Agenda

Dist. circ. 6/2

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 2, 1977

FROM : Richard A. Danca RAD
Office of the Secretary

THRU: Richard E. Rapps REA for
Secretary

SUBJECT: Pacifier Regulation

Attached for your consideration is the staff briefing package on a final pacifer regulation. In its memo, also attached, the Office of the General Counsel discusses the issue, and states that it will transmit a revised Federal Register document in the near future.

Please indicate below your vote on this matter.

APPROVE STAFF-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

_____ Signature _____ Date

APPROVE OGC-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

_____ Signature _____ Date

DO NOT APPROVE EITHER FEDERAL REGISTER DOCUMENT

_____ Signature _____ Date

ABSTAIN

_____ Signature _____ Date

Comments/Additional Instructions:

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

LM/C-1

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 2, 1977

FROM : Richard A. Danca RAD
Office of the Secretary

THRU: Richard E. Rapps RER for
Secretary

SUBJECT: Pacifier Regulation

Attached for your consideration is the staff briefing package on a final pacifer regulation. In its memo, also attached, the Office of the General Counsel discusses the issue, and states that it will transmit a revised Federal Register document in the near future.

Please indicate below your vote on this matter.

APPROVE ~~STAFF~~ OGC-DRAFTED FEDERAL REGISTER DOCUMENT ~~AS DRAFTED~~/ WITH CHANGES for 6/15/77 discussion

Signature _____ Date 6/15/77

APPROVE OGC-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

Signature _____ Date _____

DO NOT APPROVE EITHER FEDERAL REGISTER DOCUMENT

Signature _____ Date _____

ABSTAIN

Signature _____ Date _____

Comments/Additional Instructions:

JUN 2 1977
53

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 2, 1977

FROM : Richard A. Danca RAD
Office of the Secretary

THRU: Richard E. Rapps REA for
Secretary

SUBJECT: Pacifier Regulation

Attached for your consideration is the staff briefing package on a final pacifer regulation. In its memo, also attached, the Office of the General Counsel discusses the issue, and states that it will transmit a revised Federal Register document in the near future.

Please indicate below your vote on this matter.

APPROVE STAFF-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

Signature 6/16/77
Date

APPROVE OGC-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

Signature 6/16/77
Date

DO NOT APPROVE EITHER FEDERAL REGISTER DOCUMENT

Signature Date

ABSTAIN

Signature Date

Comments/Additional Instructions:

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

3 JUN 1977

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 2, 1977

FROM : Richard A. Danca RAD
Office of the Secretary

THRU: Richard E. Rapps REA for
Secretary

SUBJECT: Pacifier Regulation

Attached for your consideration is the staff briefing package on a final pacifer regulation. In its memo, also attached, the Office of the General Counsel discusses the issue, and states that it will transmit a revised Federal Register document in the near future.

Please indicate below your vote on this matter.

APPROVE STAFF-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

_____ _____
Signature Date

APPROVE OGC-DRAFTED FEDERAL REGISTER DOCUMENT ~~AS DRAFTED/~~ WITH CHANGES, per Commission discussion

Barbara H. Franklin 6-16-77
Signature Date

DO NOT APPROVE EITHER FEDERAL REGISTER DOCUMENT

_____ _____
Signature Date

ABSTAIN

_____ _____
Signature Date

Comments/Additional Instructions:

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 2, 1977

FROM : Richard A. Danca RAD
Office of the Secretary

THRU: Richard E. Rapps REA for
Secretary

SUBJECT: Pacifier Regulation

Attached for your consideration is the staff briefing package on a final pacifer regulation. In its memo, also attached, the Office of the General Counsel discusses the issue, and states that it will transmit a revised Federal Register document in the near future.

Please indicate below your vote on this matter. R. David Pittle

OGC
APPROVE ~~STAFF~~-DRAFTED FEDERAL REGISTER DOCUMENT ~~AS DRAFTED/~~ WITH CHANGES

Signature Date 6/16/77

APPROVE OGC-DRAFTED FEDERAL REGISTER DOCUMENT AS DRAFTED/ WITH CHANGES

Signature Date

DO NOT APPROVE EITHER FEDERAL REGISTER DOCUMENT

Signature Date

ABSTAIN

Signature Date

Comments/Additional Instructions:

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission
THROUGH: Richard Rapps, Secretary
THROUGH: Margaret A. Freeston, Deputy General Counsel
FROM : Carole Roth, OGC CR

DATE: MAY 26 1977

SUBJECT: Pacifier Regulation Briefing Package

We have reviewed the briefing package on the pacifier regulation and our comments are set out below. We are currently revising the Federal Register notice included with the package. We will send the revised draft to the Commission early next week.

1. Definition of a pacifier

Teething rings are not covered by the definition of a pacifier in the regulation. The chief hazard with teething rings appears to concern liquid-filled teethers with potentially injurious liquid contents. The OSCA briefing paper does not make it clear that teethers are excluded from the regulation because the regulation is designed to address the choking and strangulation hazard presented by pacifiers and not the toxicity hazard presented by liquid-filled teethers.

The Commission could conceivably regulate such teethers under the FHSA since that Act has no exclusion for "devices" as that term is defined in the Federal Food, Drug, and Cosmetic Act, as the CPSA does. Such action, however, would require a new proposal and comment period.

2. Interstate Commerce

The draft Federal Register notice at page 11 states that the regulation is to apply to pacifiers "introduced into interstate commerce" after the effective date. The phrase "introduced into interstate commerce" is then separately defined. We would recommend, as an alternative approach that would achieve the same result, that the regulation be revised to describe clearly and fully when it becomes effective and to which products it applies.

Specifically, our revised Federal Register draft will state that the regulation applies (1) to those pacifiers manufactured outside of the United States that are first brought within a U.S. port of entry after the effective date and (2) to those pacifiers manufactured in the U. S. that are first

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

sold interstate after the effective date or are first sold intrastate, if 1 or more components and/or raw materials were received interstate, after the effective date.

Although section 4(a)of the FHSA prohibits the introduction into interstate commerce of banned hazardous substances, we believe it is unnecessarily confusing to use that phrase in the regulation. The criteria for deciding which products are subject to this regulation are different from the criteria the Commission used in deciding the applicability of the bicycle regulation, although the criteria are the same as those used in the draft sharp point regulations the Commission recently considered. We have no legal problem with the Commission making different interpretations of when products are introduced into interstate commerce for the purposes of different regulations as long as these interpretations are made clear to the public. We believe the fact that there are different interpretations supports the need for a clear statement in the regulation as to its applicability.

3. Environment Assessment and Negative Declaration

The staff is currently in the process of compiling additional environmental data for purposes of the environmental assessment. This material will be forwarded to the Commission as soon as it is available.

UNITED STATES GOVERNMENT

Memorandum

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

TO : The Commission

THRU: Office of the Secretary

THRU: Office of the Executive Director

FROM : Bert Simson, Director, OPM

Bert Simson

DATE: 9 MAY 1977

SUBJECT: Pacifier Regulation Briefing Package

Attached is the briefing package on a final pacifier regulation for Commission consideration and decision.

The Federal Register Notice at Tab H, has not been fully reviewed and commented upon by the Office of General Counsel. OGC has been provided with all materials routinely. However, the OGC attorney has had priority work on the TRIS issue and has been unable to provide final comments on the Federal Register Notice for the pacifier regulation.

This package is otherwise complete and has been approved by the Offices and Bureaus of the Bethesda Office. It is being forwarded at this time so that it can be scheduled for Commission consideration at a future Executive Session. This office is prepared to work with OGC in making any final revisions to the FR notice which may be necessary.

Attachment

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

DATE : April 20, 1977

TO : Those Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation (subject) Dated April 20, 1977

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE
Office of the General Counsel		
Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director		
Bureau of Epidemiology		
Bureau of Economic Analysis		
Bureau of Engineering Sciences	JAP 4-26-77 WMS/NSt	* approved subject to changes marked in attached briefing paper & memo WMS 4/26/1977
Bureau of Biomedical Sciences		
Bureau of Information and Education		
Bureau of Compliance		
Office of Product Defect Identification		
Office of Standards Coordination and Appraisal		

All changes considered and made were appropriate. W. Menza

DATE : April 20, 1977

TO : These Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation (subject) Dated April 20, 1977

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE	
Office of the General Counsel			
Office of the Executive Director			
Office of Program Planning and Evaluation			
Office of Resource Utilization			
Office of Field Coordination			
Office of Medical Director			
Bureau of Epidemiology			
Bureau of Economic Analysis	4/26/77	Approve*	
Bureau of Engineering Sciences			
Bureau of Biomedical Sciences			
Bureau of Information and Education			
Bureau of Compliance			
Office of Product Defect Identification			
Office of Standards Coordination and Appraisal			

* with changes as suggested

All changes considered and made were appropriate. W. Menza

DATE : April 20, 1977

TO : Those Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation Dated April 20, 1977
(subject)

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE
Office of the General Counsel		
Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director		
Bureau of Epidemiology		
Bureau of Economic Analysis		
Bureau of Engineering Sciences		
Bureau of Biomedical Sciences		
Bureau of Information and Education		
Bureau of Compliance	Richard Rapp	
Office of Product Defect Identification		
Office of Standards Coordination and Appraisal		

RECEIVED
APR 21 1977
TECHNICAL ANALYSIS DIVISION

DATE : April 20, 1977

TO : Those Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation (subject) Dated April 20, 1977

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE
Office of the General Counsel		
Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director		
Bureau of Epidemiology	[signature]	✓ (WITH MODIFICATION)
Bureau of Economic Analysis		
Bureau of Engineering Sciences		
Bureau of Biomedical Sciences		
Bureau of Information and Education		
Bureau of Compliance		
Office of Product Defect Identification		
Office of Standards Coordination and Appraisal		

Modification made. W. Menza

DATE : April 20, 1977

TO : Those Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation (subject) Dated April 20, 1977

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE
Office of the General Counsel		
Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director		
Bureau of Epidemiology		
Bureau of Economic Analysis		
Bureau of Engineering Sciences		
Bureau of Biomedical Sciences		
Bureau of Information and Education		
Bureau of Compliance		
Office of Product Defect Identification	Ruby L. Wetter	✓
Office of Standards Coordination and Appraisal		

DATE : April 20, 1977

TO : Those Checked Below

FROM : William P. Menza, TAD/OSCA Rm. 818, X-26470
Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the Briefing Paper
(Standard, petition, etc.)

on Pacifiers: Final Regulation Dated April 20, 1977
(subject)

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. April 25, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION	SIGNATURE	APPROVE/DISAPPROVE	
Office of the General Counsel			
Office of the Executive Director			
Office of Program Planning and Evaluation			
Office of Resource Utilization			
Office of Field Coordination			
Office of Medical Director	Albert F. Esch	✓ 4/25/77	
Bureau of Epidemiology			
Bureau of Economic Analysis			
Bureau of Engineering Sciences			
Bureau of Biomedical Sciences			
Bureau of Information and Education			
Bureau of Compliance			
Office of Product Defect Identification			
Office of Standards Coordination and Appraisal			

UNITED STATES GOVERNMENT

Memorandum

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

TO : The Commission
Through: Office of the Secretary
Through: Office of the Executive Director
Through: Charles R. Casper, Jr., Director, TAD/OSCA

DATE: 9 MAY 1977

FROM : William P. Menza, Technical Analysis Division, OSCA

SUBJECT: Pacifier Regulation Briefing Package

Attached is a briefing package on a final pacifier regulation for Commission consideration and decision.

The package has been approved by the offices and bureaus responsible for its preparation, and was reviewed by the Office of the General Counsel as it was prepared.

Attachment

cc:
BES
OMD
BCM
BEA
BEP
BBS
BIE
OFC
OPDI
LDD/OSCA

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : The Office of the Secretary
Through: Office of the Executive Director
Through: Charles R. Casper, Jr., Director, TAD/OSCA

DATE:

FROM : William P. Menza, Technical Analysis Division, OSCA

SUBJECT: Commission Guidance on Changes to Pacifier Regulation Requirements

There are various sections of the pacifier regulation on which there are differences of opinion.

To assist the Commission in the decisions on what requirements will be changed and in what way, the various sections in question and suggested alternatives are listed below. Additional discussion of the alternatives is contained in the briefing paper and attachments.

Section 1511.2 Definitions

1. "A pacifier is an article consisting of a nipple that is intended for a young child to suck upon, and usually includes a guard or shield and a handle or ring." (As Proposed)

2. "A pacifier is an article consisting of a shield or guard and a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid. The article usually includes a handle or ring."

3. "A pacifier is an article intended for a young child to suck upon, consisting of a nipple, guard or shield, and usually a handle or ring."

4. "A pacifier is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid and usually includes a guard or shield and a handle or ring."

Section 1511.3 Guard or Shield

1. Keep the guard or shield test requirements as proposed.

2. Change the guard or shield test requirements so that a pacifier is centered in the hole of a "bow tie" shaped template, similar to the Canadian pacifier regulation test.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

Section 1511.3(b) Ventilation Holes

1. Keep the ventilation holes requirement as proposed.

2. Not require these holes at this time.

3. Also allow "V" or "U" notches in place of ventilation holes.

Section 1511.4 Protrusions

1. Add to the protrusion test requirement: "Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it."

2. Not add the above sentence to that test requirements.

Section 1511.5 Structural Integrity Tests

1. Drop the tolerance range for the gage dimensions and delete the angle dimension in Figure 2 on small parts.

2. Keep Figure 2 as it was proposed.

Section 1511.6 Ribbons, Strings, Cords etc.

1. "A pacifier shall not be sold or distributed with any ribbon, string, or cord, or other means of attachment which could fit around a child's neck." (As Proposed)

2. A pacifier shall not be sold or distributed with any ribbon, string, cord, chain or ribbon-like attachments.

Section 1511.7 Labeling

1. "WARNING: STRANGULATION DANGER - DO NOT TIE PACIFIER AROUND THE CHILD'S NECK WITH RIBBON OR STRING." (As Proposed)

2. "WARNING - DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING—IT MAY PRESENT A STRANGULATION DANGER."

3. "CAUTION - DO NOT TIE PACIFIER AROUND CHILD'S NECK."

4. "IT IS DANGEROUS TO TIE A PACIFIER AROUND CHILD'S NECK."

Effective Date:

1. Make the effective date of the regulation 8 months from the date it is published.

2. Choose some other interval of time between publication of the regulation and its effective date.

May 3, 1977

BRIEFING PAPER

on

PACIFIERS: FINAL REGULATION

William P. Menza
Technical Analysis Division
Office of Standards Coordination and Appraisal
492-6470

ISSUE:

Whether or not to publish a final Federal Hazardous Substance Act regulation that will ban from interstate commerce baby pacifiers not meeting certain safety requirements.

BACKGROUND:

On October 20, 1976, a proposed rule on hazardous pacifiers was published in the Federal Register (Tab A). The proposed regulation has requirements for pacifier:

1. guard or shield dimensions,
2. protrusion dimensions,
3. structural integrity,
4. prohibition of sale with ribbons or strings, and
5. cautionary labeling on strangulation.

The need for this regulation was demonstrated by injury data and death reports. Eight deaths, and seven choking which did not result in death, associated with pacifiers were reported between 1970 and 1975. They were mentioned in the October 20, 1976, proposal. Two of the deaths were due to choking and six to strangulation. Since that time, the Bureau of Epidemiology (BEP, Tab B) through further research, determined that there were two additional choking deaths which were not indicated in the October 1976 proposal.

One foreign and 6 domestic manufacturers, a retailer, a domestic manufacturer's association, and a foreign Trade Commission commented on the proposal. The major criticisms were about the definition of a pacifier, the guard or shield requirements especially for ventilation holes, and the cautionary labeling statement. (See Tab C)

A member of the Commission's Consumer Product Safety Advisory Council has commented that the regulation might include prohibition of teethers or pacifiers filled with toxic substances (Tab G). She referred to an incident in New York State of water-filled teethers that the Food and Drug Administration (FDA) found to contain quaternary ammonium and gram negative bacteria. The teethers were voluntarily recalled by the manufacturer after FDA determined they were adulterated and misbranded.

Water-filled teethers do not fit the definition of pacifiers as defined in the pacifier regulation, therefore, they are not within the regulation's scope. The Federal Hazardous Substance Act already prohibits sale of products with toxic substances. The Bureau of Biomedical Science (BBS) comments that the problem of the teethers in question concerned bacteriological and chemical contents which should remain under the purview of the FDA. For these reasons these teethers are not of concern in the pacifier regulation. See Tab G.

The Bureau of Engineering Sciences Laboratory Division (BESL) tested 29 assorted pacifiers to evaluate the technical feasibility and practicability for compliance testing of the proposed test procedures. Their report is in Tab C.

DISCUSSION OF REQUIREMENTS:

Section 1511.2 Definitions:

The proposed definition of a pacifier "is an article consisting of a nipple that is intended for a young child to suck upon, and usually includes a guard or shield and a handle or ring."

One commenter suggests that the definition of a pacifier be changed to:

> "A pacifier is an article intended for a young child to suck upon, consisting of a nipple, guard or shield, and usually a handle or ring."

The change would exclude from regulations teething rings with a nipple, but no guard or shield. The Bureau of Engineering Sciences (BES) recommends that this change not be made because it would exempt some pacifiers that might be a hazard.

The Office of the Medical Director (OMD) suggest the wording:

> "A pacifier is an article consisting of a shield or guard and a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid. The article usually includes a handle or ring."

This definition is believed to make clear that a guard or shield is a necessary component for an article to be a pacifier.

To clarify the exclusion of nipples intended for dispensing liquid from bottles, BES and the Bureau of Economic Analysis (BEA) suggest that the definition be changed to:

A pacifier is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid and usually includes a guard or shield and a handle or ring.

The exclusion of baby bottle nipples is similar to the one in the British proposed pacifier regulation. (See Tabs C and E.)

Section 1511.3 Guard or Shield:

The proposed guard or shield requirements call for an attempt to pull a pacifier through a 43 mm hole with 2.0 pounds of force. If it does pull through it fails the test.

The criticisms of these requirements were that (1) the template hole diameter is excessively large, (2) the most adverse orientation requirement is excessively rigorous, and (3) vent holes are not necessary or desirable. (See Tab C.)

The OMD (Tab D) suggests that the proposed guard or shield requirements be maintained until other data shows that different requirements would give the safety desired.

BES believes that the proposed regulation may have an unnecessary safety factor by requiring a pacifier not to pass through a hole 1.70 inches in diameter when in the most adverse orientation. This test may fail the majority of pacifiers now sold. Twenty-six of the 29 pacifiers tested (90%) by BESL failed the guard or shield performance requirements of the proposed ban. Staff opinion and lack of injury data on these pacifiers, especially orthodontic pacifiers which subjectively appear to have generously large and effective shields, indicates that they do not present unreasonable risk of injury by asphyxiation because of a small guard or shield. Therefore, the BES suggests that the regulation be changed to require centering of the pacifier.

