and buy any toys at all. Adults generally buy toys and give them to children in this age group. This is true whether the toy is bought from a salesperson at a toy store or from a machine. This factor does not in any way undermine the obvious fact that many toys are intended for children under 3.

The Commission is not convinced that an exemption based on the method of distribution of certain toys is justified or appropriate for the small parts regulation. This generic regulation covers the products in a particular category which present a particular unreasonable risk of injury. Unless there is a reason to exempt products from the category, based on some common characteristic of those products or on compelling economic considerations, an exemption would contradict the rationale of the regulation.

The NBVA has not provided any such reason or any such characteristic. NBVA's comments do contain assertions, but no data, concerning the economic impact the small parts regulation would have on bulk vending products. However, the Commission does not share the view that its

regulation will put members of the NBVA out of business. In its evaluation of a representative sample of bulk vended products, the Commission has found none that will be covered by the regulation. Even if some bulk vending products were banned by the small parts regulation in the future (because of new designs or changed marketing patterns), the Commission is not persuaded that the industry could not avoid serious harm by shifting away from those products.

(g) *Articles made of fabric, yarn, fuzz, and paper.* The proposed regulation excluded from the test procedure any piece or "bit" of paper, fabric, yarn, or fuzz that became detached from a toy as a result of use and abuse testing. As already discussed in this section, these exclusions (as well as exclusions for elastic and string) are contained in the final regulation (§ 1501.4 (b) (2)). They are based on the testing limitations posed by these bits of materials.

A number of commenters have suggested that products made of the same materials be added to the list of exempted products in § 1501.3. The Commission declines to do so because products made entirely of these materials present the same potential small parts risk as products made of all other materials. It is only bits of the materials which cannot be tested meaningfully and which have therefore been excluded in § 1501.4(b)(2). (For a different reason, products made of paper are already exempted. In addition, fuzz is, by definition, a bit of material and an entire product would not be made of fuzz.)

(h) *Other.* A number of other commenters supported exemptions that the Commission proposed. These included pencils and felt tip pens. The Commission has left these exemptions unchanged.

C. Regulatory Criteria

1. *Size and nature of test cylinder.* To comply with the Commission's small parts regulation, toys must be too large to fit totally within the test cylinder. Therefore, the larger the cylinder, the more stringent the test would be. One commenter has suggested that the Commission make the cylinder larger and another has suggested that it be made smaller. However, neither of these commenters provided any technical data concerning a more appropriate size. More specifically, the commenter who suggested a smaller device noted that he personally could not swallow an object 1¼ inches in diameter. However, objects this size enter the mouth and block the throat precisely because they cannot be swallowed. In fact, 19 percent of the throat lodgment incidents the Commission knows of involved objects between ¾ and 1¼ inches in maximum dimension.

Another commenter suggested that the test template the Commission has used for rattles be used in the small parts regulation. On the basis of data on choking deaths of children 0–6 years of age, a team of experts who wrote the Bendix report recommended use of the rattle template. However, the Commission believes that the truncated cylinder is more appropriate for screening out products that are too small for children under 3. The rattle template, if substituted into the regulation below, would ban many products that the Commission does not believe present an unreasonable risk of injury to such children.

In addition, Canada's Consumer Standards Directorate has informed the Commission about the size of its small parts test cylinder. The shape of Canada's cylinder is the same as the Commission's and the dimensions, recently changed to the metric system, are nearly the same. After considering the comments on the size of the proposed test cylinder, the Commission has decided not to change the dimensions for the final regulation.

Unlike the Commission's regulation, Canada's regulation specifies that a force of 1 pound be exerted on objects when they are inserted into the cylinder for testing. The Commission does not believe that such a requirement would result in any significant increase in protection for children under 3.

A human factors engineer for Arthur D. Little, Inc. has suggested that the proposed cylinder be used temporarily "with the assurance that in-depth research and analysis would follow to develop the necessary scientific information to reduce the risk of small parts and form the basis of a permanent standard." The Commission must agree that any test device can be continually refined and improved, based on continuing scientific study. However, the Commission believes that its existing regulation fairly and effectively addresses a significant portion of the small parts risk to children under 3. The regulation incorporates a test cylinder which is based on epidemiological data indicating the population at prime risk, medical data, death certificates in which the size of the offending object is reported, and injury reports in which the size of the offending object is reported (see discussion of regulatory criteria in section III, D, above). If newly-available data indicate that the regulation could be improved, there are adequate procedures for amending it.

