



Diagram 2

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Dated: May 12, 1998.

**Sadye E. Dunn,**

*Secretary, Consumer Product Safety Commission.*

#### References

The following documents contain information relevant to this rulemaking proceeding and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland:

1. Memorandum from Margaret Neily, Project Manager, Directorate for Engineering, to the Commission, "Children's Sleepwear Flammability Standards—Technical Amendments," April 27, 1998.

2. Report from C. Craig Morris, Ph.D., Directorate for Epidemiology and Health Sciences, "Clothing-Related Thermal Burns in Children Under 15 Years Old," March 1998.

3. Memorandum from Margaret Neily, Project Manager, Directorate for Engineering, to File, "Technical Amendments of the Children's Sleepwear Flammability Standards—Snug-fitting" Requirements, March 31, 1998.

4. Memorandum from Terrance R. Karels, Directorate for Economic Analysis, to Margaret Neily, Project Manager, "Children's Sleepwear Update," April 9, 1998.

5. Memorandum from Terrance R. Karels, Directorate for Economic Analysis, to Margaret Neily, Project Manager, "Economic Considerations of Revisions to the Children's Sleepwear Standard," April 9, 1998.

6. Memorandum from Patricia Fairall, Program Manager to Margaret Neily, Project

Manager, "Industry Request for clarification of sleepwear segregation of tight-fitting garments," March 3, 1998.

7. Carolyn Meiers, Directorate for Engineering, to Margaret Neily, Project Manager, "Methodology for Structured Sleepwear Observations," March 31, 1998.

8. ASTM Standards D4910-95a and D5826-95.

9. Anthropometry of Infants, Children, and Youths to Age 18 for Product Safety Design. Highway Safety Research Institute. Ann Arbor, Michigan: University of Michigan (1977).

10. Log of February 18, 1998 meeting, prepared by Margaret Neily, "Children's Sleepwear—snug-fitting requirements," March 4, 1998.

11. Memorandum from Linda Fansler, Division of Engineering, Lab Sciences, to Margaret Neily, Project Manager, "Tolerance," April 8, 1998.

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BILLING CODE 6355-01-P

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Parts 1615 and 1616

#### Proposed Clarification of Statement of Policy; Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Proposed clarification of statement of policy.

**SUMMARY:** The Commission proposes to amend the policy statements on the flammability of children's sleepwear so that infant garments (sized for a child nine months and under) and "tight-fitting" garments (as defined in the sleepwear standards) can be marketed and promoted with other sleepwear.<sup>1</sup>

**DATES:** Written comments concerning this proposed amendment are due not later than August 4, 1998.

**ADDRESSES:** Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207; telephone:

<sup>1</sup> The Commission voted 2-0 to propose clarifying the enforcement policy statement. Commissioners Mary Gall and Thomas Moore voted in favor of issuing the proposal. Chairman Ann Brown abstained.

(301) 504-0800 or delivered to the Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, Maryland 20814. Copies should be submitted in five copies and captioned "Sleepwear Policy Statement." Comments may also be filed by telefacsimile to (301) 504-0127 or by e-mail to [cpsc.os@cpsc.gov](mailto:cpsc.os@cpsc.gov).

**FOR FURTHER INFORMATION CONTACT:**

Patricia Fairall, Program Manager, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0400, extension 1369.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

The Consumer Product Safety Commission enforces two flammability standards for children's sleepwear. The flammability standard for children's sleepwear in sizes 0 through 6X is codified at 16 CFR Part 1615. The flammability standard for children's sleepwear in sizes 7 through 14 is codified at 16 CFR Part 1616.

On September 9, 1996, the Commission issued a final rule amending the flammability standards for children's sleepwear to exclude from the definition of "children's sleepwear," codified at 16 CFR 1615.1(a) and 1616.2(a), (1) garments sized for infants nine months of age or younger and (2) tight-fitting garments for children older than nine months. 61 FR 47634. The Commission found that such tight-fitting garments did not present an unreasonable risk of injury. Rather, the Commission's information showed that many severe incidents occurred with loose-fitting garments such as oversized t-shirts used inappropriately as sleepwear. The Commission concluded that garments fitting closely and that touch the body at key points should be exempt from the sleepwear standards because they do not present the same risk as loose-fitting garments. These amendments became effective on January 1, 1997. However, the Commission also issued a stay of enforcement for close-fitting garments which are labeled and promoted as underwear. That stay expires on June 9, 1998.

**B. Clarification**

The Commission has become aware that the garment industry is concerned about the policy statements in 16 CFR 1615.64(d) and 1616.65(d), which suggest segregation of items covered by the children's sleepwear standards from all fabrics and garments that are beyond the scope of the children's sleepwear standards. The purpose of the September 9, 1996 final rule was to

allow garments sized for a child nine months and under and tight-fitting garments in sizes above nine months to be sold and used as sleepwear. Therefore, the Commission proposes to modify the policy statements at 1615.64(d) and 1616.65(d) to provide that infant garments (defined in the amended sleepwear standard at 16 CFR 1615.1(c)(1) as sized for a child nine months and under) and "tight-fitting" garments (defined in the amended sleepwear standard at 16 CFR 1615.1(o) and 1616.2(m)) can be marketed and promoted with other sleepwear.

For the reasons stated above and pursuant to the authority of Section 4 of the Flammable Fabrics Act (15 U.S.C. 1193), the Commission proposes to amend 16 CFR 1615.64 and 1616.65 to read as follows:

**PART 1615—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 0 THROUGH 6X**

1. The authority citation for part 1615 continues to read as follows:

**Authority:** Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

2. Section 1615.64 is amended by revising paragraph (d) introductory text to read as follows:

**§ 1615.64 Policy to clarify scope of the standard.**

\* \* \* \* \*

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or, otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. "Infant garments" as defined by § 1615.1(c) and "tight-fitting" garments as defined by § 1615.1(o) are exempt from the standard which requires flame resistance. They may be marketed as sleepwear for purposes of this section. Additionally, retailers are advised:

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**PART 1616—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 7 THROUGH 14**

1. The authority citation for part 1616 continues to read as follows:

**Authority:** Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569-70; 15 U.S.C. 1193.

2. Section 1616.65 is amended by revising paragraph (d) introductory text to read as follows:

**§ 1616.65 Policy scope of the standard.**

\* \* \* \* \*

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or, otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. "Tight-fitting" garments as defined by § 1616.2(m) are exempt from the standard which requires flame resistance. They may be marketed as sleepwear for purposes of this section. Additionally, retailers are advised:

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Dated: May 12, 1998.

**Sadye E. Dunn,**

*Secretary, Consumer Product Safety Commission.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 334**

[Docket No. 78N-036L]

RIN 0910-AA01

**Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.