Moreover, BES recommends that the test fixture be changed to include slots on either side of the circular opening so that a pacifier is centered in a fixture similar to the Canadian pacifier regulation. (See Tab C.) This will prohibit the sale of pacifiers which have a simple bar at right angles to the nipple axis which would not be an effective substitute for a guard or shield and to lessen the burden of complying with two regulations with essentially similar requirements the bureau suggests that the diameter of the circular opening be reduced from 1.70 inches to 1.68 inches (an insignificant amount) to agree with the Canadian regulation.

Section 1511.3(b) Ventilation Holes:

The proposed guard or shield requirements include two or more symmetrically located ventilation holes.

The criticisms on this proposed requirement were that (1) it has no merit, (2) it is unhygenic, (3) it will prevent sucking, (4) it will weaken the shield, and (5) it will provide holes by which to attach strings to fasten the pacifier around a child's neck. One manufacturer recommended that other means of providing air flow, like "V" or "U" notches, be permitted.

OMD (Tab C) notes the purpose of the ventilation holes are to (1) provide an auxiliary pathway for air to the lungs including the insertion of a nasal catheter if throat tissue should occlude the air passage and (2) give a means for using a hook to pull out a pacifier impacted in the throat.

On the criticisms of this requirement, OMD points out that at least 2 holes are required so that the possibility of throat tissue blocking the holes is reduced. Dirt trapped in the holes would not have any greater amount of bacteria or dirt than elsewhere on the pacifier. The nipple and not the shield is sucked on by the child. Required cautionary labeling should minimize consumers using the holes to tie a pacifier around a child's neck.

BESL punched or drilled ventilation holes in several shields to see if they would weaken the shield. No weakening was noticed.

BES would prefer that performance and not the proposed design requirements be allowed for ventilation holes because design requirements tend to be overly restrictive. If design requirements are to be used, the Bureau suggests that greater specification on the location of the holes may be indicated and a greater number of holes may be required to prevent blockage of the airway by the tongue or palate.

Section 1511.4 Protrusions:

The proposed protrusion requirements limit any protrusion from the face of the guard or shield opposite the nipple measured after applying a 2 pound force to it.

Criticisms of this requirement were that it is unnecessary or should be clarified.

To clarify it, BES recommends that the requirement be changed to:

> "Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple."

Section 1511.7 Structural Tests:

The proposed requirements are for nipples to remain intact when pulled with 10 pounds of force before and after boiling them; and that pacifiers not have small parts that fit into the small parts cylinder.

Only one commenter suggest that the boiling time be reduced. Other commenters agree with the requirements.

One of the 29 pacifiers tested by BESL failed the structural test before the boiling cycles. After the boiling test, 2 nipples and 3 handles became detached. Two liquid-filled teethers (which may not fall within the scope of the regulation) were totally deformed after one boiling cycle.

The small parts test was applied to the five nipple or handle components that separated from their parent pacifiers. Three failed the specification.

Figure 2, small parts gage, of the regulation has been changed to be consistent with the previous dimension of the same cyclinder as it appears in the proposed small parts regulation (January 23, 1973, 38 FR 2180), a voluntary standard for toys, and a foreign standard for pacifiers. The change is the dropping of a tolerance range for the gage dimensions and deleting the angle dimension.

Section 1511.6 Ribbons, Strings, Cords Etc.:

The proposed requirement is that a pacifier shall not be sold or distributed with any ribbon, string, or cord, or other means of attachment which could fit around a child's neck.

BESL notes that the wording of this requirement is ambiguous. It tends to qualify the length of the ribbon, string or cord when its intention is to prohibit means of attaching the pacifier.

BES suggests a more clearly worded requirement is:

> "A pacifier shall not be sold or distributed with any ribbon, string, cord, chain or ribbon-like attachments."

Section 1511.7 Labeling:

The proposed requirements call for the labeling statement "WARNING: STRANGULATION DANGER--DO NOT TIE PACIFIER AROUND THE CHILD'S NECK WITH RIBBON OR STRING."

Some of the public criticisms of this requirement is that it is not necessary or should be worded differently. Suggested wording is:

1. WARNING - DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING--IT MAY PRESENT A STRANGULATION DANGER.

2. CAUTION - DO NOT TIE PACIFIER AROUND CHILD'S NECK.

3. IT IS DANGEROUS TO TIE A PACIFIER AROUND CHILD'S NECK.

BES and BCM find the first statement adequate.

ECONOMIC IMPACT ANALYSIS:

The BEA estimates (Tab E) that some 15 million pacifiers are sold annually in the U.S. Most if not all new production will have to be modified to meet the regulation.

Substantial retooling costs will be incurred by some manufacturers to comply with the guard and ventilation hole requirements. These costs are primarily those associated with modification or replacement of injection molding equipment.

The Bureau also estimates that retail prices of some pacifier models may rise from 2 to 10 cents each. For other models, retail prices will probably not show any increase. Some models of pacifiers may be discontinued, or replaced with other models which can be more easily modified to meet the regulation. One manufacturer has indicated that, should major mold changes be required, it may discontinue all pacifier production. It also appears that some wholesale and retail buyers intend to delay buying pacifiers until the regulation is published and complying merchandise is available.

EFFECTIVE DATE:

BEA (Tab E) believes that domestic manufacturers can make the changes to comply with the proposed regulation within 6 months. One domestic firm claims to have a complying product at this time. It would take importers 1 or 2 months longer than domestic manufacturers to comply because of transoceanic shipping time.

COMPLIANCE STRATEGY:

The compliance strategy of BCM (Tab F) for the final regulation in summary is:

1. Conduct an industry seminar on testing procedures in New York City.

2. Inspect all firms for compliance and collect samples for Commission compliance testing.

3. Establish a dock surveillance program to sample imported pacifiers for compliance testing.

4. If failures occur, enforcement action will be dependent upon the failure rate of the units tested and upon the percent of total product failure projected from the sample results. In borderline cases, additional samples may be taken to confirm or refute the original projection.

5. Conduct an information program, including "fact sheets" and the final regulation mailed to chain stores, retail associations and consumers. (See the Bureau of Information and Education memorandum in Tab F for the costs of information programs.)

RECOMMENDATIONS:

If the proposed regulation is published as a final one, the following changes are suggested. They include suggested changes to the October 20, 1976 proposed regulation.

1. Include in the definition of a pacifier [1511.2(a)] the phrase "but is not designed to facilitate a baby's obtaining fluid ..." This would clarify the exclusion of nipples intended for dispensing liquid from bottles.

2. Change the guard or shield dimension tests [1511.3(a)] to require the pacifier to be centered in a "bow-tie" test template similar to the one in the Canadian pacifier regulation. This would allow orthodontic pacifiers with effective guards or shields to be sold but would prohibit pacifiers with ineffective ones.

3. Change the protrusion test's requirement [1511.4(b)] to: "Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple." This clarifies the test.

4. Change the wording on the prohibition of sale of a pacifier with a ribbon or string [1511.6] to: "A pacifier shall not be sold or distributed with any ribbon, string, cord, chain or ribbon-like attachments." This more clearly prohibits means of attachment.

5. Change Figure 2, small parts gage, [1511.7] by dropping the tolerance range for dimensions and deleting the angle dimension. This makes the figure consistent with the previous small parts proposal and some existing standards.

6. Change the warning label [1511.7] to: "WARNING DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING-IT MAY PRESENT A STRANGULATION DANGER." This definition appears to meet public and staff criticisms of the proposed labeling statement

7. Make the effective date of the regulation 8 months from the date it is published. This allows reasonable time for foreign as well as domestic manufacturers to comply with the requirements.

ALTERNATIVES:

1. Publish a final pacifier regulation

   a. with some or all of the suggested changes presented in this briefing material

   b. with no changes made to the October 20, 1976, proposed regulation.

2. NOT publish a final pacifier regulation because the one prepared does not satisfactorily address the mechanical hazards presented by pacifiers.

The Federal Register Notice in Tab H can be used for a final regulation. It contains all the suggested changes listed under Recommendations.

LIST OF ATTACHMENTS

Schedule P–4—Public service revenues and air transport revenues—other and transport-related revenues and expenses; Explanation of extraordinary items and cumulative effect of accounting changes on prior years; Explanation of dividends declared

(a) This schedule shall be filed by all Group II supplemental air carriers.

(b) Transport-related operations shall be reported in this schedule in conformance with instructions in section 9–4800, Transport-Related Revenues, and sections 10–7100 and 11–7100 Transport-Related Expenses.

(c) The totals of transport-related gross revenues and gross expenses reported in this schedule shall agree with the corresponding amounts reported for classifications 4800 and 7100 on schedule P–1.

(d) Each extraordinary item shall be fully identified and reported in gross amount in this schedule.

(e) Extraordinary credits to income during the current accounting period shall be identified in positive amounts and any extraordinary debits to income shall be identified by asterisks (*).

(f) Extraordinary items and extraordinary income tax credit and debit items shall be reported separately.

(g) The net of extraordinary items and the net of extraordinary income tax items reported on this schedule shall agree with corresponding amounts reported on schedule P–1.

(h) Prior period adjustments and dividends declared shall be fully explained in the bottom section of this schedule. If a dividend is not payable in cash, the values of amounts declared shall be completely described.

29. Amend CAB Form 41 schedules to reflect the foregoing changes in accounting, as shown in the exhibits attached hereto and made a part hereof as follows:

Schedule No.:	Exhibit
B–1	A
B–2	B
B–3	C
B–4(a)	D
B–4(b)	E
B–5	F
B–6	G
B–7	H
B–7(b)	I
B–8	J
B–10	K
B–11	L
B–12	M
B–43	N
B–46	O
B–47	P
P–1.1	Q
P–1.2	R
P–1(a)	S
P–2	T
P–2(a)	U
P–3	V
P–3(a)	W
P–3(b)	X
P–4	Y
P–5.1	Z
P–5.2	AA
P–6	BB
P–7	CC
P–8	DD

(Sections 204(a) and 407 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743 and 766; 49 U.S.C. 1324, 1377.)

By the Civil Aeronautics Board:

PHYLLIS T. KAYLOR,
Secretary.

EXHIBIT A

SECURITIES AND EXCHANGE COMMISSION

September 1, 1976.

CIVIL AERONAUTICS BOARD,
Washington, D.C.

GENTLEMEN: This letter will serve to indicate that the Securities and Exchange Commission will accept the proposed CAB Form 41 reports to be filed by certified air carriers with the Civil Aeronautics Board is satisfaction of the financal statement requirements of Form 10–K and Form 10–Q, when the proposed CAB Form 41 reports comply with the requirements for financial statements set forth in Form 10–K, Form 10–Q and Regulation S–X. We understand that, because of your efforts to establish a SEC/CAB singular reporting system, the proposed CAB Form 41 reports now meet the requirements for financial statements to be included in Form 10–K and Form 10–Q filings and that you plan to maintain on a current basis the CAB's Uniform System of Accounts and Reports to comply with generally accepted accounting principles and the disclosure requirements of the SEC.

You have informed us that the proposed singular reporting system is to be used by all certified air carriers in reporting to the CAB. The air carriers will not be required to submit these forms to the SEC; however, those air carriers with air tranpsort operations only or air carriers with nonconsolidated subsidiaries engaged in operations other than air transport may meet their SEC annual and quarterly financial statement filing obligations with the CAB Form 41 reports, if the proposed singular reporting system is adopted and maintained to meet SEC requirements.

Sincerely,

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc.76-30628 Filed 10-19-76;8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Parts 1500, 1511]

HAZARDOUS PACIFIERS BAN

Revised Proposal

In this document the Consumer Product Safety Commission proposes for public comment a regulation (16 CFR Part 1511) prescribing safety requirements for pacifiers and a regulation (16 CFR 1500.18(a)(8)) banning from interstate commerce pacifiers not meeting such safety requirements. These actions are taken under the Federal Hazardous Substances Act.

BACKGROUND

Section 2(f)(1)(D) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f)(1)(D)) provides for the classification of any toy or other article intended for use by children as a hazardous substance upon a determination by regulation, in accordance with section 3(e)(1) of the act (15 U.S.C. 1262(e)(1)), that it presents a mechanical hazard. Section 2(q)(1)(A) provides that such a toy or article is also banned hazardous substance. "Mechanical hazard" is defined by section 2(s) of the act and other banned toys and banned children's article are listed in 16 CFR 1500.18.

In the FEDERAL REGISTER of October 18, 1972 (37 FR 22000), the Commissioner of the Food and Drug Administration (FDA) proposed 21 CFR 191.9a(a)(8), a regulation banning pacifiers not designed and constructed in accordance therewith, and proposed 21 CFR 191.18, a regulation prescribing a method for determining the durability of pacifiers.

Effective May 14, 1973, functions of the FDA under the Federal Hazardous Substances Act were transferred to the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

Subsequently, on September 27, 1973 the Consumer Product Safety Commission revised and transferred the regulations under the Federal Hazardous Substances Act from Title 21 of the CFR to Title 16 of the CFR (38 FR 27012). Accordingly, this revised proposal involves 16 CFR Parts 1500 and 1511 instead of 21 CFR Part 191.

DEMONSTRATION OF NEED

The need for banning hazardous pacifiers has been preliminarily demonstrated to the Commission by investigations, studies, staff analyses, and NEISS (National Electronic Injury Surveillance System) data showing that pacifiers are, or can be, a contributing factor in the serious injury and death of children.

In-depth investigations of pacifier accidents reported in the NEISS system, conducted from 1970 through 1975 by the Commission staff, show that there were at least eight deaths during this period. One victim died when the pacifier stimulated vomiting causing strangulation on the victim's vomitus, and another died when an adult gave the child a disassembled pacifier which lodged in his throat causing suffocation. In addition six victims died when they were strangled by the ribbon or string used to secure the pacifiers around their necks. Other NEISS in-depth investigations revealed that one victim suffered lacerations of the mouth from a pacifier, and two others choked on pacifiers which came apart. Another victim swallowed a pacifier but was saved when pounding on her back dislodged it, and she swallowed it and later passed it.

In February 1976, a five month old boy died when a flexible pacifier shield was lodged in his throat and could not be removed prior to his being asphyxiated. The Commission staff has also investigated this incident.

After consideration of the injury data and death reports, the Commission preliminarily finds that pacifiers and their components present an unreasonable risk of personal injury or illness to children from aspiration, ingestion and strangulation because of their design and manufacture and therefore present a mechanical hazard.

PROPOSAL

The original proposal would have required, in general terms, that all pacifiers and similar articles:

(1) have a flexible guard (or shield) at least 43 mm in diameter or an inflexible guard (or shield) at least 38 mm in diameter;

(2) have a hinged or collapsible handle or ring;

(3) contain no object or substance that is non-sterile or could be aspirated or ingested during normal use or when subjected to reasonably foreseeable damage or abuse;

(4) do not break into pieces smaller than the dimensions in (1), above, when tested according to specified methods for determining durability [these test methods involve pulling on the handle and nipple with a force of 10 pounds applied in various directions (load tests) and boiling the pacifiers for 10 cycles];

(5) do not consist in whole or in part of any food; and

(6) be otherwise designed and constructed to prevent the possibility of injury or illness by ingestion, aspiration, or laceration.

RESPONSE TO PROPOSAL

Comments were received from industry and consumers in response to the original FDA proposal of October 18, 1972. A total of eleven comments were received: six from manufacturers, one from a trade association, three from consumers, and one from a consumer association. The significant issues raised by the comments and the Commission's conclusions thereon are as follows:

1. The definition of "pacifier or other similar article" is vague and unclear, and should be limited to items with a nipple, shield and handle. The definitions of "flexible" and "inflexible" are also vague and unclear. The Commission has modified the definition of pacifier and the terms "flexible" and "inflexible" are no longer used in the regulation.

2. Other commenters urged that the boiling test criteria be reduced to allow pacifiers to cool to room temperature instead of 100° F and that the boiling time be reduced from 10 minutes to three minutes because three minutes is the usual time used by a consumer to sterilize a pacifier. The Commission has modified the regulation so that the pacifiers are cooled in room temperature and the boiling time is 5 minutes for each cycle.

3. Other comments suggested a possible exemption for certain "food-filled" pacifiers, alternative sterilizing methods to boiling, and a "lead time" of at least 180 days that would allow for production changes.

The regulation no longer contains a prohibition on "food-filled" pacifiers because there is insufficient data to show that such pacifiers present an unreasonable risk of injury. Sterilization of pacifiers by boiling them in water is not only the most common method of sterilization used by parents but is also considered the most medically acceptable method of sterilization and therefore no additional methods have been included. The comments concerning "lead time" were considered and a period of 180 days is now being proposed for additional comment.

4. One commenter urged that a standard minimum pull of at least 6 pounds but no more than 10 pounds be used to test durability and structural integrity. The Commission considered this comment and decided that the 10 pound requirement is justified and necessary. As discussed below under "Revised Proposal", this requirement is consistent with the Use and Abuse Testing Procedures.

REVISED PROPOSAL

Having considered the injury and death reports, the original FDA proposal and comments thereon, a report compiled for the Commission by the National Bureau of Standards, and engineering information from the Bureau of Engineering Sciences, the Commission concludes that the original proposal should be withdrawn and that a revised proposal with changes should be withdrawn and that a revised proposal with changes should be published as set forth below.

When defining the scope of this regulation the staff looked at teething rings and found that available hazard information did not show them to present an unreasonable risk of injury. Since they do not have nipples, they are excluded from this regulation by definition.

The staff also considered orthodontic pacifiers and found that they should be covered by the regulation because they potentially present the same risk of injury as regular pacifiers. Orthodontic pacifiers do fall within the regulation's definition of pacifier.

The original proposal used a dimensional design requirement to address the hazard of a pacifier entering a child's mouth and causing death by asphyxiation. "Inflexible" pacifier guards were required to be no smaller than a specified dimension and "flexible" pacifier guards could be no smaller than a slightly larger dimension (to account for possible bending at the edges which would make entry into a child's mouth easier). The intent of the dimensional requirements was that a pacifier with a large enough guard would not enter a baby's mouth.

The reproposed guard or shield requirements (1511.3(a)) address the same hazard of asphyxiation by using a performance approach. A circular opening in a test fixture simulates a baby's mouth. If a pacifier, regardless of whether it is "flexible," or "inflexible", can be drawn through the fixture, it fails the test because of the hazard that it could asphyxiate a baby by entering its mouth.

The size of the opening is based on sample measurements of children's mouths taken by the Maryland State Department of Health and Mental Hygiene. The test force for pulling the pacifier against the test fixture was determined by measurements in the Commission's Bureau of Engineering Sciences Laboratory. It is the force required to extract a pacifier from ten subjects who were sucking on pacifiers (because adult subjects were used, a margin of safety is incorporated into the force requirement obtained).

A ventilation requirement (1511.3(b)) has been added to the guard or shield requirements in the reproposed regulation. It requires the pacifier shield or guard to have at least two holes. These holes are intended to provide an emergency oxygen supply and to provide a rapid means of removing the pacifier from the child's throat.