The Arthur D. Little engineer has also suggested that the Commission replace the proposed cylinder with cylinders of graduated sizes that reflect the range of differences in size and function of a child's aerodigestive system during the first three years of life. The Commission has adopted this type of approach, as one example, in certain provisions of its use and abuse regulations. Based on the fact that a child's strength increases with age, these provisions are divided into three parts (0–18, 19–36, and 37–96 months) which have differing test criteria. However, a child's gaining of strength occurs gradually and continually, rather than in an abrupt or discrete process. Therefore, these test criteria represent a compromise between the existing data and practicality. The compromise is justified only because the relevant data indicated an increasing trend and several benchmarks on which the Commission could base the different levels of test criteria.

In contrast, substantially less is known about the sizes of children's mouths, throats, windpipes and other critical passages. No data currently indicate even that the passages increase in size with age. Without such data and without the necessary benchmarks, a series of cylinders, as suggested by the Arthur D. Little engineer, is impractical. Although the Commission believes it would take years to develop a method for measuring these passages, it will periodically consider whether any available data would permit adoption of the suggested approach.

Finally, the same engineer has raised a potential problem concerning "implied safety." If a toy meets the Commission's standard and nevertheless presents a risk to children, there may be a false sense of security by purchasers of the toy. The Commission does not believe that all toys meeting the regulation are safe. However, the fact that some people may believe this is not a sufficient reason to withhold issuance of a regulation which will increase the safety of many toys.

Commenting on a different aspect of the test device, a toy manufacturer has suggested that the absence of dimensional tolerances and material or hardness requirements for the cylinder could contribute to inaccurate results. The Commission's test cylinders are manufactured from acrylic plastic. However, the Commission believes that any test cylinder made of a material sufficiently rigid to maintain the stated dimensions will yield equivalent results.

Neither hardness nor material requirements are necessary.

On the issue of tolerances, the Commission's cylinders will be designed and constructed to ensure that they will be no larger than the specified dimensions. In contrast, the Commission advises manufacturers to ensure that their test cylinders are nó smaller than the specified dimensions. Manufacturers can provide themselves with a margin of safety, and increase the likelihood that their toys will comply with the regulation when tested by the Commission, by using a test cylinder that is slightly larger than the specified dimensions.

2. *Use and abuse test procedures.* Incorporated as part of the small parts test procedure are the "use and abuse" test methods at 16 CFR 1500.51 and 52. A number of commenters have raised a question about how the tension test method should be applied to toys and toy components made of porous materials such as polyurethane foam. The commenters are concerned that a failure will occur at the site of the clamps used for testing, and that such a failure would lead to a ban of their toys. Such a ban would be unfair if the failure were caused by the nature of the clamps rather than by the weakness of the material being tested. To assure that this result does not occur, the Commission will not ban any toys based on failures occurring at clamp sites during performance of the tension test.

D. Statutory Approach

As proposed, the Commission's small parts regulation would classify all noncomplying toys as "banned hazardous substances" under the FHSA. Many industry commenters have urged the Commission to substitute a two-stage banning procedure for the proposed procedure. The main basis for this comment seemed to be the concern that insufficient due process procedures would be available to permit manufacturers to contest questionable Commission judgments that their noncomplying toys are intended for children under 3 and thus banned. (This comment is also discussed in section B(1), above.)

The Commission uses a two-stage procedure to ban certain toys, intended for children under 8 years of age, that present unreasonable risks due to sharp points or sharp edges. In the first stage, the Commission uses its regulations to define what edges and points are both sharp and accessible (16 CFR 1500.48 and .49). After evaluating the risk presented by these points and edges, the Commission must then decide whether they present an unreasonable risk of injury to children under 8. If so, the Commission must complete a second stage, an informal notice and comment rulemaking procedure, before determining that the toys are banned under the FHSA.

The Commission decided to regulate sharp points and sharp edges on toys intended for children under 8 years of age using this two-stage procedure because the sharp point and sharp edge test devices classified as sharp some points and edges that might not under all circumstances present an unreasonable risk of injury to children under 8. Because of the extremely broad scope of products covered, the Commission wanted to evaluate the edges and points classified as sharp on an individual basis before deciding that the toys containing them should be banned. In addition, the nature of the risks of injury involved—less than life-threatening lacerations, avulsions, and punctures—did not require that the more expeditious one-stage approach be used.