The protrusion limitation requirement (1511.4(a)), not included in the original proposal, is designed to address the hazard pattern of a child falling forward or rolling over in a crib. In this situation a long protrusion on a pacifier, most commonly a handle, could drive the pacifier against the child's mouth and force it inside. This presents the same asphyxiation hazard that was discussed above.

Because a pacifier protrusion will sink into a crib mattress, protrusions that are sufficiently short will not present this hazard. In addition, other pacifiers may not present this hazard because their protrusions will bend rather than remain rigid when a force is exerted against them.

The protrusion test (1511.4(b)) involves the measurement of a protrusion while 2 pounds of force are applied to it. In selecting this force, the Commission staff has taken into account the weight of a child's head and the distribution of that weight over different parts of the child's face. The 0.63-inch limitation on the length of a protrusion (when measured according to this test) takes into account the distance that the protrusion will sink into a crib mattress.

The reproposed regulation includes structural integrity requirements (1511.5) in which tests are performed on pacifiers in whole or on various components to determine whether a pacifier can maintain its structural integrity when subject to mechanical and thermal forces and possible degradations which a pacifier is subject to in normal use. The force levels are selected from the Use and Abuse Testing Procedures for tension which are applicable to articles intended for use by children 18 months of age or less (16 CFR 1500.51(f)(3)). The heat cycle deterioration test, modified from those originally proposed, are representative of the common sterilizing techniques used by mothers and institutions.

Should any pacifier release components or fragments when subjected to the structural integrity tests, such components or fragments shall be subject to the small parts test which will determine whether they could be lodged in a child's throat and cause suffocation. The dimensions involved in the small parts test are based on present medical advice obtained by the Commission's Office of the Medical Director. These dimensions were used in the designing of the truncated cylinder (Fig. 2) which is incorporated into the test.

Two new sections have been added to address the strangulation hazard that results from tying a pacifier around a child's neck with ribbons or strings. A required warning label (1511.7) would alert to this hazard parents and others who take care of children. A prohibition against selling pacifiers with ribbons, cords, strings, etc. (1511.6) would also address this strangulation hazard.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)

(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304–05, 83 Stat. 187–89; 15 U.S.C. 1261, 1262) and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a); 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission proposes to amend Title 16, Chapter II, Subchapter C, by adding a new § 1500.18(a)(8) and a new Part 1511 as follows:

§ 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:

* * * * *

(8) Any pacifier that does not meet the requirements of 16 CFR Part 1511 and that is introduced into interstate commerce after 180 days following the date of publication in the FEDERAL REGISTER of the final form of this regulation.

* * * * *

PART 1511—REQUIREMENTS FOR PACIFIERS

Sec.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304–05, 83 Stat. 187–89; 15 U.S.C. 1261, 1262.

§ 1511.1 Scope of Part 1511.

This Part 1511 sets forth the requirements whereby pacifiers (as defined in § 1511.2(a)) are not banned articles under § 1500.18(a)(8) of this chapter.

§ 1511.2 Definitions.

(a) A "pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, and usually includes a guard or shield and a handle or ring.

(b) "Guard or shield" means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth.

(c) "Handle or ring" means the structure usually located adjacent to the guard or shield used for holding or grasping the pacifier. A hinged handle or ring is one that is free to pivot about an axis parallel to the plane of the shield or guard.

§ 1511.3 Guard or shield performance requirements.

(a) Place the pacifier in the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier protrudes through the back of the fixture as shown in Figure 1(b). Apply a tensile force of 2.0 pounds (8.9 newtons) to the end of the pacifier nipple in the direction shown. The force shall be gradually applied within a period of 5 seconds and maintained for an additional 10 seconds. The placement of the pacifier in the fixture shall be in the most adverse orientation, i.e., that which will result in the lowest force to cause the pacifier to be drawn through the aperture in the fixture. Any pacifier which can be completely drawn through the fixture by such a force shall fail the test in this section.

(b) *Ventilation holes.* The pacifier shield or guard shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier shield or guard.

§ 1511.4 Protrusions.

(a) *Protrusion limitation.* No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16 millimeters) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) *Protrusion test.* Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be gradually applied to any protrusion from the guard shield with a force of 2 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Measure the greatest distance from the plane surface to the guard or shield.

§ 1511.5 Structural integrity tests.

(a) *Nipple.* Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force of 10 pounds (44.5 newtons) to the nipple in any possible direction within a period of five seconds and maintain this load for an additional ten seconds.

(b) *Handle or ring.* Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force applied shall be gradually increased to 10 pounds (44.5 newtons) within five seconds and maintained for ten seconds.

(c) *Heat cycle deterioration.* All pacifiers shall be subject to the following tests: Submerge the pacifier in boiling water for five minutes and then remove the pacifier and allow it to cool for five minutes in room temperature air, 68° to 78°F (20° to 25° C). After the cooling period, resubmerge the pacifier in the boiling water for five minutes. The process shall be repeated for a total of six boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and § 1511.3.

(d) *Small parts.* Any components or fragments which are released as a result of the tests specified in paragraphs (a), (b) and (c) shall be placed in the truncated cylinder as shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

§ 1511.6 Ribbons, strings, cords, etc.

A pacifier shall not be sold or distributed with any ribbon, string, cord or other means of attachment which could fit around a child's neck.

§ 1511.7 Labeling.

(a) As required by paragraphs (b) and (c) below, pacifiers shall be labeled with the statement: "WARNING: STRANGULATION DANGER—DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH RIBBON OR STRING."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

Interested persons are invited to submit, on or before November 19, 1976, written comments regarding this proposal. Comments and any accompanying data or material should be submitted, preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the Office of the Secretary, Washington, D.C., during working hours Monday through Friday.

Dated: October 14, 1976.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

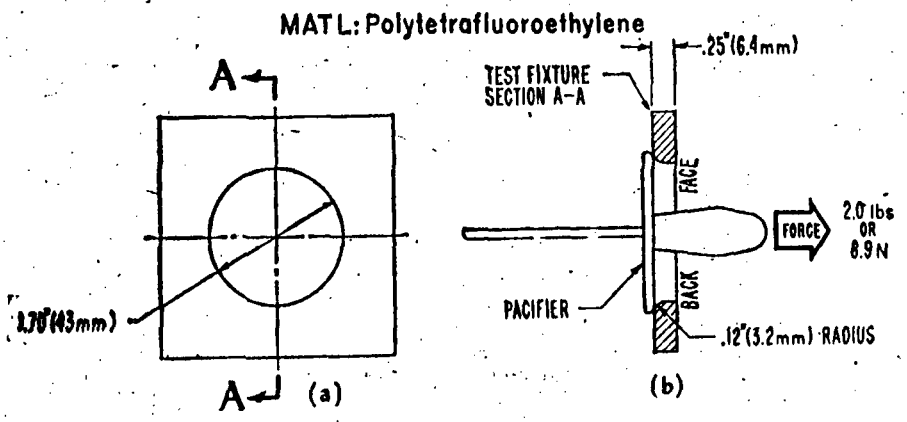
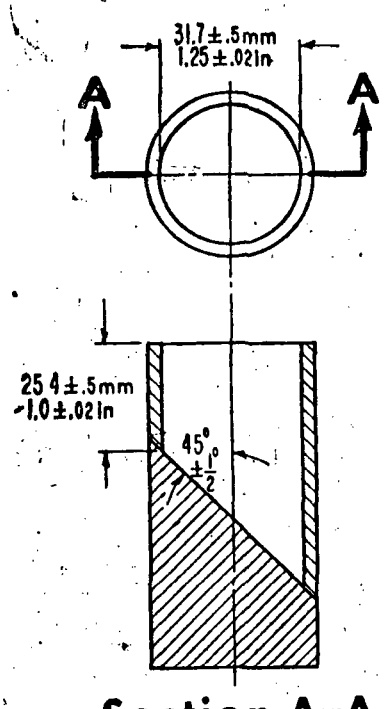


FIG 1-PACIFIER TEST FIXTURE



Section A-A

FIG 2-SMALL PARTS GAGE

[FR Doc.76-30838 Filed 10-19-76;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 73]

[Docket No. 20954; RM-2684]

TABLE OF ASSIGNMENTS, FM BROADCAST STATIONS; CROZET, VIRGINIA

Notice of Proposed Rule Making

Adopted: October 5, 1976.

Released: October 19, 1976.

1. *Petitioner, proposal and comments.* (a) The Commission has under consideration both a petition filed on January 23, 1976, and an amendment[1] to the petition filed on April 29, 1976, by Lee Garlock. The petition seeks to amend the FM Table of Assignments by the assignment of Class B Channel 259 to Crozet, Virginia, as its first FM assignment.

(b) This channel may be assigned without affecting any existing FM assignments.

(c) An Opposition to the proposal was timely filed on June 14, 1976, by Clay Realty Company, licensee of Stations WCHV(AM) and WCCV-FM, Charlottes, Virginia. Subsequently, a Reply was timely submitted on June 28, 1976, by the petitioner. These documents will be considered below.

2. *Demographic Data.*

(a) *Location:* Crozet is located approximately 177 kilometers (110 miles) southwest of Washington, D.C., and 16 kilometers (10 miles) west of Charlottesville, Virginia.

(b) *Population:* (1970 U.S. Census)—Crozet, 1,433; Albermarle County, 37,800.

(c) *Local aural services:* Crozet's local aural service consists solely of daytime-only AM Station WPED (Class II-D).

(d) *Economic Conditions:* Crozet is an unincorporated area having several large industrial plants which employ in excess of 2,000 persons. Petitioner alleges that Crozet is both a growing community and the business center for the western portion of Albermarle County. Petitioner points out that, according to the Albermarle County Planning Commission, the county had an annual growth rate in population of 5% from 1960 to 1970, compared to a 1.3% growth rate for the United States and a 1.8% growth rate for the Commonwealth of Virginia. Petitioner states that Crozet is the site for a new high school which will serve western Albermarle County and will be the second major high school for Albermarle County. Petitioner also states that the recent grant of funds for the construction of a sewer intercepter line to Crozet from Charlottesville will result in new development and construction in Crozet.

3. *Preclusion Considerations:* If Class B Channel 259 is assigned to Crozet small areas of preclusion would occur on Channels 257A and 259, including the following five communities in Virginia having populations greater than 1,000 persons which would be precluded from the use of Channel 259; Charlottesville (pop. 38,800), Staunton (pop. 24,504), Waynesboro (pop. 16,707), Bridgewater (pop. 2,828), and Grottoes (pop. 1,166). Nevertheless, all of these communities have at least two Class A channels available for assignment. In addition, Staunton and Bridgewater have a Class B channel available for assignment. It should also be noted that three of these communities have local radio service. Charlottesville is served locally by three fulltime AM stations, one commercial Class A FM station, and one commercial Class B FM station. Recently, the Commission assigned Channel 224A to Charlottesville as its third FM assignment. Staunton has one fulltime AM station, one daytime-only AM station and one Class A FM station. Waynesboro is served locally by two fulltime AM stations but does not have an FM assignment.

4. *Radio Quiet Zone:* Crozet is located within a "radio quiet zone" in which harmful interference is minimized so that the study of radio astronomy can be pursued by the National Radio Astronomy Observatory at Green Bank, West Virginia, and by the Naval Radio Research Observatory at Sugar Grove, West Virginia. Section 73.215(a) of the Commission's Rules. However, since both the National Radio Astronomy Observatory and the Naval Radio Research Observatory have not objected to the assignment of Channel 259 to Crozet, we are proposing this assignment herein. It should be noted that our Rules afford these two observatories a period of twenty days in which to raise any objections to our grant of a construction permit to a station within the radio quiet zone. See Section 73.215(a) of the Commission's Rules.

5. *Comments.*

(a) *Crozet's Need for a Class B Channel:* In its Opposition, Clay argues that Crozet neither needs nor deserves the requested assignment of Class B Channel 259. Clay points out that under our policy, Class B service is designed for large cities and metropolitan areas, not for relatively small communities like Crozet. Moreover, Clay contends that Crozet does not fit into the Commission's exception allowing a Class B or C assignment at a small community which is both the commercial center of a large rural area and which is far removed from large centers of population. *Memphis, Texas*, 3 F.C.C. 2d 671, 675 (1966); *Oberlin, Kansas*, 42 F.C.C. 2d 442, 443 (1973). In this regard, Clay indicates that Crozet *is located only 16 kilometers (10 miles)* from the large urban area of Charlotte

[1] The petitioner filed the amendment to its petition in response to a letter of March 30, 1976, from the Broadcast Bureau, requesting the petitioner to submit a *Roanoke-Rapids* study and evidence of consent by the National Radio Astronomy Observatory and the Naval Radio Research Observatory to the proposed assignment due to the fact that Crozet is located in a "radio quiet zone." *Public Notice* of the filing of the petition and the amendment was subsequently issued on May 14, 1976 (Report No. 981), Mimeo No. 64895).

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menza, SCAT
Through: Joann Langston, AED, HIA, EX;
Dr. Robert Verhalen, Director, BEPH

DATE: February 9, 1977

FROM : George Rutherford, BEPH

SUBJECT: Response to Comments on Proposed Pacifier Regulation

Several commentors raised questions about the documentation of injury data to support provisions addressing choking in the proposed standard. In order to clarify confusion, the Bureau of Epidemiology has compiled the list of incidents below.

Deaths

2-10-76 New York 760212 BEP7003	Victim sucked in pacifier and choked on it. Mother was unable to remove the pacifier. Victim died of anoxia.	5 mo.	M
9/1/74 Death Certificate	Asphyxiation by choking on rubber nipple of pacifier. Dead.	5 mo.	M
1971 Maryland Medical Examiner	Victim was found dead with pacifier wedged in his mouth. Pacifier had rigid plastic guard. Diameter 31 mm. Rigid handle may have driven pacifier deeper.	2 mo.	M
11/25/66 Miami, Florida Medical Examiner	Impaction of pacifier in oropharynx and hypopharynx. Solid shield asphyxiation.	3 mo.	M

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

Choking incidents not resulting in death. Incidents which may have resulted in death if an adult had not been present.

Injury Surveillance Desk 4/22/75	Baby swallowed nipple portion of pacifier. Mother found that pacifier had broken and nipple lodged in trachea. Mother, a registered nurse, tried 2 methods to dislodge nipple, finally reached down throat and grasped it and removed it.	8 mo.	F
Injury Surveillance Desk 12/19/74	Pacifier came apart. Baby choked on it.	6 mo.	M
10/27/70 A27382	Handle broke off pacifier, victim swallowed nipple. Had to be removed at hospital. Shield was not in place and handle was easily removable. Nipple was 1-1/4" by 1/2."	10 mo.	F
FDA	Sucked in nipple portion of 3-part pacifier. Mother dislodged nipple by pounding on back. Victim was able to swallow it.	7 mo.	F
Injury Surveillance Desk	Babysitter noticed baby began to gasp. Upon removing pacifier from baby's mouth, babysitter noticed nipple lodged in throat, pulled it out by putting finger down baby's throat.	6 mo.	F
Injury Surveillance Desk	Pacifier came apart while victim chewed on it. Rubber part caught in throat. Victim's mother was able to get it out.		M
Injury Surveillance	Pacifier came apart and baby started to choke. Pacifier removed.		

Ingestion of Pacifier or Part of Pacifier

7/11/75 756028 OPD7153	Baby swallowed nipple and passed it 3 days later.	13 mo.	M
Injury Surveillance Desk	Baby removed nipple and swallowed it. Passed 3 days later.	11 mo.	M

Altogether, these incidents total 4 deaths; 7 incidents which did not result in deaths because an adult removed the pacifier, and 2 incidents of ingested nipple.

As can be seen from these data, which include 2 choking deaths not previously identified, which occurred in 1966 and 1971, death data presented by CPSC cannot be assumed to be comprehensive. It is merely indicative that a probability exists for a type of accident.

Unless pacifier deaths were in fact epidemic, existing data sources would not demonstrate large numbers of deaths. What must be remembered is that these are not injuries, they are deaths resulting from a condition with a sudden onset and rapidly fatal consequences. Since pacifiers are frequently used to quiet a baby while an adult is out of the room, the sudden and potentially fatal features of choking incidents can occur before a parent can take action.

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, OSCA/TAD
THRU: James I. Price, Director, BESB

DATE: DEC 23 1976

FROM : A. Pong, BESB

SUBJECT: BESB Interim Review of Comments to the Proposed Pacifier Regulations

The following is a interim review of the comments to the proposed pacifier regulation published in the October 20, 1976 Federal Register. A more complete report will be submitted to OSCA/TAD after BESL has tested pacifiers according to the proposed test procedures and to amended procedures. BESB will amend test procedures as per recommendation of CPSC staff and in light of data obtained from foreign documents pertaining to pacifiers and from other sources. BESB will be able to consider and incorporate suggestions from CPSC staff on test procedures if received before tests are carried out by BESL about the middle of January.

BESB Interim Position on Comments to Pacifier Proposed:

In reviewing the comments to the reproposed pacifier regulations, the comments were summarized according to sections, which were based on the prevention of deaths due to:

1) asphyxiation on an intact pacifier ingested or accidentally impacted into the pharynx
2) asphyxiation on a disassembled pacifier
3) strangulation on a string or ribbon attached to the pacifier.

Section 1511.2 Definitions:

One commentor (Questor) suggests a change which will exclude from regulations some items (i.e., hybrid teether/pacifiers, etc.) which the Commission considers as pacifiers, but are sold under other names. BESB recommends

U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

no change or an explicit inclusion of hybrid pacifier/ teethers and other devices intended to be placed in a child's mouth.

Section 1511.3 Guard or Shield

Sections 1511.3, Guard or Shield Requirements, and 1511.4 Protrusions, were developed to prevent the pacifier from being either ingested or impacted into a child's pharynx. The comments were largely 1) that the template hole diameter was excessively large; 2) the most adverse orientation requirement is excessively rigorous and that 3) vent holes aren't necessary or desirable.

Section 1511.3(a) Guard or Shield Dimensional Requirements

A final BESB position on the efficacy of the size requirement will not be made until after the BESL tests are performed. The majority of commentors believe the proposed template hole diameter (figure 1) of 1.70 inches (43mm) is excessive. They cite other regulations, Sweden and Denmark at 40mm and the U.K. at 38mm as being more reasonable. A pacifier regulation in effect in Canada, however, requires the guard or shield to resist passage through a hole in a template which is basically 43mm in diameter, but has "bow-tie" shaped extensions (see attached figure). A major difference between this Canadian regulation and the CPSC proposal is in the orientation of the pacifier during this test. The proposal requires that the pacifier resist passage through the template when "in the most adverse orientation". The Canadian regulation requires the pacifier be centered over the hole in the template before applying a similar force.

It is the opinion of BESB that the proposal may have an unnecessary safety factor if the pacifiers must resist passage through a hole 1.70 inches in diameter when in the most adverse orientation. It appears that the majority of pacifiers on the market would fail the test as proposed. Subjective opinion and lack of injury data on these pacifiers indicates that they do not present unreasonable risk of injury by asphyxiation due to having too small a guard or shield. On the other hand, we know of one reported incident, resulting in no injury, in which a child ingested an orthodontic pacifier by placing it sideways into its mouth. We also know of a physician who observed a 4 month old child completely engulfing in its mouth a disc 50mm diameter and 2mm thick.

Since the guard/shield diameter requirement appears to be of major economic concern to manufacturers, we would like to have the opinions of other bureaus and offices, in particular OMD, prior to conducting the BESL tests.

Following receipt of documents, comments, and staff recommendations relating to the size of objects which have become lodged in the throats of infants and children, BESB is considering testing various templates and comparing the results with professional opinions on what is a safe pacifier. Elimination of the most adverse orientation requirements and substituting a template much like the Canadian Pacifier test or the Canadian rattle test template is being considered.

A final position on the size and shape of the template hole and test procedures will be taken after BESL tests have been completed.

Section 1511.3(b) Ventilation Holes

BESB prefers performance requirements rather than design requirements which tend to be overly restrictive. A performance test for vent holes may be difficult to devise if it is to be realistic in testing their effectiveness. However, BESB defers to OMD and is prepared to comment on any tests which OMD may develop.

Section 1511.4 Protrusions

The limitation on protrusions is designed to prevent the impaction of a pacifier into a child's pharynx. This test does allow for the deflection of a handle at the hinge. BESB recommends changing the last sentence of 1511.4 from "Measure the greatest distance from the plane surface to the guard or shield" to "Measure the distance from the plane surface to the guard or shield at the base of the nipple".

Section 1511.7 Structural Tests

No changes recommended. The commentors are largely in agreement with CPSC on the need for and on the test procedures.

Section 1511.7 Labeling

Several of the commentors recommended that statements

be either voluntary or be changed. BESB suggests that the warning statement be changed to "CAUTION: TYING PACIFIERS TO THE CHILD OR TO THE CRIB HAVE RESULTED IN STRANGULATIONS. PACIFIERS SHOULD BE HANDHELD BY YOUR INFANT WHEN IN USE". This would provide three needed elements in a cautionary label, the warning, description of the specific danger and the recommended safe usage.

Attached for your use is a summary of the comments by sections.

Attachment

DRAFT

SUMMARY OF COMMENTS

§1511.2 Definition:

Questor:

- Change to: "A pacifier is an article intended for a young child to suck upon, consisting of a nipple, guard or shield, and usually a handle or ring."

- From: "A Pacifier is an article consisting of a nipple that is intended for a young child to suck upon, and usually includes a guard or shield and a handle or ring.

The Questor change would exclude from regulations teething rings with a nipple, but no guard or shield.

§1511.3 Guard or Shield Performance Requirements

§1511.3(a) Dimensional Requirements

Lewis Woolf Griptight (Binky):

- Sweden and Denmark have 40mm shield requirements
- United Kingdom has 38mm shield requirements
- Pacifiers with 35mm shield are safe if there is no protrusion greater than 20mm and the nipple is less than 35mm in length
- 43mm excessive, uncomfortable and potentially dangerous

Baby World:

- 1.70 inches diameter template should be reduced to 1.25 inches
- 2 lbf. test requirement should be reduced to 1 lbf.
- Children are not as strong as adults, cannot develop suction which adult lab workers attained

Questor:

- 43mm diameter requirement should be reduced to 32mm (1.25 in.)
- Adverse orientation should be dropped

Reliance:

- 43mm requirement would block breathing

- Dimensions should be 1.4375 for flexible shields and 1.25 inches for inflexible shields

Binky:

- 1.70 requirement would result in uncomfortable pacifiers
- Regulations should be changed to dimensional requirement for shields of 1.5 inches for inflexible shields and 1.75 inches for flexible shields with a 1-7/16 test fixture

Insitut Fur Industrial Design (Roehrig & Co):

- Test fixture should have a 40mm diameter which coincides with Scandinavian safety regulations.
- Regulations should define area measurements. Oval or elliptical shields providing the same safety as a circular shield of the same size could fail

TMA:

- Shields large enough to pass test would interfere with breathing. "Suffocation could occur..."

§1511.3(b) Vent Holes

Lewis Woolf: Not needed, hygienic risks

Baby World: No merit, hygiene hazard

Crib-Mates: .020 inch diameter not effective (requirement is for .20 holes)

Questor: Eliminate requirement, prevents sucking

Reddy: Not necessary

Reliance:

- Would weaken shield
- Increase chance of ingestion
- Not effective in providing breathing holes
- Not hygienic
- Provide location for tying strings to fasten around child's neck

Binky:

- o Requirement should be dropped
- o Unhygienic
- o Weakens shield

Institut Fur Industrial Design (Roehrig & Co):

- o Recommend specification of minimum area to provide sufficient air flow--allow use of holes, V or U notches.

Giant:

- o What is the rationale?
- o If there is a need for vent holes, 4 holes would assure alignment with breathing passage

TMA:

- o Vent holes would not be effective in providing ventilation
- o Would increase chances of ingestion
- o Make cleaning difficult

§1511.4 Protrusions:

Lewis Woolf: Change to 18mm
Questor: Eliminate requirement
Reddy: Clarify tests
Binky: Is a necessary requirement

§1511.5 Structural Integrity Tests:

Lewis Woolf: Nipple should not be longer than 30mm--Boiling time should not be less than 5 minutes.

Questor: In agreement

Reliance: Necessary except that boiling time should be reduced to 3 minutes.

§1511.7 Labeling:

Baby World: Labels should be placed on ribbons and strings

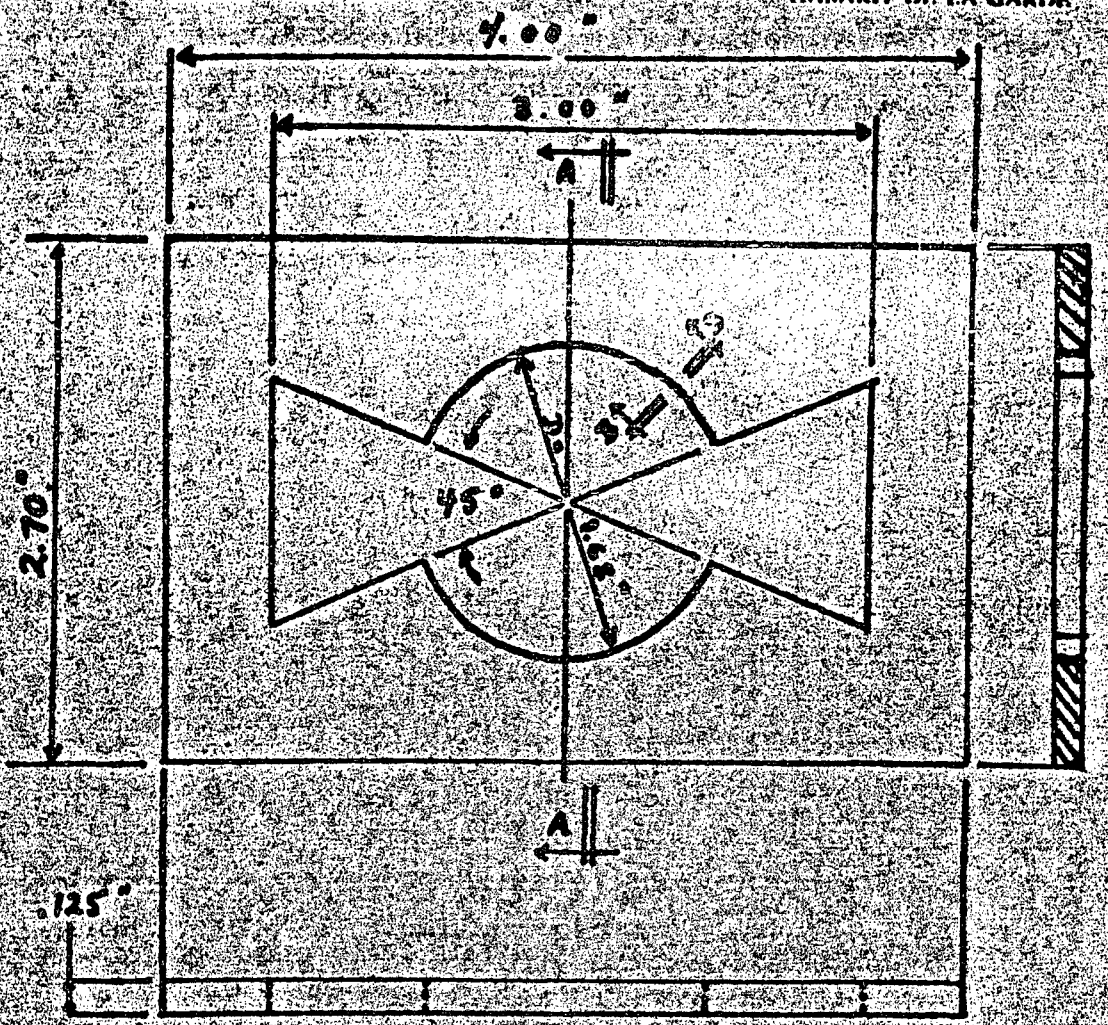
Crib-Mates:	If needed, change to: "CAUTION - PACIFIERS SHOULD BE HANDHELD BY YOUR INFANT WHEN IN USE. NEVER TIE TO THE CRIB OR CHILD".
Questor:	Label should read: "WARNING: DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING. IT MAY PRESENT A STRANGULATION DANGER".
Reliance:	Label not necessary, use voluntary labeling such as: "CAUTION: DO NOT TIE PACIFIER AROUND CHILD'S NECK".
TMA:	Same as Reliance.

SCHEDULE I

GUARD TEMPLATE

ANNEXE I

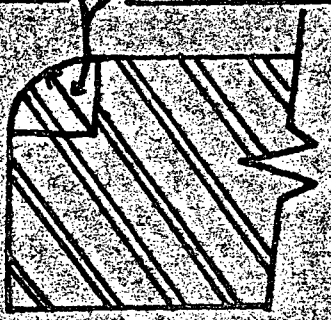
GABARIT DE LA GARDE



SECTION AA

RADIUS - 0.030"

RAYON: 0.030"



ENLARGED SECTION BB

REMARQUES

1. Le rayon de tous les bords de l'ouverture doit être de 0.030".
2. Le matériau doit être une plaque d'aluminium.
3. Tolérance de dimension ± 0.005"

SECTION BB AGRANDIE

Notes

1. Radius of all edges of opening to be 0.030"
2. Material to be Aluminium Plate
3. Dimensional Tolerance ± 0.005"

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, SCAD

DATE: MAR 3 1977

THROUGH: James I. Price, Director, BESB

FROM : Alvin Pong, BESB

SUBJECT: Review of Comments to the Proposed Pacifier Regulation

REF : "BESB Interim Review of Comments to the Proposed Pacifier Regulations" memo to W. Menza from A. Pong dated Dec 23, 1976

The following recommendations for amendments to the proposal for a pacifier regulation are in addition to our previous opinions forwarded in a memo on December 23, 1976. Our recommendations are based in part on the BESL report on the proposed pacifier regulation dated February 10, 1977, (attached) and in part on further discussion with staff and manufacturers.

Preample, Revised Proposal

The following sentence should be added to the paragraph on the size and force for the guard or shield test, sixth paragraph, second column: "This also approximates the force that will develop if a child should rest his face on a crib mattress with a pacifier in his mouth."

1511.2 Definitions

To clarify the exclusion of nipples intended for dispensing liquid from bottles, it is suggested that this paragraph be amended as follows: "A pacifier is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid and usually includes a guard or shield and a handle or ring."

1511.3(a) Guard or Shield Performance Requirements

To provide answers to the comments regarding guard or shield size, BESB requested that the Engineering Laboratory (BESL) conduct tests on a sample of currently available

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

pacifiers. These tests were conducted according to the procedure of the proposed regulation with an additional test for guard or shield size compliance to the regulation currently in effect in Canada (P.C. 1974-1102).

The requirements of the Canadian and proposed CPSC guard or shield size test differ mainly in orientation of the pacifier in the test template (Figure 1 of proposed regulation). Both regulations were developed to prohibit commerce of pacifiers with a simple bar at right angles to the nipple. Both Canadian and CPSC staffs felt that these shields are ineffective. The Canadian regulation requires that the pacifier be centered in the hole of the template with the "bow-tie" or wedge shape slots centered on the circle which would allow a simple bar pacifier to pass through the template. The CPSC proposal intended to fail these pacifiers by specifying "placement in the most adverse orientation." The CPSC proposal would ban orthondontic style pacifiers with large and effective shields. Such pacifiers with non-circular shields having an area greater than the hole in the template may fail the test if the minor dimension of the shield is only slightly less than the template hole diameter. BESB recommends that §1511.3 of the proposed regulation be amended to require that the pacifier be centered in the template hole before conducting the test. If this is adopted then to prevent a pacifier with a simple bar at right angles to the nipple axis from complying with the regulation, the "bow-tie" or similar shaped slots must be added to the template hole as in the Canadian regulation.

Since the diameters of the template holes in the Canadian and CPSC proposal are very similar (1.68 inch vs 1.70 inch) and since the CPSC proposal dimension was derived by rounding the fraction 1 11/16 inches (1.6875 inch), we further recommend adopting the entire Canadian template. The dimensions of this template are shown in Figure 2 of the attached BESL report.

Accordingly, we suggest that Figures 1(a) and 1(b) of the proposal be changed to depict the Canadian template, and §1511.3(a) should be changed as follows: Center the pacifier in the opening of the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier protrudes through the back of the fixture as shown in Figure 1(b). Apply a tensile force of 2.0 pounds (8.9 newtons) to the end of the pacifier nipple in the direction shown. The force shall be gradually applied within a period of 5 seconds and

maintained for an additional 10 seconds. Any pacifier which can be completely drawn through the fixture by such a force shall fail the test in this section.

1511.3(b) Ventilation Holes

To determine if ventilation holes would weaken the guard or shield, BESL punched or drilled holes through the shields of several pacifiers. Contrary to comments, the holes did not measurably weaken the shields. However in the opinion of BESB, the comments by Reliance, Giant, and TMA that this requirement may not provide an air passage has considerable merit. If a pacifier is in a child's mouth, the holes, located as they may be in accordance with this requirement, could be covered by the child's tongue or palate. If a design requirement is to be used, greater specification on the location of the holes and perhaps a greater number of holes (as per comment by Giant) may be required. BESB would prefer a performance requirement that would allow whatever notches or holes that would facilitate the performance which OMD feels is required for a safe pacifier.

1511.4(b) Protrusion Test

For clarity, BESB recommends deletion of the last sentence in this paragraph and addition of the following: "Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple."

1511.6 Ribbons, Strings, Cords, etc.

The BESL report draws attention to the ambiguity of this paragraph. As it is presently worded, it could be interpreted that a pacifier sold with a ribbon, string, or cord attached in the form of a loop small enough to prevent passage over the baby's head would comply with the regulation. The clause "any other means of attachment which could fit around a child's neck" was intended to prohibit other means of attachments. The clause tends to be interpreted as qualifying the length of ribbon, string, or cord prohibited. As pointed out in the BESL report, no test method or length limitations are provided. To avoid this ambiguity, this paragraph could simply list all possible ribbon, cord, chain, or ribbon-like attachments.

For reasons of clarity, BESB suggests that this paragraph be changed to the following: "A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, or ribbon-like attachments."

Compliance Strategy

The BESL report notes the absence from the regulation of any requirements for multiple testing of an individual pacifier prior to declaring an item a banned hazardous substance. BESB recommends that before issuing a final regulation, the size of a sample for compliance testing should be determined together with the number of pacifiers in that sample that would have to fail the test before a banning order would be issued. These requirements could be a part of the compliance strategy which must be included in the briefing package.

TECHNICAL REPORT

Evaluation of Proposed CPSC Hazardous Pacifiers Ban

Deborah Anne Kale
Bureau of Engineering Sciences Laboratory

10 Feb 1977

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

CONSUMER PRODUCT SAFETY COMMISSION

Bureau of Engineering Sciences Laboratory

PROPOSED HAZARDOUS PACIFIERS BAN

Compliance Testing Verification and Evaluation

February 10, 1977

SUMMARY

The Bureau of Engineering Sciences Laboratory was requested to assist the Bureau's Division of Product Standards in the technical assessment and evaluation of the Hazardous Pacifiers Ban. Testing and evaluation of the proposed Ban and specific sections of the Canadian Hazardous Products Act (CHPA) reflected the following:

- Twenty-six of the twenty-nine (90%) specimens tested failed the guard or shield performance requirements of the proposed Ban; nineteen of the twenty-nine (66%) specimens were found to be non-compliant with the guard performance requirements of the CHPA.
- The addition of ventilation holes educed no general trends in guard strength performance during tensile testing.
- Twenty of twenty-nine (69%) samples were found to be non-compliant with the specified protrusion limitation of 16 millimeters (0.63 inch).
- All twenty-nine nipples tested remained structurally intact during the requisite tensile loading conducted before heat cycling.
- One ring/handle of twenty-nine specimens (3%) separated from its parent guard during the specified tensile loading conducted prior to heat cycling.

- Subsequent to the six boiling/cooling cycles specified by the proposed Ban, the majority of samples remained structurally intact when resubjected to the load requirements of the Ban. Of the twenty-nine pacifiers tested, two nipples (7%) and three handles (10%) became detached from the body of their respective pacifiers. The two liquid-filled teethers were totally deformed after one boiling cycle.

- Of the seven samples tested to the small parts requirement of the proposed Ban, five (71%) failed the specification; this reflects a total population failure of 17%.

- None of the samples received was commercially distributed with ribbon, string, cord, or other means of attachment which could fit around a child's neck.

- None of the individually wrapped pacifiers was labeled with the required cautionary statement.

I. INTRODUCTION

Twenty-nine assorted pacifier models, representative of twelve commercial distributors, were received by the Bureau of Engineering Sciences Laboratory Division (BESL) for analysis and evaluation to the proposed Hazardous Pacifiers Ban. All samples conformed to the basic definitional construction requirements stipulated by the Ban for the nipple, guard or shield, and handle or ring. Two models were liquid-filled and designed to be used as gum soothers or teething rings.

Testing was conducted to provide BESL input concerning the technical feasibility and practicability of the test procedures from a compliance testing standpoint. All samples were subjected to the prescribed test methods defined in the proposed Ban; additionally, these samples or duplicate specimens were tested to the guard performance test of the Canadian Hazardous Products Act to provide a source of comparative data. Ventilation holes, as required by the proposed Ban, were bored in selected specimens, and these specimens reevaluated for subsequent possible weaknesses in guard or shield strength. Resultant data is tabulated in the appendix.