Before deciding on a statutory approach for small parts, the Commission considered many of the same factors it had considered before deciding in favor of a two-stage approach for sharp points and sharp edges. Despite some articulate comments from the industry favoring the same approach for small parts, the Commission believes that it should be basically a one-stage banning regulation, with a modification to address this industry concern. Specifically, the ten-day opportunity for submissions, discussed above, does provide affected persons and firms with an opportunity to present to the Commission staff any contentions that their noncomplying toys are not intended for children under 3, before they or their toys are subjected to any enforcement action. This effectively addresses industry's concern without imposing the delay that is inherent in a two-stage procedure.

There are a number of reasons why different procedures are justified for the small parts and sharp points/sharp edges regulations:

1. The severity of the risk from small parts is extreme, especially when compared to the risk from sharp points and sharp edges. Some avulsions, lacerations, and punctures are serious, but the Commission knows of no incidents in which children injured by a sharp point or edge did not recover. In contrast, a small part can totally cut off a child's air supply within a few moments, causing death or irreversible brain damage. The industry comments did not discuss the severity of the risk as a factor to consider.

2. If a small part exists, it presents a direct danger to children. This contrasts with the sharp points and edges regulations in which the location of the point or edge on the toy needs to be carefully evaluated before the Commission can be sure that an unreasonable risk is present. The added uncertainty of this factor is an additional reason for adopting the two-stage approach in those regulations.

3. The small parts regulation covers only toys intended for children under 3. This is a much smaller range than the 0–8 years age range covered by the sharp point and sharp edge regulations. As discussed above, the Commission believes that the regulation is sufficiently clear so that toys in this category are readily identifiable.

If an industry member needs advise on the applicability of the regulation to a particular toy, the Commission staff will be happy to provide it, either before or after the regulation becomes effective. (A particular example of this, one that concerns bulk vending products, is discussed under Economic Considerations (see item 1 under section F, below).) In addition, the Commission has a policy on the granting of emergency exemptions from regulations (16 CFR 1009.9; 43 FR 19215–16, May 4, 1978). In a qualifying situation, an industry member could escape liability for marketing what the Commission considers to be a noncomplying product.

E. Effective Date

Many commenters discussed the issue of the effective date of the small parts regulation. Manufacturers uniformly have expressed a preference that it coincide with the established marketing cycle of the toy industry, and should not impact the industry in mid-season, between June and October, when toys are being shipped. The manufacturers have objected to the proposed 6-month effective date, and have recommended instead that the small parts regulation become effective during the first part of calendar year 1980, or one year from the date of final publication in the **Federal Register**, whichever is later.

Non-industry commenters on the effective date, including local consumer protection offices, have urged the Commission to make the final regulation effective immediately. They have pointed out that this would keep dangerous toys off the market during the 1979 Christmas season.

The Commission believes that some lead time is necessary, even though evidence suggests that many toys

already meet the small parts regulation. If six months of lead time were provided, as the Commission proposed, the regulation would become final just before Christmas this year. Some of the many toys sold for Christmas might be covered, but the vast majority of such toys would have already been introduced into interstate commerce and would not be covered.

The potential added safety stemming from a pre-Christmas effective date must be balanced against the disruption to the marketplace which it could cause. In addition to the impact on the industry, consumers would not know which toys on the shelves were covered by the regulation and which were not. In fact, if the regulation became effective just before or during the Christmas buying season, toy purchasers might relax their vigilance against small parts hazards. They would likely assume, wrongly, that all the toys on the shelves were covered by the newly-effective small parts regulation.

After balancing all of the relevant considerations, the Commission has decided to make the small parts regulation effective on January 1, 1980 so that toys introduced into interstate commerce after that date will be covered.

F. Economic Considerations

Aside from comments on the effective date, the major comment on economic considerations came from the National Bulk Vendors Association. As representatives of the distributors, manufacturers, and operators of bulk vending equipment and products, NBVA has claimed that the small parts regulation could destroy their industry by banning up to 33 percent of the products currently sold; by forcing many of their members out of business; by causing loss of jobs among the 10,000 to 15,000 employees in the industry; and by making millions of dollars of equipment obsolete. NBVA has commented that "[t]he drastic economic impact of the regulation * * * outweighs any possible benefit which might accrue from banning small toy items."

It is of course possible that the small parts regulation will have some future adverse economic impact on a segment of the bulk vending industry. This was discussed in the May 1978 staff economic report referenced in the October 1978 proposal (see section III, G, above). However, NBVA's assertions seem clearly to be based on "worst case" economic projections and speculation. NBVA has not provided the Commission with specific data showing the likelihood that severe economic consequences will result.