II. TEST EQUIPMENT AND FIXTURES

The following equipment and fixtures were used in the performance and evaluation of the test procedures:

Canadian Pacifier Template
Chatillon Force Gauge, Model DPP-5, 5 lbs Full Scale, with Gripping Device and Compression Plate Adapter
Chatillon Force Gauge, Model DPP-25, 25 lbs Full Scale, with Tensile Hook, Gripping Device, and Compression Plate Adapter
Erlenmeyer Flask, 250 ml, with Slit Gum Rubber Cap
Metric Scale
Nipple Test Fixture
Proposed Standard Pacifier Template
Small Parts Gauge

III. TESTING AND RESULTS OF THE PROPOSED BAN

1511.3 Guard or Shield Performance Requirements

(a) Performance Test

Testing was performed according to the guard or shield performance requirements of the proposed Hazardous Pacifiers Ban and the Canadian Hazardous Products Act (CHPA); for the purposes of this evaluation, however, the BESL was requested to provide recorded numerical data concerning the measurement of force required to induce failure in a specimen, rather than a Pass/Fail notation. Figures 1 and 2 present dimensioned plan and section views of the required test templates. The templates were clamped horizontally during testing and loading was manually applied vertically downward, as illustrated in Photo 1. The horizontal template placement permitted specimens of comparatively small diameter to pass through the template without load application; additionally, this procedure simplified centering of the pacifier guard over the template requisite for the CHPA. Tensile loads were applied with a five pound full-scale force gauge; the force required to pull the pacifiers through the template was recorded.

Twenty-six of the twenty-nine (90%) specimens tested failed the proposed Ban; nineteen of the twenty-nine (66%) specimens were found to be non-compliant with the CHPA.

(b) Ventilation Holes

Specimens duplicate to those which marginally passed the Canadian Standard were also tested to the Canadian guard performance requirements as in §1511.3 (a). Ventilation holes 5.5 millimeters (0.22 inch) in diameter were then bored through the guard/shield of these specimens, as depicted in Photo 2; the specimens were subsequently retested to the Canadian Standard before and after heat cycling. These replicate specimens, tested prior to heat cycling, reflected no general trend in guard strength performance after the addition of ventilation holes, as shown in Table 1.

1511.4 Protrusions

(a) Protrusion Limitation

(b) Protrusion Test

The nipple of each specimen was inserted into a slit incised through a rubber cap attached about the lip of a horizontally mounted Erlenmeyer flask, as shown in Photo 3. A two pound compression force was manually applied along the horizontal axis of the nipple, as illustrated in Figure 3, with a five pound full-scale force gauge. Measurement of greatest distance from the compression plane surface to the guard or shield was recorded.

Twenty of twenty-nine (69%) samples were found to be non-compliant with this requirement.

1511.5 Structural Integrity Test

(a) Nipple

The nipple of each pacifier tested was inserted through a 13 millimeter (0.51 inch) hole centrally bored through a right angle test fixture, as shown in Photo 4. A continuously adjustable gripping device was then placed about the nipple base and a ten pound tensile force manually applied along the horizontal axis of the nipple, as illustrated in Figure 3, with a twenty-five pound full-scale force gauge.

All twenty-nine nipples tested remained structurally intact during testing.

(b) Handle or Ring

The guard or shield of each specimen manufactured with a ring was captivated behind two wooden slats appropriately spaced to permit protrusion of the ring, as shown in Photo 5. A ten pound tensile force was manually applied along the vertical axis of the nipple, as illustrated in Figure 3, with a twenty-five pound full scale force gauge. Samples manufactured with a handle, rather than a ring, were placed atop the wooden slats with the nipple protruding downward, and a ten pound compression load was manually applied to the handle along the vertical axis of the nipple.

One ring of the twenty-nine specimens tested (3%) separated from its parent guard during loading.

(c) Heat Cycle Deterioration

All samples were subjected to six alternate boiling/cooling cycles as specified in the proposed Ban. Subsequent to this requirement, the specimens were retested to §1511.3 and §1511.5 (a) and (b).

There was a general loss in guard or shield strength for the majority of samples after heat cycling relative to the values obtained prior to the cycling. Percentage changes from original values are tabulated in Table 1. Per the Canadian test requirements, the strength losses do not differ significantly between unventilated and ventilated samples. Any strength increases noted may be attributed to any of three heat induced phenomena: plastic deformation, post-mold curing, or thermal setting of the plastic material.

The majority of samples remained structurally intact when subjected to the load requirements of the proposed Ban. Of the twenty-nine pacifiers tested, two nipples (7%) and three handles (10%) became detached from the body of their respective pacifiers. The two liquid-filled teethers were totally deformed after one boiling cycle

(d) Small Parts

The small parts test was applied to five of twenty-nine (17%) nipple or handle components that separated from their parent pacifiers. Additionally, the two teethers collapsed under heat cycling to an extent necessitating this requirement. Of these seven samples tested, five (71%) failed the specification; this reflects a total population failure of 17%. A plan and section view of the small parts gauge or cylinder in presented in Figure 4.

1511.6 Ribbons, Strings, Cords, etc.

None of the samples received was commercially distributed with ribbon, string, cord, or other means of attachment which could fit around a child's neck.

1511.7 Labeling

None of the individually wrapped pacifiers was labeled with the required cautionary statement.

IV. DISCUSSION AND EVALUATION

During the execution and evaluation of the proposed Hazardous Pacifiers Ban, a number of significant factors emerged. Of major importance is test reliability, or the extent to which a test yields the same results on repeated trials; this is obviously of particular importance in a "banning regulation." The proposed Ban does not stipulate or provide for the multiple testing on individual pacifiers, nor does it mention the testing of duplicate specimens within a single sample group. Substantial experimental error may arise from the failure of two or more identically treated units to yield identical results; additionally, significant experimental error could accrue from multiple measurements of the same unit. In either particular situation, this experimental error may reflect (1) errors of experimentation, (2) errors of observation, (3) errors of measurement, (4) variations of the materials under evaluation, or (5) the combined effects of all extraneous factors which could influence the parameters under study. In any experiment, true and complete independence of error can never be achieved; however, an increased number of replications or repetitions of each test helps to ensure that uncontrolled variables, such as experimental error or product variability, are minimized through randomization. It can then be assumed that these non-systematic errors will be randomly distributed or homogeneous; with increased sample size, the error variance will approach a mean of zero.

Force gauges were utilized for application of the requisite stress loading to the pacifier samples. These instruments, however, may provide a real source of possible experimental

error because of the difficulty in precisely maintaining the required load. A 0.1 lbf fluctuation in load application would result in a five percent error in a two lbf tensile or compression test. Five percent is substantially in excess of the accepted standard laboratory test error of 2-3%. For this reason, compliance testing to a finalized ban may require a procedure utilizing a constant load to minimize investigator error.

A comparison of non-ventilated pacifiers to ventilated pacifiers may not ve valid. No significant strength trends could be detected with the addition of ventilation holes; this may be due, however, to the limited number of specimens tested. Clearly, if it is desired to detect such a small difference between the two treatments, a large number of replications would be necessary.

The proposed Ban dictates that "pacifiers shall not be sold or distributed with any ribbon, string, cord, or other means of attachment which could fit around a child's neck." However, no test methods or pertinent anthropometric data are provided for evaluation of this requirement.

Deborah Kale

Deborah Kale, Analyst

A.B. Riley

A.B. Riley, Head, Mechanical Branch, BESL

TABLE 1

Percent Change in Guard Strength Subsequent to Heat Cycling and/or Addition of Ventilation Holes

Sample	After Addition of Holes (%)	After Heat Cycling Proposed (%)	After Heat Cycling Canadian w/o Holes (%)	After Heat Cycling Canadian w/ Holes (%)
1A	---	-100*	-23*	---
2A	---	+10	-91	---
B	+2	---	---	-53%
3A	---	-25	-33	---
4A	---	-44	-65	---
5A	---	+140	-40	---
6A	---	-31	-73	---
B	-17	---	---	-47
7A	---	-46	-36	---
B	+15	---	---	-35
8A	---	0	0	---
9A	---	0	-17	---
10A	---	0	-67	---
11A	---	0	0	---
B	0	---	---	0
12A	---	-31	-69	---
13A	---	0	-68	---
14A	---	-74	-13	---
15A	---	-100	-68	---
B	---	+2	+10	---
16A	---	0	-47	---
17A	---	0	0	---
B	0	---	---	0
18A	---	0	-32	---
B	0	---	---	-10
19A	---	-57	-60	---
B	-10	---	---	-17
20A	---	-35	-79	---
21A	---	-25	-44	---
22A	---	0	-38	---
23A	---	-25	-34	---
B	+4	---	---	-49
24A	---	0	0	---
B	0	---	---	0
25A	---	0	0	---
26A	---	0	-18	---
27A	---	-100	0	---
28A	---	-100	0	---
29A	---	-100	-100	---

* +/- indicate relative increases or decreases in tensile strength of guard

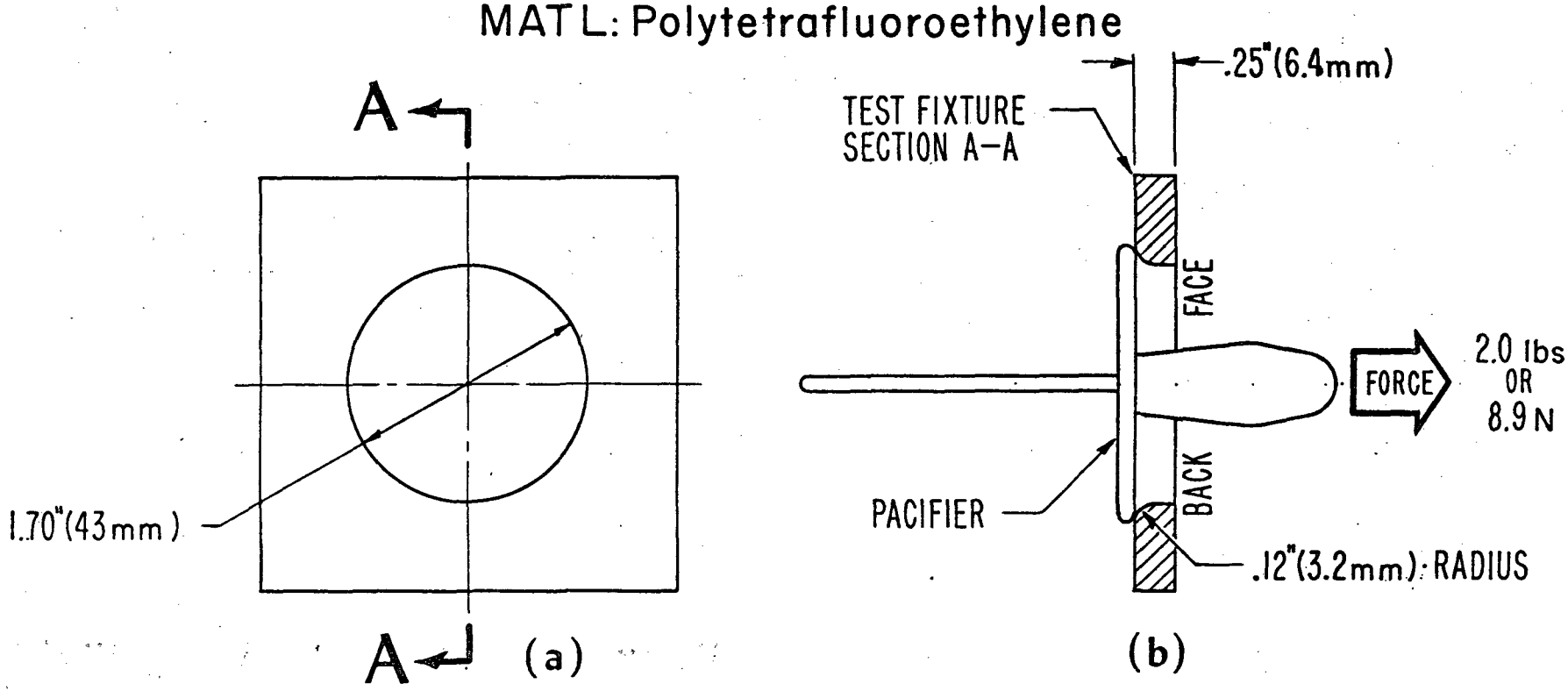
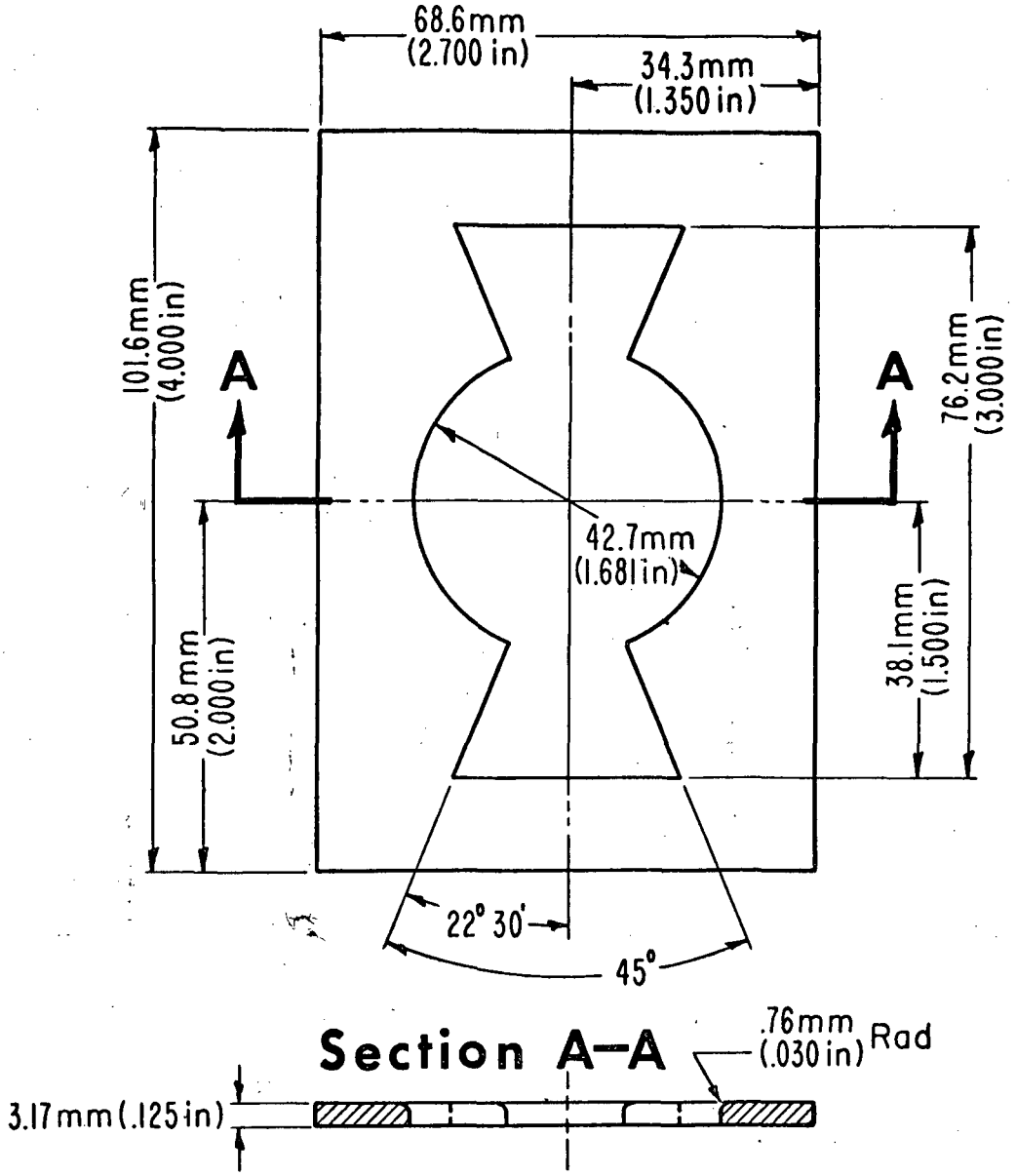


FIG 1-PACIFIER GUARD TEST TEMPLATE



MAT L: Polytetrafluroethylene

FIG 2–PACIFIER GUARD TEST TEMPLATE
(Canadian Design)

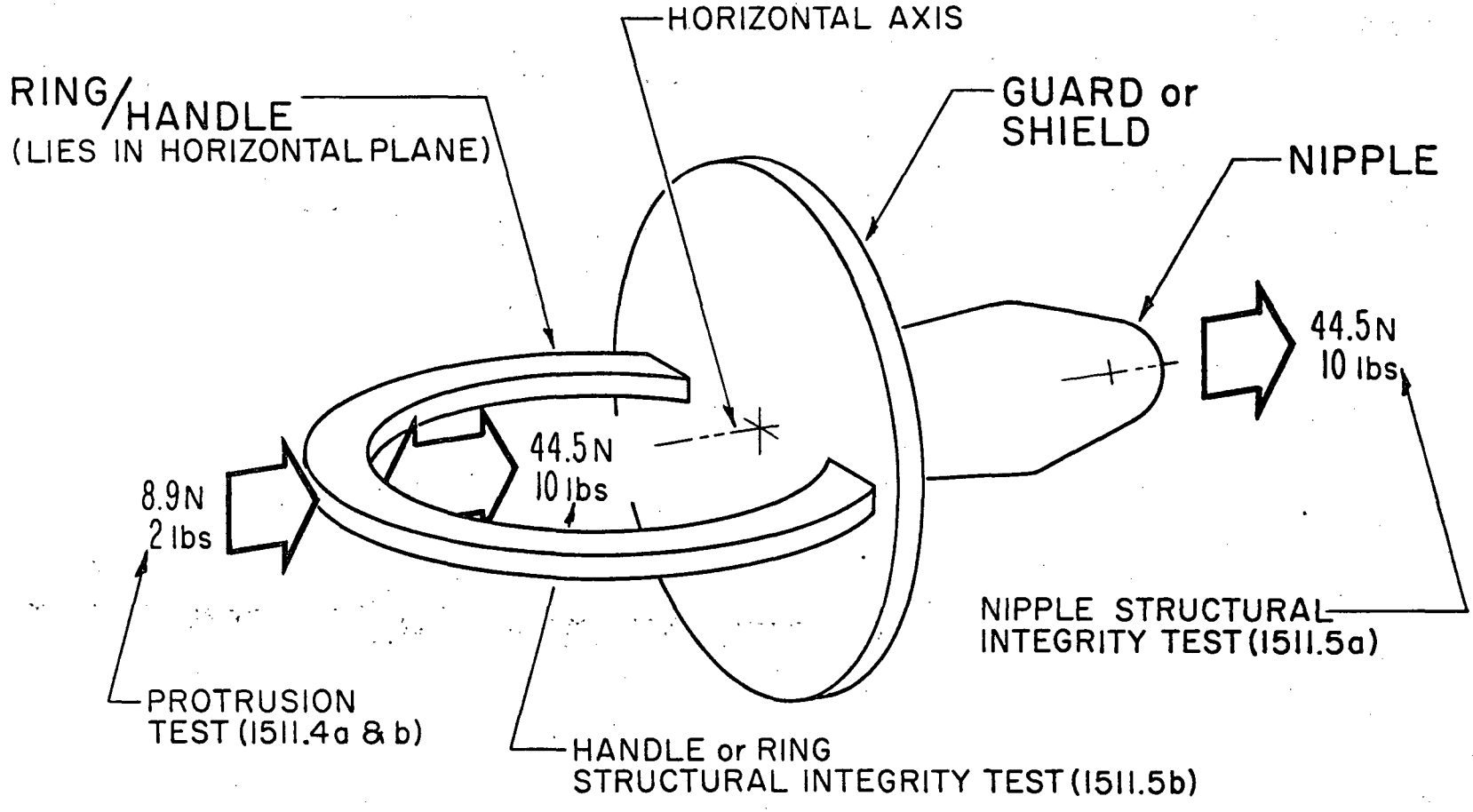
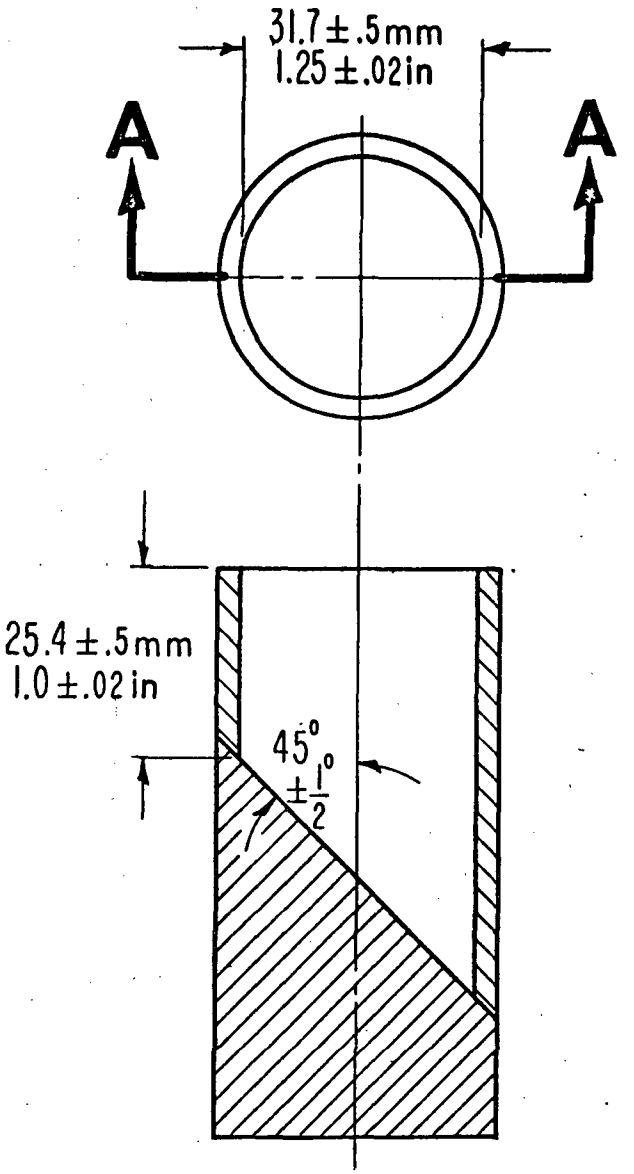