As examples, the following points undercut NBVA's points on economic impact:

1. The Commission staff has obtained (in most cases from NBVA) and evaluated a large number of products which are dispensed by random selection bulk vending machines and which it believes are representative of the products dispensed by the machines. As discussed above, the Commission believes that none of these products is "intended for use by children under 3," according to the criteria which define the scope of the small parts regulation (§ 1501.2).

2. NBVA has claimed that adverse safety-related publicity might hurt the sales of vending machine toys which are not banned. However, this would be no more true for vending machine toys for children over 3 than for any other toys.

3. Bulk vended toys and novelties for all ages represent only 33 percent of the industry's total revenue from bulk vending operations, although for some individual firms the percentage is much higher (figures provided by NBVA). Based on the anticipated banning of some portion of these items, NBVA has claimed that the entire industry could be destroyed. This claim remains unsupported by the submission by NBVA of any data or convincing arguments. Therefore, it is just as possible that the bulk vending products unaffected by the Commission's regulation—gum balls, other food, complying items, and items for children over 3—would pick up the slack caused by any items banned in the future. It may even be that the shift to products not banned would stimulate machine manufacturing and employment, as obsolete machines are retrofitted or replaced.

4. The manufacture of toys and novelties sold in bulk vending machines apparently occurs largely in foreign countries. Even if employment in these industries were temporarily affected, non-U.S. markets could probably be developed.

G. Miscellaneous

1. A number of commenters expressed disagreement with the entire small parts regulation because it represents government interference in an area where parents have the responsibility to protect their children. Especially because deaths are occurring, the Commission believes that parental discretion alone is not sufficient to provide children under 3 with the protection they need and deserve.

2. A commenter has asked what percentage of defective products will be considered acceptable by the Commission. This raises the issue of whether a sampling plan is necessary. The Commission acknowledges that it is impossible to be 100 percent certain that every product will comply with the regulation. A test of every toy, especially with the use and abuse procedures, is impossible.

Nevertheless, the Commission will not use a specific sampling plan. If Commission testing indicates a violation, the Commission will perform additional testing and will examine a manufacturer's testing records. Before taking any enforcement action, the Commission will decide whether there is a violation which could affect significant numbers of the product. In addition, the Commission expects manufacturers to design their toys to exceed the minimum performance levels required by the regulation. Such design would likely eliminate the need for any sampling plan that sanctions the manufacture and distribution of non-complying toys.

3. NBVA has proposed that the Commission address the small parts risk by requiring cautionary labeling on bulk vending machines instead of by banning noncomplying bulk vended toys intended for children under 3. Bulk vending machine labeling is generally equivalent to package labeling for other toys and signs in stores where other toys are sold. The Commission believes that none of these alternatives would provide the same degree of protection as a ban of noncomplying toys. In addition, while the Commission encourages voluntary cautionary labeling, it would demand unrealistic staff resources to enforce any such mandatory requirements.

V. Final Regulation

In October 1971, the FDA proposed for public comment a regulation which addressed the aspiration, ingestion, and other risks of injury presented by certain dolls, stuffed animals, and similar toys (36 FR 19980, October 14, 1971). Based in part on its publication of the small parts regulation below, the Commission withdraws that FDA proposal.

The Commission finds that certain toys and other articles intended for use by children under 3 years of age present an unreasonable risk of injury to children in this age group. Before making this finding, the Commission balanced the relevant economic, epidemiological, and other considerations associated with the small parts regulation issued below.

The regulation, applicable to the very broad category of "toys and other articles intended for use by children under 3," covers many products. However, the only aspect of the toy which is regulated is the size (this should not be confused with the discussion of the scope of the regulation, section IV, A(2) above, where it is explained that size and other factors led to the Commission's determination that only certain products would be regulated). In addition, the size is regulated by a performance requirement so that toy design is affected as little as possible.

Also balanced against the broad scope of the small parts regulation is the severe risk that it addresses. Children under 3 die every year from small parts. This occurs, in part, because they indiscriminately put things in their mouths and lack the protective reactions and knowledge of older children and adults. Children over 3 and even adults choke to death on small parts, but the regulation below does not address the risk to them. Similarly, the regulation recognizes that children under 3 cannot be protected from every small part and the regulation does not include every product with which they may come into contact.

The Commission has exempted from the regulation certain products which do serve a functional, educational, or other positive need. There is widespread compliance with the regulation among toys currently on the market which are not exempted. Therefore, most toys for children under 3 will not have to be redesigned or modified in any way to comply with the size requirement. For those that do, it is reasonable to require that they be constructed large enough and sturdy enough so that they will not fracture, disassemble or otherwise expose children under 3 to hazardous small parts.

Available injury data show that chokings, aspirations, and ingestions are caused by the small size of certain toys intended for children under 3 that are on the market. The Commission expects the small parts regulation to address this risk. It is an unreasonable risk because the relatively small economic impact that would result from regulation of these products is far outweighed by the reduction of the risk that will also result from the regulation.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(D), 2(q)(1)(A), 2(s), 3(e)(1) and 10, 74 Stat. 372, 374, 375 as amended 80 Stat. 1304–05, 83 Stat. 187–89 (15 U.S.C. 1261, 1262, 1269)), in accordance with the provisions of 5 U.S.C. 553, and under authority vested in the Commission by the Consumer Product Safety Act (Pub. L. 92–573, sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)), the Commission amends title 16, chapter II, subchapter C by adding a new paragraph (a)(9) to § 1500.18 and by adding a new part 1501, as follows:

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

§ 1500.18 Banned toys and other banned articles intended for use by children.

(a) *Toys and other children's articles presenting mechanical hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

* * * * *

(9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by Part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. For purposes of this regulation, introduction into interstate commerce is defined as follows: A toy or children's article manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy or children's article manufactured in the United States is introduced into interstate commerce (1) at the time of its first interstate sale, or (2) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier. Part 1501 defines the term "toy or other article intended for use by children under 3," as used in this regulation, and exempts certain products from banning under this regulation.

PART 1501—METHOD FOR IDENTIFYING TOYS AND OTHER ARTICLES INTENDED FOR USE BY CHILDREN UNDER 3 YEARS OF AGE WHICH PRESENT CHOKING, ASPIRATION, OR INGESTION HAZARDS BECAUSE OF SMALL PARTS

Sec.

1501.1 Purpose.
1501.2 Scope.
1501.3 Exemptions.
1501.4 Size requirements and test procedure.
1501.5 Enforcement procedure.

Authority—Sec. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), and 10; 74 Stat. 372, 374, 375 as amended 80 Stat. 1304–05, 83 Stat. 187–89 (15 U.S.C. 1261, 1262, 1269).

§ 1501.1 Purpose.

Section 1500.18(a)(9) of this chapter classifies as a banned hazardous substance any toy or other article intended for use by children under 3 years of age that presents a choking, aspiration, or ingestion hazard because of small parts. This Part 1501 describes certain articles that are subject to § 1500.18(a)(9); lists certain articles that are specifically exempted; and provides a test method for determining whether an article is hazardous to children under 3 because it, or one of its components that can be detached or broken off during normal or reasonable foreseeable use, is too small.

§ 1501.2 Scope.

(a) This regulation (§ 1500.18(a)(9) and the criteria described in § 1501.4 below) applies to all toys and other articles intended for use by children under 3 years (36 months) of age that are introduced into interstate commerce after the effective date. Such articles include, but are not to limited to: squeeze toys; teethers; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures; preschool toys, games and puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy

cars, trucks, and other vehicles intended for use by children under 3. In addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.

(b) In determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevent: the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.

(c) This regulation does not apply to toys or articles which are solely intended for use by children 3 years of age or older. In addition, it does not apply to all articles to which children under 3 years of age might have access simply because of presence in a household. Certain articles which are specifically exempted from this regulation are listed in § 1501.3 below.

§ 1501.3 Exemptions.

The following articles are exempt from this regulation (§§ 1500.18(a)(9) and 1501.4 below):

(a) Balloons;

(b) Books and other articles made of paper;

(c) Writing materials such as crayons, chalk, pencils, and pens;

(d) Children's clothing and accessories, such as shoe lace holders and buttons;

(e) Grooming, feeding, and hygiene products, such as diaper pins and clips, barrettes, toothbrushes, drinking glasses, dishes and eating utensils;

(f) Phonograph records;

(g) Modeling clay and similar products;

(h) Fingerpaints, watercolors, and other paint sets;

(i) Rattles (as defined at 16 CFR 1510.2); and

(j) Pacifiers (as defined at 16 CFR 1511.2(a)).

§ 1501.4 Size requirements and test procedure.

(a) No toy or other children's article subject to § 1500.18(a)(9) and to this Part 1501 shall be small enough to fit entirely within a cylinder with the dimensions shown in Figure 1, when tested in accordance with the procedure in paragraph (b) of this section. In testing to ensure compliance with this regulation, the dimensions of the Commission's test cylinder will be no greater than those shown in Figure 1. (In addition, for compliance purposes, the English dimensions shall be used. The metric approximations are included only for convenience.)