FIG 3-PACIFIER TEST REQUIREMENTS



Section A-A

FIG 4-SMALL PARTS GAGE

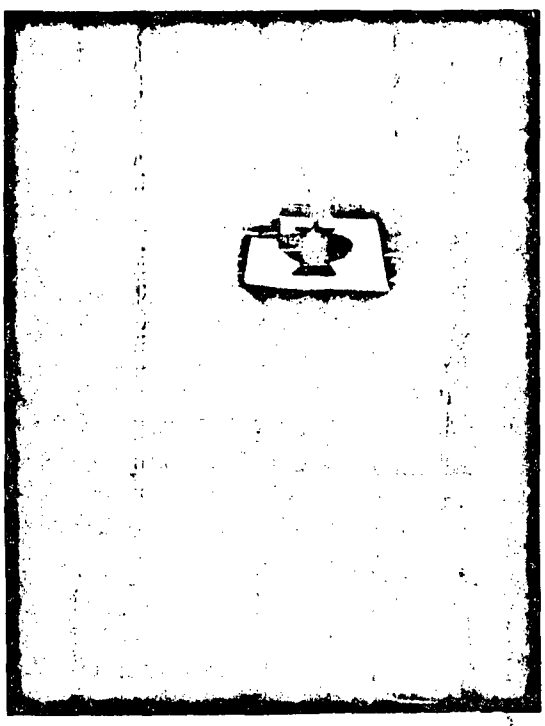


PHOTO 1. Guard Performance Testing
(Canadian Template)

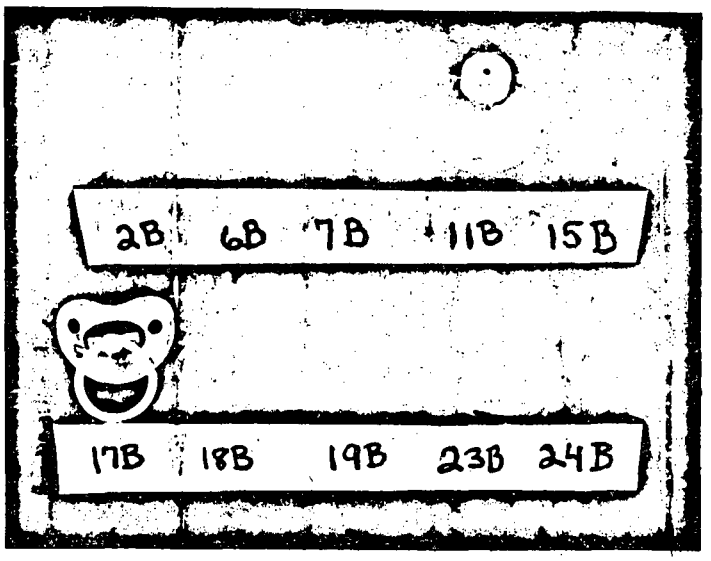


PHOTO 2. Placement of Ventilation Holes

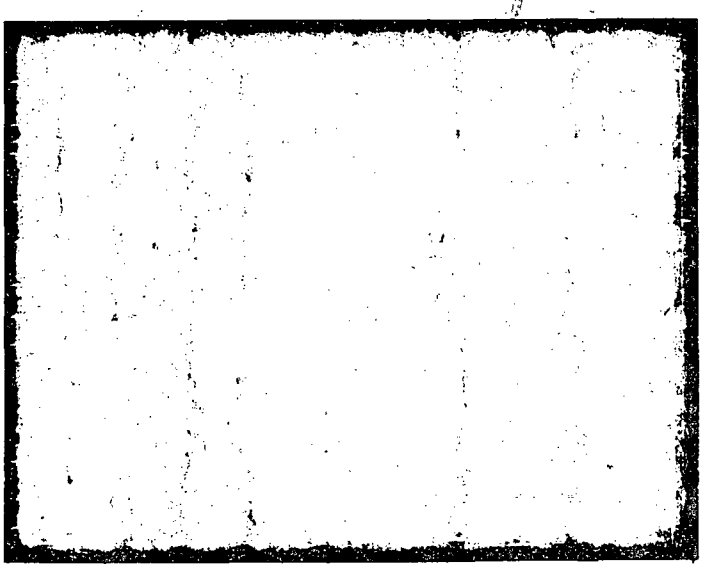


PHOTO 3. Protrusion Testing

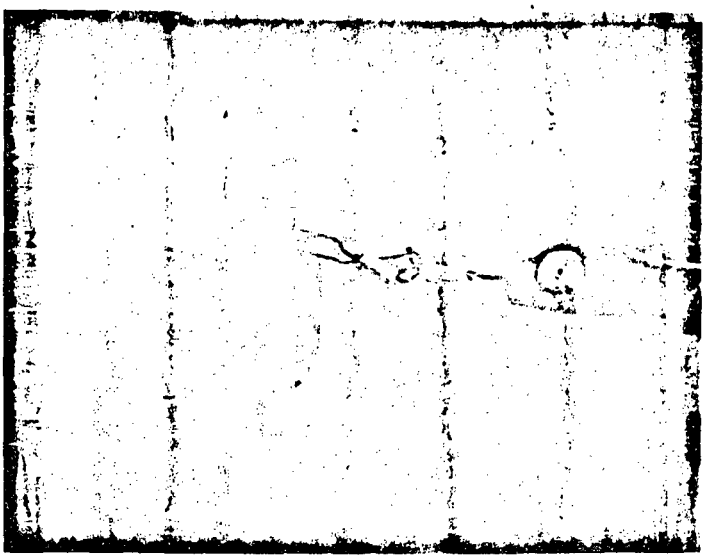


PHOTO 4. Structural Integrity of Nipple

PHOTO 5. Structural Integrity of Handle or Ring

APPENDIX

Sample	Brand	Model	Distributer	Performance, Guard Force						Protrusions		Structural Integrity					Labeling
				Original			After Heat					Original		After Heat			
				Proposed	Canadian w/o Holes	Canadian w/ Holes	Proposed	Canadian w/o Holes	Canadian w/ Holes			Nipple	Handle	Nipple	Handle	Small Parts	
1A	The First Years	1201	Kiddie Products, Inc.	N.C.* .95 lbs	N.C.* .65 lbs		N.C.* .00 lbs	N.C.* .50 lbs		N.C.*	38 mm	C.*	C.*	C.*	C.*	C.*	N.C.*
2A	The First Years	1203	Kiddie Products, Inc.	N.C. .50 lbs	C. 2.25 lbs		N.C. .55 lbs	N.C. .20 lbs		N.C.	39 mm	C.	C.	C.	C.	C.	N.C.
B	The First Years	1203	Kiddie Products, Inc.		C. 2.85 lbs	C. 2.90 lbs			N.C. 1.35 lbs								
3A	Tommee Tippee	TT181	Tommee Tippee	N.C. .20 lbs	N.C. .75 lbs		N.C. .15 lbs	N.C. .50 lbs		N.C.	37 mm	C.	C.	C.	C.	C.	N.C.
4A	Reddy		The Reddy Co.	N.C. .45 lbs	N.C. 1.15 lbs		N.C. .25 lbs	N.C. .40 lbs		N.C.	37 mm	C.	C.	C.	C.	C.	N.C.
5A	Gerber	6155	Gerber Products Co.	N.C. .25 lbs	N.C. 1.75 lbs		N.C. .60 lbs	N.C. 1.05 lbs		N.C.	40 mm	C.	C.	C.	C.	C.	N.C.
6A	Happy-Mates	H404	Electroplastics, Inc.	N.C. .65 lbs	N.C. 2.05 lbs		N.C. .45 lbs	N.C. .55 lbs		C.	14 mm	C.	C.	C.	C.	C.	N.C.
B	Happy-Mates	H404	Electroplastics, Inc.		C. 2.70 lbs	C. 2.25 lbs			N.C. 1.20 lbs								
7A	Sani-Flex	176	Sani-Toy, Inc.	N.C. 1.30 lbs	C. 2.75 lbs		N.C. .70 lbs	N.C. 1.75 lbs		N.C.	28 mm	C.	C.	C.	C.	C.	N.C.
B	Sani-Flex	176	Sani-Toy, Inc.		C. 2.70 lbs	C. 3.10 lbs			N.C. 2.00 lbs								
8A	Chicco	50046	Shelcore, Inc.	N.C. .00 lbs	N.C. .00 lbs		N.C. .00 lbs	N.C. .00 lbs		C.	11 mm	C.	N.C.	C.	N.C.	N. C.-Handle	N.C.
9A	Baby-Joy Orthoflex	411	Louis A. Boettiger, Inc.	N.C. .00 lbs	N.C. .30 lbs		N.C. .00 lbs	N.C. .25 lbs		C.	10 mm	C.	C.	C.	C.	C.	N.C.
10A	Baby-Joy Paciflex	408	Louis A. Boettiger, Inc.	N.C. .00 lbs	N.C. .15 lbs		N.C. .00 lbs	N.C. .05 lbs		C.	14 mm	C.	C.	C.	C.	C.	N.C.
11A	Tommee Tippee	TT180	Tommee Tippee	C. 5.00+lbs	C. 5.00+lbs		C. 5.00+lbs	C. 5.00+lbs		N.C.	20 mm	C.	C.	C.	C.	C.	N.C.
B	Tommee Tippee	TT180	Tommee Tippee		C. 5.00+lbs	C. 5.00+lbs			C. 5.00+lbs								
12A	Gerber Ortho	6159	Gerber Products, Inc.	N.C. 1.30 lbs	N.C. 1.75 lbs		N.C. .90 lbs		N.C. .55 lbs	N.C.	27 mm	C.	C.	C.	C.	C.	N.C.

--N.C. - Sample is not compliant with Standard; C. - Sample is compliant with Standard

Sample	Brand	Model	Distributer	Performance, Guard Force						Protrusions	Structural Integrity					Labeling
				Original			After Heat				Original		After Heat			
				Proposed	Canadian w/o Holes	Canadian w/ Holes	Proposed	Canadian w/o Holes	Canadian w/ Holes		Nipple	Handle	Nipple	Handle	Small Parts	
13A	*The First Years*	*1202*	*Kiddie Products, Inc.*	N.C.* .00 lbs	N.C.* 1.10 lbs		N.C.* .00 lbs	N.C.* .35 lbs		N.C.* 31 mm	C.*	C.*	C.*	C.*	C.*	N.C.*
14A	The First Years	1204	Kiddie Products, Inc.	N.C. 1.35 lbs	N.C. .75 lbs		N.C. .35 lbs	N.C. .65 lbs		N.C. 31 mm	C.	C.	C.	C.	C.	N.C.
15A	Happy-Mates	H406	Electro-Plastics Inc.	N.C. 1.60 lbs	C. 2.50 lbs		N.C. .00 lbs	N.C. .80 lbs		N.C. 30 mm	C.	C.	N.C.	N.C.	N.C. - Nipple	N.C.
B	Happy-Mates	H406	Electro-Plastics Inc.		C. 2.45 lbs	C. 2.50 lbs			C. 2.75 lbs							
16A	Sani-Toy	076	Sani-Toy, Inc.	N.C. .00 lbs	N.C. 1.80 lbs		N.C. .00 lbs	N.C. .95 lbs		N.C. 32 mm	C.	C.	C.	C.	C.	N.C.
17A	NUK	530	Reliance Products Inc.	N.C. .00 lbs	C. 5.00+ lbs		N.C. .00 lbs	C. 5.00+ lbs		C. 12 mm	C.	C.	C.	C.	C.	N.C.
B	NUK	530	Reliance Products Inc.		C. 5.00+ lbs	C. 5.00+ lbs			C. 5.00+ lbs							
18A	Happy-Mates	H408	Electro-Plastics Inc.	N.C. .00 lbs	C. 5.00+ lbs		N.C. .00 lbs	C. 3.40 lbs		C. 15 mm	C.	C.	C.	C.	C.	N.C.
B	Happy-Mates	H408	Electro-Plastics Inc.		C. 5.00+ lbs	C. 5.00+ lbs			C. 4.50 lbs							
19A	Plakie	292-293	Plakie Toys	N.C. 1.50 lbs	N.C. 2.10 lbs		N.C. .65 lbs		N.C. .85 lbs	N.C. 30 mm	C.	C.	C.	C.	C.	N.C.
B	Plakie	292-293	Plakie Toys		N.C. 1.00 lbs	N.C. .90 lbs		C. .75 lbs								
20A	Happy-Mates	H408 (not 18A)	Electro-Plastics, Inc.	N.C. 1.30 lbs	N.C. 1.40 lbs		N.C. .85 lbs	N.C. .30 lbs		N.C. 31 mm	C.	C.	C.	C.	C.	N.C.
21A	Binky Superlatex	---	Binky Baby Prods. Co., Inc.	N.C. 1.20 lbs	N.C. 1.70 lbs		N.C. .90 lbs	N.C. .95 lbs		N.C. 23 mm	C.	C.	C.	C.	C.	N.C.
22A	Binky Orthodontic	962242	Binky Baby Prods. Co., Inc.	N.C. .00 lbs	C. 5.00+ lbs		N.C. .00 lbs	C. 3.10 lbs		C. 14 mm	C.	C.	C.	C.	C.	no package
23A	Binky Superlatex	---	Binky Baby Prods. Co., Inc.	N.C. 1.40 lbs	C. 2.50 lbs		N.C. 1.05 lbs	N.C. 1.65 lbs		N.C. 19 mm	C.	C.	C.	C.	C.	N.C.
B	Binky Superlatex	---	Binky Baby Prods. Co., Inc.		C. 2.85 lbs	C. 2.95 lbs			C. 1.50 lbs							

N.C. - Sample is not compliant with Standard; C. - Sample is compliant with Standard

Sample	Brand	Model	Distributer	Performance, Guard Force						Protrusions		Structural Integrity					Labeling
				Original			After Heat					Original		After Heat			
				Proposed	Canadian		Proposed	Canadian				Nipple	Handle	Nipple	Handle	Small Parts	
					w/o Holes	w/ Holes		w/o Holes	w/ Holes								
24A	MAM	---	Austro-Hahn	N.C.* .00 lbs	C.* 5.00+lbs		N.C.* .00 lbs	C.* 5.00+lbs		C.*	12 mm	C.*	C.*	C.*	C.*	C.*	N.C.*
B	MAM	---	Austro-Hahn		C. 5.00+lbs	C. 5.00+lbs			C. 5.00+lbs								
25A	Evenflo Cork	---	Questor Corp.	N.C. .00 lbs	C. 2.90 lbs		N.C. .00 lbs	C. 2.90 lbs		C.	14 mm	C.	C.	C.	C.	C.	N.C.
26A	Evenflo Zipper	---	Questor Corp.	N.C. .00 lbs	N.C. 1.70 lbs		N.C. .00 lbs	N.C. 1.40 lbs		N.C.	32 mm	C.	C.	C.	C.	C.	N.C.
27A	NUK Gum Soother	536	Reliance Prods., Inc.	C. 5.00+lbs	N.C. .00 lbs		N.C. .00 lbs	N.C. .00 lbs		N.C.	52 mm	C.	C.	N.C.	N.C.	N.C.-soother heat deformed	N.C.
28A	Happy Mates Teether	H414	Electro-Plastics, Inc.	C. 5.00+lbs	N.C. .00 lbs		N.C. .00 lbs	N.C. .00 lbs		N.C.	54 mm	C.	C.	N.C.	N.C.	N.C.-teether heat deformed	N.C.
29A	Unmarked	---	----	N.C. .75 lbs	N.C. 1.00 lbs		N.C. .00 lbs	N.C. .00 lbs		N.C.	42 mm	C.	C.	N.C.	N.C.	N.C. - nipple	no package

N.C. - Sample is not compliant with Standard; C. - Sample is compliant with Standard

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Parts 1500, 1511]

HAZARDOUS PACIFIERS BAN

Revised Proposal

In this document the Consumer Product Safety Commission proposes for public comment a regulation (16 CFR Part 1511) prescribing safety requirements for pacifiers and a regulation (16 CFR 1500.18(a)(8)) banning from interstate commerce pacifiers not meeting such safety requirements. These actions are taken under the Federal Hazardous Substances Act.

BACKGROUND

Section 2(f)(1)(D) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f)(1)(D)) provides for the classification of any toy or other article intended for use by children as a hazardous substance upon a determination by regulation, in accordance with section 3(e)(1) of the act (15 U.S.C. 1262(e)(1)), that it presents a mechanical hazard. Section 2(q)(1)(A) provides that such a toy or article is also banned hazardous substance. "Mechanical hazard" is defined by section 2(s) of the act and other banned toys and banned children's article are listed in 16 CFR 1500.18.

In the FEDERAL REGISTER of October 18, 1972 (37 FR 22000), the Commissioner of the Food and Drug Administration (FDA) proposed 21 CFR 191.9a(a)(8), a regulation banning pacifiers not designed and constructed in accordance therewith, and proposed 21 CFR 191.18, a regulation prescribing a method for determining the durability of pacifiers.

Effective May 14, 1973, functions of the FDA under the Federal Hazardous Substances Act were transferred to the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

Subsequently, on September 27, 1973 the Consumer Product Safety Commission revised and transferred the regulations under the Federal Hazardous Substances Act from Title 21 of the CFR to Title 16 of the CFR (38 FR 27012). Accordingly, this revised proposal involves 16 CFR Parts 1500 and 1511 instead of 21 CFR Part 191.

DEMONSTRATION OF NEED

The need for banning hazardous pacifiers has been preliminarily demonstrated to the Commission by investigations, studies, staff analyses, and NEISS (National Electronic Injury Surveillance System) data showing that pacifiers are, or can be, a contributing factor in the serious injury and death of children.

In-depth investigations of pacifier accidents reported in the NEISS system, conducted from 1970 through 1975 by the Commission staff, show that there were at least eight deaths during this period. One victim died when the pacifier stimulated vomiting causing strangulation on the victim's vomitus, and another died when an adult gave the child a disassembled pacifier which lodged in his throat causing suffocation. In addition six victims died when they were strangled by the ribbon or string used to secure the pacifiers around their necks. Other NEISS in-depth investigations revealed that one victim suffered lacerations of the mouth from a pacifier, and two others choked on pacifiers which came apart. Another victim swallowed a pacifier but was saved when pounding on her back dislodged it, and she swallowed it and later passed it.

In February 1976, a five month old boy died when a flexible pacifier shield was lodged in his throat and could not be removed prior to his being asphyxiated. The Commission staff has also investigated this incident.

After consideration of the injury data and death reports, the Commission preliminarily finds that pacifiers and their components present an unreasonable risk of personal injury or illness to children from aspiration, ingestion and strangulation because of their design and manufacture and therefore present a mechanical hazard.

PROPOSAL

The original proposal would have required, in general terms, that all pacifiers and similar articles:

(1) have a flexible guard (or shield) at least 43 mm in diameter or an inflexible guard (or shield) at least 38 mm in diameter;

(2) have a hinged or collapsible handle or ring;

(3) contain no object or substance that is non-sterile or could be aspirated or ingested during normal use or when subjected to reasonably foreseeable damage or abuse;

(4) do not break into pieces smaller than the dimensions in (1), above, when tested according to specified methods for determining durability [these test methods involve pulling on the handle and nipple with a force of 10 pounds applied in various directions (load tests) and boiling the pacifiers for 10 cycles];

(5) do not consist in whole or in part of any food; and

(6) be otherwise designed and constructed to prevent the possibility of injury or illness by ingestion, aspiration, or laceration.

RESPONSE TO PROPOSAL

Comments were received from industry and consumers in response to the original FDA proposal of October 18, 1972. A total of eleven comments were received: six from manufacturers, one from a trade association, three from consumers, and one from a consumer association. The significant issues raised by the comments and the Commission's conclusions thereon are as follows:

1. The definition of "pacifier or other similar article" is vague and unclear, and should be limited to items with a nipple, shield and handle. The definitions of "flexible" and "inflexible" are also vague and unclear. The Commission has modified the definition of pacifier and the terms "flexible" and "unflexible" are no longer used in the regulation.

2. Other commenters urged that the boiling test criteria be reduced to allow pacifiers to cool to room temperature instead of 100° F and that the boiling time be reduced from 10 minutes to three minutes because three minutes is the usual time used by a consumer to sterilize a pacifier. The Commission has modified the regulation so that the pacifiers are cooled in room temperature and the boiling time is 5 minutes for each cycle.

3. Other comments suggested a possible exemption for certain "food-filled" pacifiers, alternative sterilizing methods to boiling, and a "lead time" of at least 180 days that would allow for production changes.

The regulation no longer contains a prohibition on "food-filled" pacifiers because there is insufficient data to show that such pacifiers present an unreasonable risk of injury. Sterilization of pacifiers by boiling them in water is not only the most common method of sterilization used by parents but is also considered the most medically acceptable method of sterilization and therefore no additional methods have been included. The comments concerning "lead time" were considered and a period of 180 days is now being proposed for additional comment.

4. One commenter urged that a standard minimum pull of at least 6 pounds but no more than 10 pounds be used to test durability and structural integrity. The Commission considered this comment and decided that the 10 pound requirement is justified and necessary. As discussed below under "Revised Proposal", this requirement is consistent with the Use and Abuse Testing Procedures.

REVISED PROPOSAL

Having considered the injury and death reports, the original FDA proposal and comments thereon, a report compiled for the Commission by the National Bureau of Standards, and engineering information from the Bureau of Engineering Sciences, the Commission concludes that the original proposal should be withdrawn and that a revised proposal with changes should be withdrawn and that a revised proposal with changes should be published as set forth below.

When defining the scope of this regulation the staff looked at teething rings and found that available hazard information did not show them to present an unreasonable risk of injury. Since they do not have nipples, they are excluded from this regulation by definition.

The staff also considered orthodontic pacifiers and found that they should be covered by the regulation because they potentially present the same risk of injury as regular pacifiers. Orthodontic pacifiers do fall within the regulation's definition of pacifier.

The original proposal used a dimensional design requirement to address the hazard of a pacifier entering a child's mouth and causing death by asphyxiation. "Inflexible" pacifier guards were required to be no smaller than a specified dimension and "flexible" pacifier guards could be no smaller than a slightly larger dimension (to account for possible bending at the edges which would make entry into a child's mouth easier). The intent of the dimensional requirements was that a pacifier with a large enough guard would not enter a baby's mouth.

The reproposed guard or shield requirements (1511.3(a)) address the same hazard of asphyxiation by using a performance approach. A circular opening in a test fixture simulates a baby's mouth. If a pacifier, regardless of whether it is "flexible," or "inflexible", can be drawn through the fixture, it fails the test because of the hazard that it could asphyxiate a baby by entering its mouth.

The size of the opening is based on sample measurements of children's mouths taken by the Maryland State Department of Health and Mental Hygiene. The test force for pulling the pacifier against the test fixture was determined by measurements in the Commission's Bureau of Engineering Sciences Laboratory. It is the force required to extract a pacifier from ten subjects who were sucking on pacifiers (because adult subjects were used, a margin of safety is incorporated into the force requirement obtained).

A ventilation requirement (1511.3(b)) has been added to the guard or shield requirements in the reproposed regulation. It requires the pacifier shield or guard to have at least two holes. These holes are intended to provide an emergency oxygen supply and to provide a rapid means of removing the pacifier from the child's throat.

The protrusion limitation requirement (1511.4(a)), not included in the original proposal, is designed to address the hazard pattern of a child falling forward or rolling over in a crib. In this situation a long protrusion on a pacifier, most commonly a handle, could drive the pacifier against the child's mouth and force it inside. This presents the same asphyxiation hazard that was discussed above.

Because a pacifier protrusion will sink into a crib mattress, protrusions that are sufficiently short will not present this hazard. In addition, other pacifiers may not present this hazard because their protrusions will bend rather than remain rigid when a force is exerted against them.

The protrusion test (1511.4(b)) involves the measurement of a protrusion while 2 pounds of force are applied to it. In selecting this force, the Commission staff has taken into account the weight of a child's head and the distribution of that weight over different parts of the child's face. The 0.63-inch limitation on the length of a protrusion (when measured according to this test) takes into account the distance that the protrusion will sink into a crib mattress.

The reproposed regulation includes structural integrity requirements (1511.5) in which tests are performed on pacifiers in whole or on various components to determine whether a pacifier can maintain its structural integrity when subject to mechanical and thermal forces and possible degradations which a pacifier is subject to in normal use. The force levels are selected from the Use and Abuse Testing Procedures for tension which are applicable to articles intended for use by children 18 months of age or less (16 CFR 1500.51(f)(3)). The heat cycle deterioration test, modified from those originally proposed, are representative of the common sterilizing techniques used by mothers and institutions.

Should any pacifier release components or fragments when subjected to the structural integrity tests, such components or fragments shall be subject to the small parts test which will determine whether they could be lodged in a child's throat and cause suffocation. The dimensions involved in the small parts test are based on present medical advice obtained by the Commission's Office of the Medical Director. These dimensions were used in the designing of the truncated cylinder (Fig. 2) which is incorporated into the test.

Two new sections have been added to address the strangulation hazard that results from tying a pacifier around a child's neck with ribbons or strings. A required warning label (1511.7) would alert to this hazard parents and others who take care of children. A prohibition against selling pacifiers with ribbons, cords, strings, etc. (1511.6) would also address this strangulation hazard.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)

(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262) and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a); 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission proposes to amend Title 16, Chapter II, Subchapter C, by adding a new § 1500.18(a)(8) and a new Part 1511 as follows:

§ 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:

• • • • •

(8) Any pacifier that does not meet the requirements of 16 CFR Part 1511 and that is introduced into interstate commerce after 180 days following the date of publication in the FEDERAL REGISTER of the final form of this regulation.

• • • • •

PART 1511—REQUIREMENTS FOR PACIFIERS

Sec.
1511.1 Scope of Part 1511.
1511.2 Definitions.
1511.3 Guard or shield performance requirements.
1511.4 Protrusions.
1511.5 Structural integrity tests.
1511.6 Ribbons, strings, cords, etc.
1511.7 Labeling.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262.

§ 1511.1 Scope of Part 1511.

This Part 1511 sets forth the requirements whereby pacifiers (as defined in § 1511.2(a)) are not banned articles under § 1500.18(a)(8) of this chapter.

§ 1511.2 Definitions.

(a) A "pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, and usually includes a guard or shield and a handle or ring.

(b) "Guard or shield" means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth.

(c) "Handle or ring" means the structure usually located adjacent to the guard or shield used for holding or grasping the pacifier. A hinged handle or ring is one that is free to pivot about an axis parallel to the plane of the shield or guard.

§ 1511.3 Guard or shield performance requirements.

(a) Place the pacifier in the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier protrudes through the back of the fixture as shown in Figure 1(b). Apply a tensile force of 2.0 pounds (8.9 newtons) to the end of the pacifier nipple in the direction shown. The force shall be gradually applied within a period of 5 seconds and maintained for an additional 10 seconds. The placement of the pacifier in the fixture shall be in the most adverse orientation, i.e., that which will result in the lowest force to cause the pacifier to be drawn through the aperture in the fixture. Any pacifier which can be completely drawn through the fixture by such a force shall fail the test in this section.

(b) *Ventilation holes.* The pacifier shield or guard shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier shield or guard.

§ 1511.4 Protrusions.

(a) *Protrusion limitation.* No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16 millimeters) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) *Protrusion test.* Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be gradually applied to any protrusion from the guard shield with a force of 2 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Measure the greatest distance from the plane surface to the guard or shield.

§ 1511.5 Structural integrity tests.

(a) *Nipple.* Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force of 10 pounds (44.5 newtons) to the nipple in any possible direction within a period of five seconds and maintain this load for an additional ten seconds.

(b) *Handle or ring.* Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force applied shall be gradually increased to 10 pounds (44.5 newtons) within five seconds and maintained for ten seconds.

(c) *Heat cycle deterioration.* All pacifiers shall be subject to the following tests: Submerge the pacifier in boiling water for five minutes and then remove the pacifier and allow it to cool for five minutes in room temperature air, 68° to 78°F (20° to 25° C). After the cooling period, resubmerge the pacifier in the boiling water for five minutes. The process shall be repeated for a total of six boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and § 1511.3.

(d) *Small parts.* Any components or fragments which are released as a result of the tests specified in paragraphs (a), (b) and (c) shall be placed in the truncated cylinder as shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

§ 1511.6 Ribbons, strings, cords, etc.

A pacifier shall not be sold or distributed with any ribbon, string, cord or other means of attachment which could fit around a child's neck.

§ 1511.7 Labeling.

(a) As required by paragraphs (b) and (c) below, pacifiers shall be labeled with the statement: "WARNING: STRANGULATION DANGER—DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH RIBBON OR STRING."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

Interested persons are invited to submit, on or before November 19, 1976, written comments regarding this proposal. Comments and any accompanying data or material should be submitted, preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the Office of the Secretary, Washington, D.C., during working hours Monday through Friday.

Dated: October 14, 1976.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

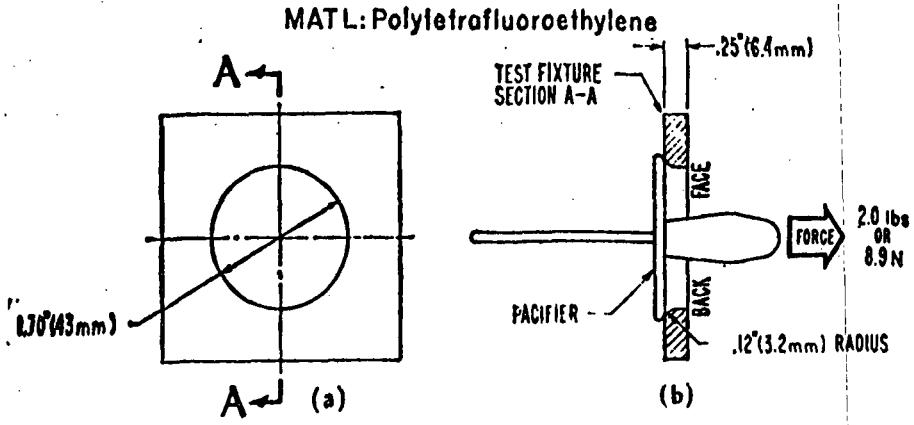
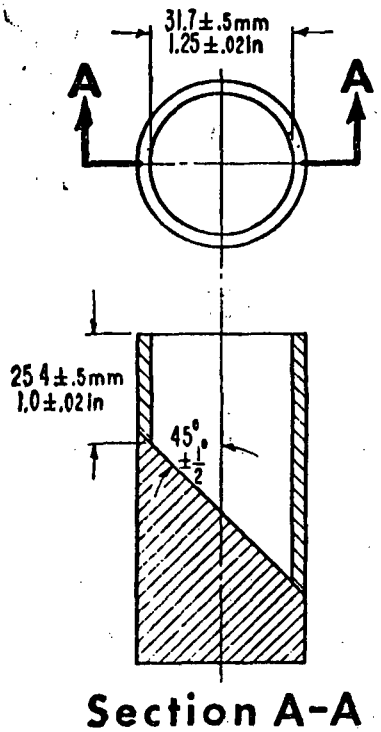


FIG 1-PACIFIER TEST FIXTURE



Section A-A

FIG 2-SMALL PARTS GAGE

[FR Doc.76-30838 Filed 10-19-76;8:45 am]

P.C. 1974-1102
14 May, 1974

HIS EXCELLENCY THE GOVERNOR GENERAL IN COUNCIL, on the recommendation of the Minister of Consumer and Corporate Affairs, pursuant to section 7 of the Hazardous Products Act, is pleased hereby to make the annexed Regulations respecting the Advertising, Sale and Importation of Hazardous Products (Pacifiers), effective May 14, 1974.

CERTIFIED TO BE A TRUE COPY - COPIE CERTIFIÉE CONFORME

REGULATIONS RESPECTING THE ADVERTISING, SALE AND IMPORTATION OF HAZARDOUS PRODUCTS (PACIFIERS)

Short Title

1. These Regulations may be cited as the Hazardous Products (Pacifiers) Regulations.

Interpretation

2. In these Regulations,

"Act" means the Hazardous Products Act;
"product" means a product included in item 26 of Part II of the schedule to the Act.

General

3. A person may advertise, sell or import into Canada a product only if it meets the requirements of these Regulations.

Advertising and Labelling

4.(1) No reference, direct or indirect, to the Act or to these Regulations shall be made in any written material applied to or accompanying a product or in any advertisement thereof.

(2) No representation in respect of the use of or modification to a product shall be made in any written material applied to or accompanying the product or in any advertisement thereof, which use or modification would result in the failure of the product to meet a requirement of these Regulations.

Sterility and Toxicity

5 (1) Every product, including all its parts and components, when tested in accordance with the Sterility Tests described in pages 851 to 857, both inclusive, of the Pharmacopeia of the United States of America, Eighteenth Revision, shall be sterile.

(2) Every product, including all its parts and components shall meet the requirements of Section 10 of the Hazardous Products (Toys) Regulations.