(b)(1) Place the article, without compressing it, into the cylinder. If the article fits entirely within the cylinder, in any orientation, it fails to comply with the test procedure. (Test any detached components of the article the same way.)

(2) If the article does not fit entirely within the cylinder, subject it to the appropriate "use and abuse" tests of 16 CFR 1500.51 and 1500.52 (excluding the bite tests of §§ 1500.51(c) and 1500.52(c)). Any components or pieces (excluding paper, fabric, yarn, fuzz, elastic, and string) which have become detached from the article as a result of the use and abuse testing shall be placed into the cylinder, one at a time. If any such components or pieces fit entirely within the cylinder, in any orientation and without being compressed, the article fails to comply with the test procedure.

§ 1501.5 Enforcement procedure.

The Commission will enforce this regulation, unless it determines that an emergency situation exists, only in accordance with Chaper 2C—Letters of Advice/Notices of Noncompliance of the CPSC Enforcement Policy and Procedural Guides, issued in May 1979 and available from the CPSC's Office of the Secretary, 1111 18th Street, NW., Washington, D.C. 20207. Under the procedure described in this chapter, firms must be informed by letter that they or their products may be the subject of enforcement action and must be provided ten days within which to submit evidence and arguments that the products are not violative or are not covered by the regulation, prior to the initiation of enforcement action by the Commission or by its delegated staff member. The function of approving such enforcement actions is currently delegated by the Commission to the Associate Executive Director for Compliance and Enforcement (copies of the existing delegation documents are also available from the CPSC's Office of the Secretary).

Effective date: January 1, 1980.

Dated: June 12, 1979.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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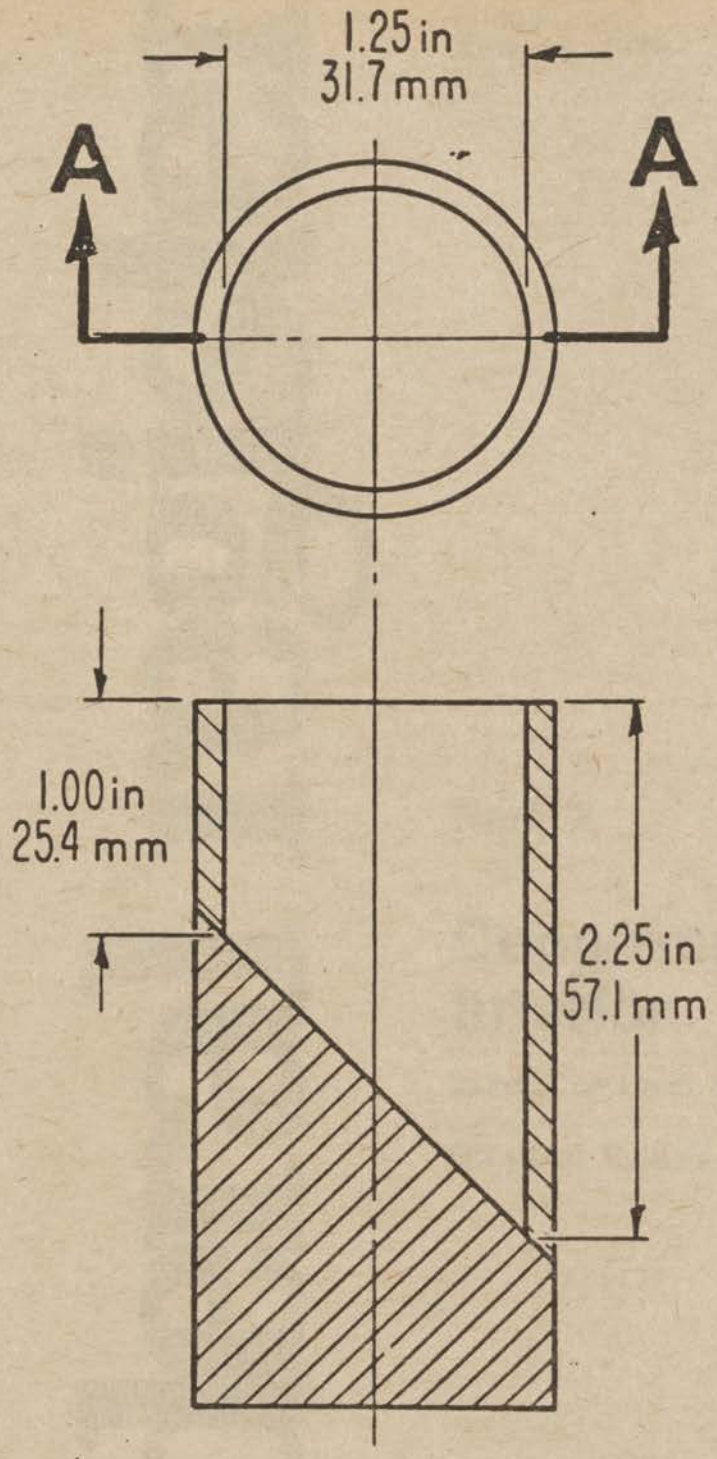

Section A-A

FIG 1-SMALL PARTS CYLINDER

[FR Doc. 79-18676 Filed 6-14-79; 8:45 am]

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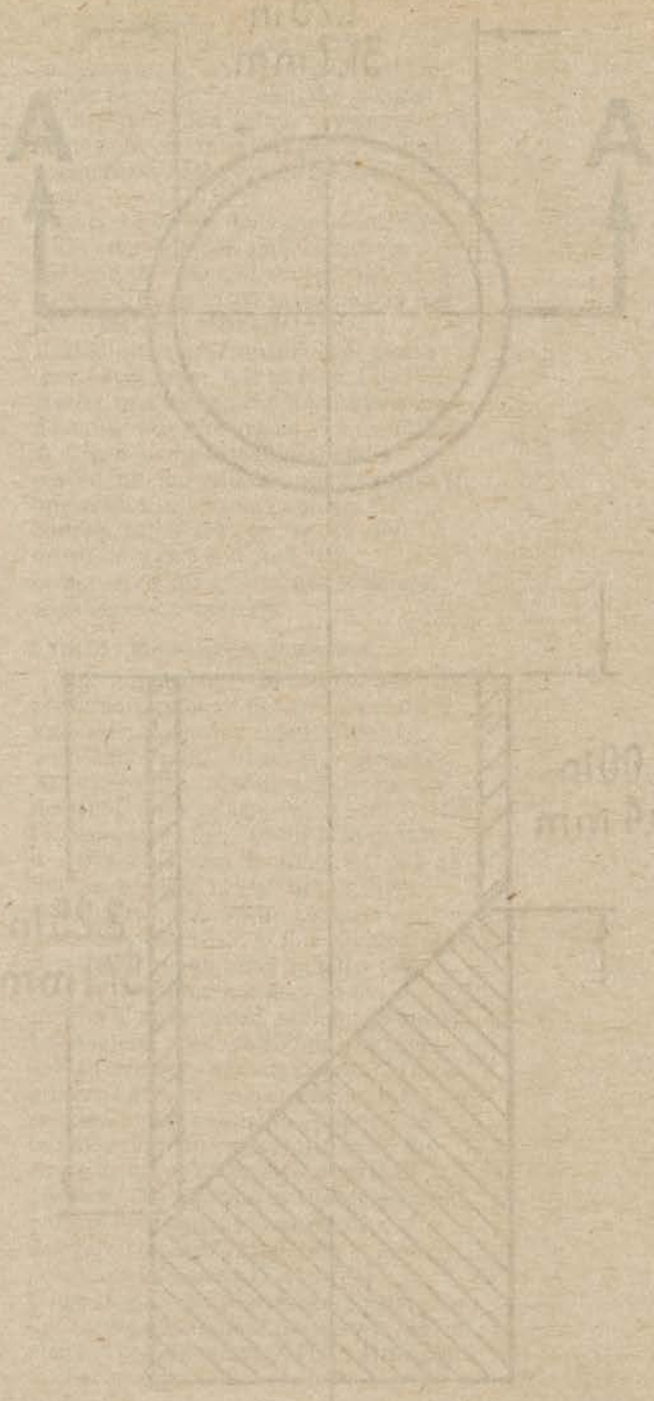
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federal register

Friday
June 15, 1979

Part X

Department of the Interior

Bureau of Land Management

Off-Road Vehicle Use

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

43 CFR Part 420

Off-Road Vehicle Use

AGENCY: Bureau of Reclamation, Interior.

ACTION: Adoption of Amendments to final rules.

SUMMARY: On August 23, 1974, final regulations of the Bureau of Reclamation concerning off-road vehicles on Bureau of Reclamation lands became effective. These regulations have been reviewed in accordance with Executive Order 11989, May 24, 1977 (relating to off-road vehicles on public lands), which amends Executive Order 11644. These amendments fulfill requirements set forth in Executive Order 11989, and require all Bureau lands to be closed to off-road vehicle use unless designated "open" under the regulation.

DATE: These amendments become effective June 15, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. L. David Williamson, Senior Staff Assistant for Land Resources Management, Operation and Maintenance Policy Staff, Bureau of Reclamation, Washington, D.C. 20240 (202) 343–5204.

SUPPLEMENTARY INFORMATION: On August 22, 1978, proposed amendments to Title 43 CFR Part 420 were published in the **Federal Register.** These amendments were designed to bring the Bureau of Reclamation's regulations into agreement with provisions of Executive Orders 11644 and 11989. The three changes made by these amendments are: (1) add to the exclusions from Off-Road Vehicles (ORV) "combat vehicles used in support of national defense;" (2) add a restatement of Section 420.2 into Section 420.21 by inserting the phrase "All Bureau lands shall be closed to off-road vehicle use unless designated open;" and (3) make provisions for Bureau Regional Directors to order the closure of off-road vehicle lands under their jurisdiction when, in their opinion, considerable adverse effects are being caused by the vehicles.

Comments received generally supported these amendments except for the general closing of the lands, which was merely a restatement of rules already in effect (43 CFR 420.2). Since Reclamation's lands have been acquired or withdrawn from the public domain for the construction of water impoundment and distribution and for agricultural development, the unrestricted use of ORV's on these lands would be unwise. In fact, the nature of these lands and their intended use dictates that the majority of these lands be closed to such ORV use. For the above reasons, the amendment to the rules proposed in the **Federal Register,** page 37206, Vol. 43, No. 163, of Tuesday, August 22, 1978, are adopted, unchanged, as follows.

The impacts of the implemention of Executive Order 11644, as amended by Executive Order 11989 (42 FR 26959), are evaluated under final Environmental impact statement (FES 78–5) entitled "Departmental Implementation of Executive Order 11644, as amended by Executive Order 11989, pertaining to use of Off-Road Vehicles on the Public Lands." Bureau of Reclamation existing regulations for off-road vehicle use, as modified by these amendments, implement the Department of the Interior's policy which was evaluated in the final environmental impact statement, and require all Bureau lands to be closed to off-road vehicle use unless designated open under procedures of Section 420.21. Notice of the availability of this final environmental impact statement was published in the **Federal Register** on April 21, 1978, (FR Vol. 43 page 17063).

Primary author of this document is Mr. Terence G. Cooper, Staff Assistant for Land Resources Management, Operations and Maintenance Policy Staff, Bureau of Reclamation.

DETERMINATION OF SIGNIFICANCE: The Department of the Interior has determined that this document is not a significant rule and does not require a regulatory analysis under Executive Order 12044 and 43 CFR Part 14.

Dated: June 4, 1979.

Guy R. Martin,

Assistant Secretary of the Interior.

Pursuant to the authority of the Secretary of the Interior contained in Executive Order No. 11989 of May 24, 1977, Part 420 of Title 43 is amended as follows:

PART 420—OFF-ROAD VEHICLE USE

1. Paragraph (a) is amended by redesignating (5) "official use" vehicles as number (6) and adding a new paragraph (5) to read as follows:

§ 420.5 Definitions.

(a) * * *

(5) any combat or combat support vehicle when used in times of national defense emergencies; and (6) "official use" vehicles

* * * * *

2. Immediately following the section heading and preceding the words "The Regional Director shall . . . ," insert the following sentence: "All Bureau lands shall be closed to off-road vehicle use under Section 420.2 unless designated as open under the following procedures." Paragraph (c) is amended to read as follows:

§ 420.21 Procedure for designating areas of off-road vehicle use.

* * * * *

(c) The Regional Director will inspect designated areas and trails periodically to determine conditions resulting from off-road vehicle use. If he determines that the use of off-road vehicles will cause or is causing considerable adverse effects on the soil, vegetation, wildlife, wildlife habitat, or cultural or historic resources of particular areas or trails of the public lands, he shall immediately close such areas or trails to the type of off-road vehicle causing such effects. No area or trail shall be reopened until the Regional Director determines that adverse effects have been eliminated and that measures have been implemented to prevent future recurrence. The public shall be notified of restrictions or closure in accordance with § 420.23.

[FR Doc. 79–18670 Filed 6–14–79; 8:45 am]

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