Design and Construction

6 (1) Every product shall

(a) be designed and constructed in such a manner as to protect the user, under reasonably foreseeable conditions of use, from

(i) obstruction of the pharyngeal orifice,

(ii) strangulation,

(iii) ingestion or aspiration of the product or any part or component thereof, and

(iv) wounding;

(b) be designed and constructed so that,

(i) the nipple is attached to a guard or shield of such dimensions that it cannot pass through the opening in the template illustrated in Schedule I when the nipple is centered on the opening and a load of 2.2 pounds is applied axially to the nipple in such a way as to induce the guard or shield to pull through the opening in the template,

(ii) any loop of cord or other material attached to the product is not more than 14 inches in circumference,

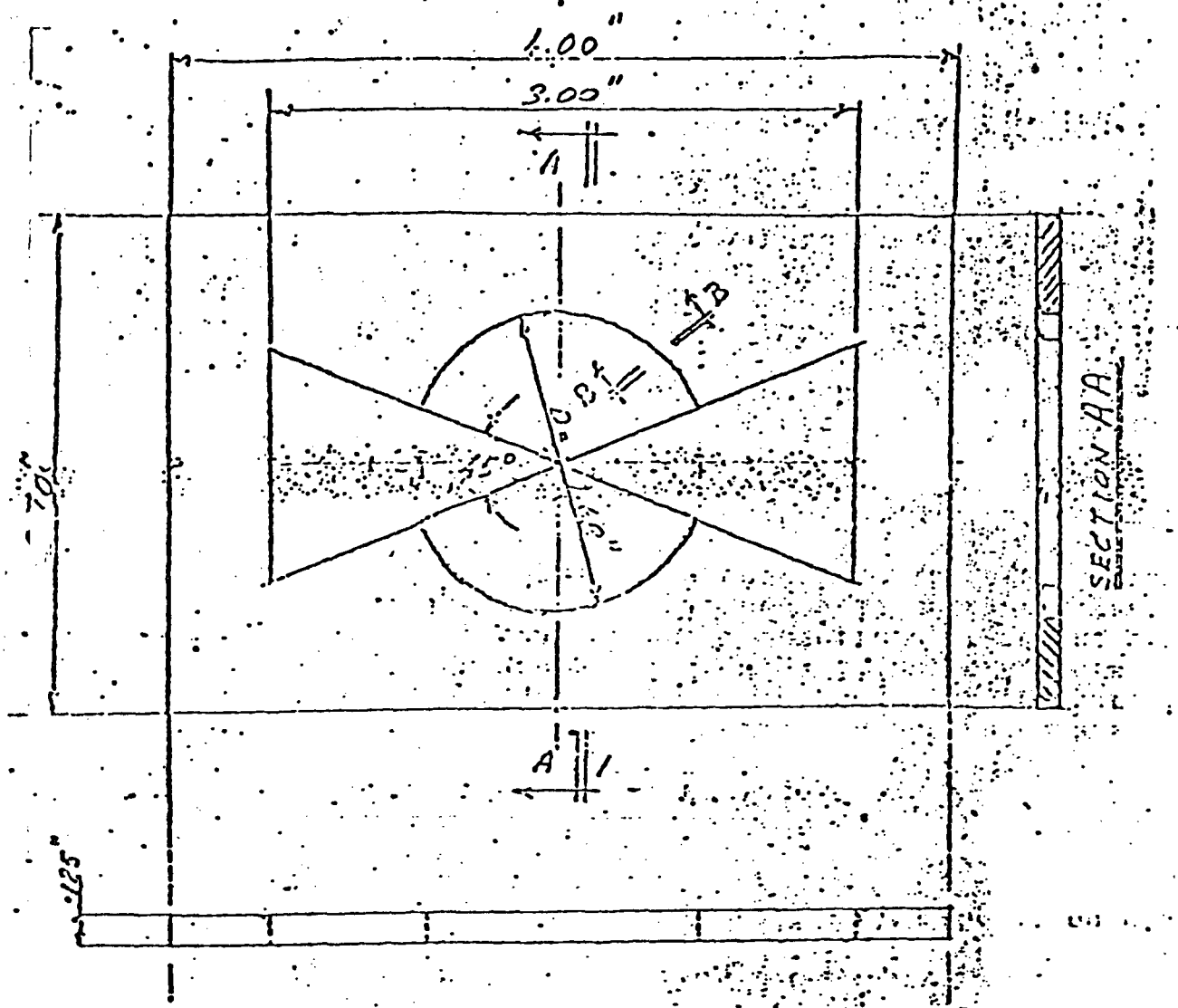
(iii) when tested in accordance with the procedure described in Schedule II

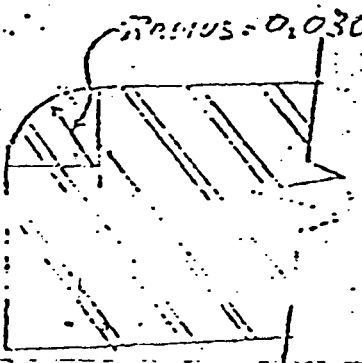
(A) the nipple remains attached to the guard or shield described in subparagraph (i), and

(B) no part or component is separated or broken free from the product that will fit, in a non-compressed state, into the truncated right circular cylinder illustrated in Schedule III, and

(iv) any ring or handle is hinged, collapsible or flexible

GUARD TEMPLATE





NOTES

1- RADIUS OF ALL EDGES

3- DIMENSIONAL TOLERANCE

± 0.005"

SCHEDULE II

Testing Procedure

1. Hold the nipple of the pacifier in a fixed position. Apply a load of 10 ± 0.25 pounds in the plane of the axis of the nipple to the handle of the pacifier at a rate of 1 ± 0.25 pounds per second and maintain the final load for 10 ± 0.5 seconds.

2. Hold the guard or shield of the pacifier in a fixed position. Apply a load of 10 ± 0.25 pounds in a plane normal to the axis of the nipple to the handle of the pacifier at a rate of 1 ± 0.25 pounds per second and maintain the final load for 10 ± 0.5 seconds.

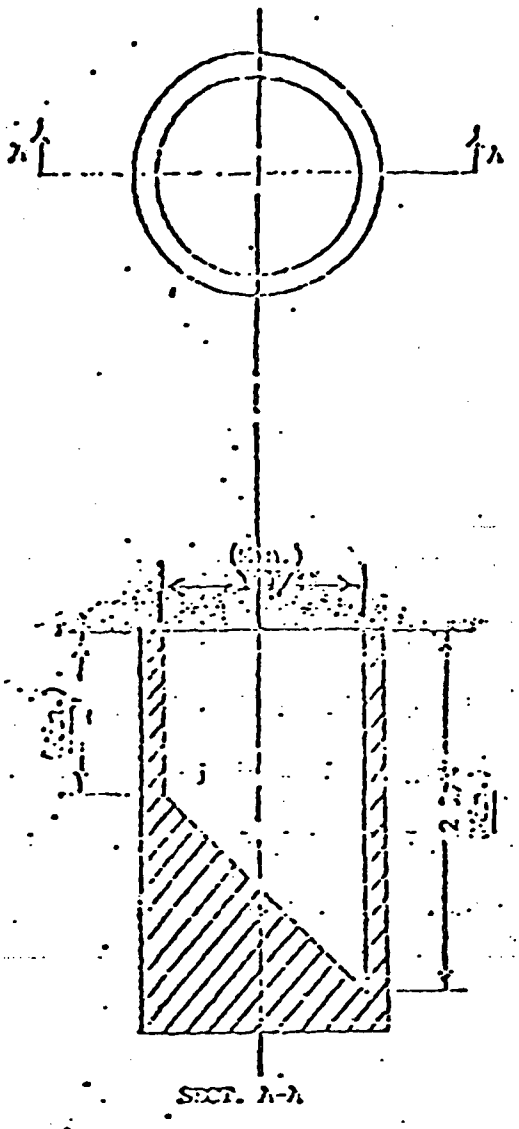
3. Repeat the procedure described in section 2 with the load applied to the nipple of the pacifier.

4. Immerse the pacifier in boiling water for 10 ± 0.5 minutes. Remove the pacifier from the boiling water and allow to cool in air at 70 ± 5 degrees Fahrenheit for 15 ± 0.5 minutes. Repeat the tests described in sections 1, 2 and 3.

5. Repeat the entire procedure described in section 4 nine times.

SCHEDULE III

Truncated Right Circular Cylinder



TRUNCATED RIGHT CIRCULAR CYLINDER

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, TAD/OSCA DATE: February 22, 1977

THRU: Albert F. Esch, M.D., Director, OMD Albert F. Esch

FROM : Charles T. Desmond, M.D., Director, OMDR
Donald T. Van Houten, OMDH D.T. Van Houten C.T. Desmond

SUBJECT: Pacifiers - OMD response to comments

The Office of the Medical Director has reviewed the comments submitted in response to the proposed pacifier regulation published in the Federal Register on October 20, 1976. We are submitting comments on the two major issues; 1) the ventilation holes and 2) the requirements for the shield size.

Ventilation Requirements

In our August 30, 1976 memo essentially three reasons were cited for drafting ventilation requirements:

1) To provide an auxiliary oxygen pathway exchange to the lungs to reduce the possibility of producing anoxia resulting in death, in the event a pacifier shield occluded the airway.

2) To provide a partial airway during the period of time for transfer of the patient to a medical facility. The requirement will provide a pathway by which oxygen can be administered en route to the hospital. This could be lifesaving.

3) To provide an accessibility point through which an instrument such as forceps or a hook could be inserted in the event the shield became impacted and could not be extracted manually.

The requirements proposed in the FEDERAL REGISTER notice state that; "The pacifier shield or guard shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches(5 millimeters) to the perimeter of the pacifier shield or guard."

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

The comments submitted on behalf of the public fell into five areas:

1) The ventilation requirement is ineffective or will not work.

2) There are hygenic risks associated with the openings, i.e. the holes are dirt traps.

3) The openings would prevent sucking implying the utility of the pacifier would be destroyed.

4) The presence of holes would weaken the shield structure thereby increasing the potential of the shield entering the mouth.

5) The holes could be utilized as attachment points for strings, ribbons, etc; thereby increasing the hazard rather than reducing it.

In response to these comment areas OMD wishes to submit the following;

1) In regard to the potential efficacy of the ventilation requirement OMD believes that two or more holes in a pacifier shield could reduce the chance for a tragic suffocation death. A specific example for documentation of this point is shown in the following case report.

Case Report (From Pediatrics, Vol 58, No. 6, Dec. 1976, p 853)

"W.B., a healthy, 5 month-old boy was sitting in his high chair while his mother prepared the evening meal in the same room. He was sucking his pacifier(Fig. 1). While his mother's back was turned, she suddenly heard a gasping sound and turned around to notice him choking on his pacifier. She tried to pull it from the back of his mouth but was unable get it out. She ran frantically with the baby to her next door neighbor who, inexplicably at the time, also failed in the attempt to remove it. The baby was still struggling to breathe and the father, police, and an ambulance were called to the house. After several more attempts they were still unable to remove the pacifier, although they were able to grasp it between thumb and forefinger. Attempts to remove

it seemed to push it further in, rather than out. Pounding on the back also did not help. The police officers started mouth to mouth ventilation with external cardiac message and took the baby to the emergency room of the Montefiore Hospital and Medical Center.

On arrival he was "clinically dead." On direct laryngoscopy, the mouse's head-shaped portion of the pacifier was observed in the back of the baby's mouth and an attempt to remove it with forceps was unsuccessful. Final, the resident physician was able to loop her fingers around the "neck" of the "mouse" and by exerting an extraordinary amount of force was able to extract the rubber portion of the pacifier by forcing the nipple through the center hole of the plastic flange of the pacifier (Fig. 2). Unknown at the time, the plastic flange still remained wedged in the hypopharynx, but the hole in the flange allowed enough air passage to permit bag-and-mask ventilation. With the restoration of ventilation, external cardiac massage and other resuscitative measures restored circulation with return of a heart beat. Apnea was estimated at 20 minutes and cardiac arrest had lasted at least six minutes. When endotracheal intubation was then attempted, the plastic flange was discovered still in the hypopharynx and was easily removed.

The patient was then admitted to the Montefiore Pediatric Special Care Unit and maintained on a respirator. He died six days after admission without regaining consciousness and with clinical brain death.

Several observations and/or questions can be formulated from this case:

1) The victim was 5 months-old and possessed sufficient space (or tissue flexibility) to admit and contain a shield 38 mm in diameter. Since children frequently use pacifiers up through the age of 2 years, it is reasonable to "assume" these 2 year olds have an <u>even greater</u> ability to admit and contain shields in excess of 38 millimeters in diameter.

2) The 8 mm hole which was created when the nipple and handle were removed was sufficient to permit ventilation of the victim by mechanical means. If this hole had been preexisting the victim might have been saved.

Several of the commentors stated that the holes would work only under the most ideal of conditions, that is, the holes would likely be blocked by surrounding tissue which might overlap the edges of shield.

OMD is cognizant of the potential blockings of the holes and has attempted to counter this situation by requiring two or more holes. Should both holes be blocked, the insertion of a nasal catherter through the shield holes for the administration of oxygen could be instituted.

Several commentors claimed the holes would be dirt traps and result in a health hazard. OMD disagrees. We do not believe there would be any greater accumulation of pathogenic bacteria or dirt in the holes than would occur on the shield per se or in cracks or crevices which exist in multipiece pacifiers. We, therefore, believe the comments to be inaccurate.

One comment stated the pacifier would prevent the infant from sucking on the pacifier and thereby decrease it's utility.

OMD disagrees. An infant does not utilize the shield for sucking but rather the nipple. If the child should be able to get a substantial portion of the shield into his mouth, we believe the holes will assist in preventing the child from sucking the pacifier into the oral pharynx. The generation of a negative pressure would be prevented.

Several comments stated the presence of holes in the shield would weaken the structure and increase the liklihood of the pacifier entering the childs mouth.

Our suggested response to these comments are that regardless of whether the holes weaken any particular design, it is the manufacturers responsibility to adjust his product accordingly to conform with the requirements, i.e., if the holes weaken the shield to the extent it will not pass the guard performance requirements, then the manufacturer must make appropriate adjustments.

Finally, one comment pointed out that the required holes could serve as attachment points for strings, ribbons, etc., potentially increasing the likihood of external strangulation.

OMD suggests that the proposed labling requirements should alert consumers sufficiently to minimize the occurrance of this problem.

Shield Size

The bulk of the comments pertaining to shield size stated that the opening in the test device was excessive in that shields passing the test would block a childs nostrils. Further, these comments cited a number of foreign standards which contained varying requirements for shield dimensions ranging from approximately 38 millimeters to 43 millimeters.

The Commission has obtained limited data from the Maryland Office of the Chief Medical Examiner pertaining to the range in size of infants mouths. This data range is 22 millimeters to 40 millimeters and is based on a sample of 25 subjects up to 4 months of age.

On the basis of the data, the Maryland Medical Examiner suggested that flexible pacifier shields should be at least 43 mm based on the greatest infant dimension which was obtained. A similar recommendation was made regarding rigid pacifier shields. The Commission has relied on this recommendation and data in the absence of documented alternative information. Bethesda Office staff have requested the rationale for the Canadian pacifier standard which differs from the CPSC proposal. Pending evaluation of the rational, OMD suggests the proposed shield requirements be maintained.

UNITED STATES GOVERNMENT

Memorandum

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

TO : Bill Menza, TAD/OSCA DATE: March 11, 1977

THRU : Albert F. Esch, M.D., Director, OMD Albert F. Esch

FROM : Charles T. Desmond, M.D., Director, OMDR C.T. Desmond, M.D.

SUBJECT: Comments on BESB Memorandum dated March 3, 1977, Proposed Pacifier Regulation

The statement is made on page 3 under 1511.3(b) Ventilation Holes:

> "However in the opinion of BESB, the comments by Reliance, Giant, and TMA that this requirement may not provide an air passage has considerable merit. If a pacifier is in a child's mouth, the holes, located as they may be in accordance with this requirement, could be covered by the child's tongue or palate."

Admittedly an occasion could arise when the tongue or soft palate might occlude the air passage, but by inserting a nasal catheter through the hole it would dislodge the soft tissue of the tongue and soft palate, thus assuring an airway for the administration of oxygen. This is one of the major reasons the ventilation holes were included in the proposal.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

William Menza, TAD/OSCA

April 28, 1977

THRU : Albert F. Esch, M.D., Director, OMD

Donald T. Van Houten, OMDH

Pacifiers

This memo is in response to your request of this morning which pertained to alternate methods for meeting the ventilation requirements. Specifically, one or more comments suggested that certain shield geometrics or shapes could fulfill the intent of the ventilation requirement. The specific example given was a guard which forms a figure 8. It was purported that the narrow area of the shield (which forms a "U" or a "V") would suffice as a ventilation passage.

OMD concurs with the concept presented but has no method for evaluating the efficacy of the design. OMD wishes to point out several practical problems in evaluating alternate concepts for ventilation. As BES has stated, the requirements for ventilation are currently phrased in terms of design specifications rather than the preferred performance requirements. A performance test would respond to comments and would permit alternatives to the holes. OMD believes that an appropriate performance test cannot be developed at this time because of an absence of human data which virtually precludes any ability to evaluate alternate concepts. Further, OMD points out that the ventilation holes also serve as a readily available means for removing the pacifier shield from a child's throat. If an infinite number of variations are permitted, emergency personnel will be faced with a situation of not knowing what type of opening for which they are searching. This would result in an unnecessary waste of time and would virtually negate one of the purposes of the ventilation holes.

We therefore, believe the current design requirements are the most practical and effective means for accomplishing our purpose.

bcc:
OMD Chron
Pacifier File
Reading File
Van Houten

DTVANHOUTEN/FJE 4-28-77

UNITED STATES GOVERNMENT

Memorandum

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

DATE: Feb. 8, 1977

TO : Bill Menza, TAD/OSCA
THRU : Walter R. Hobby, Director, BEA
FROM : Joann Langston, Acting AED/HIA
Dale Ray, BEA

SUBJECT: Pacifier Regulation Effective Date

We have recently contacted six of the eight known domestic pacifier manufacturers (some of which are also importers) on the subject of the effective date of the upcoming regulation. These firms account for a substantial majority of domestic production; we also believe that they are representative of firms carrying imported lines. As a result of our contact with these firms, we conclude that domestic manufacturers can make the changes required to achieve compliance with the regulation as reproposed in 1976, including the modification or replacement of molds, within six months. At least one domestic firm already claims to have a product that will meet the provisions of the reproposal. In addition, most manufacturers appear to carry sufficiently small finished goods inventories (generally not more than a few months) to be able to clear them within that time period. Thus, the proposed effective date of six months after the date of publication of the regulation in the Federal Register appears to be sufficient for the domestic producers.

Some importers may find that they will be at a competitive disadvantage should the regulation become effective six months after the date of publication. Since transoceanic shipping time (which typically ranges from one to two months, depending on the country of origin) has not been allowed for in this time period, complying domestically-produced pacifiers may be available to consumers before imported ones. If these are viewed as being superior by consumers, then the relative sales of imports may decrease. Thus, some adjustment in the effective date (to eight months, perhaps) to compensate for this additional lead time may be desirable.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : Bill Menza, TAD/OSCA

DATE: Feb. 18, 1977

THRU : Walter R. Hobby, Director, BEA

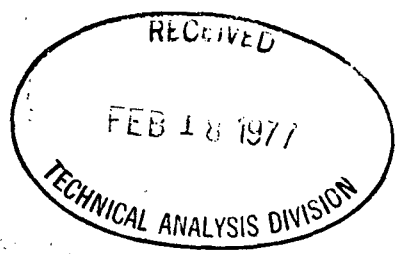
FROM : Joann Langston, Acting AED/HIA
Dale Ray, BEA

SUBJECT: Definition of Pacifiers in Federal Register Notice

We have noticed in reviewing the materials on pacifiers that the wording of the definition in the reproposal is such that nipples (like those intended for use on baby bottles) would be included. Since it is not the Commission's intention to regulate nipples, we suggest that the wording of the British pacifier regulation be used in our definition as follows:

> A "pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, usually including a guard or shield and a handle or ring, and not designed to facilitate a baby's obtaining fluid.

In addition, some types of gum soothers may be included in the definition. BES should be consulted on this point; perhaps a clarification of which types are covered should be issued in the Federal Register notice.



*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-5[illegible]/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, TAD/OSCA

DATE: April 15, 1977

THRU: Walter R. Hobby, Director/BEA
Joann Langston, Acting AED/HIA

FROM : Dale R. Ray, BEA

SUBJECT: Economic Impact and Environmental Assessment of the Pacifier Regulation

Attached are BEA's report on the potential economic effects of the pacifier regulation and our environmental assessment of the regulation. The basic assumption made in our investigation is that the regulation will be promulgated as reproposed on October 20, 1976. Significant changes in the regulation's guard or ventilation hole requirements will alter our assessment of the regulation's effects.

An exception to the above assumption is in the definition of the product. We believe that a clarifying statement regarding the applicability of the regulation to teethers and gum soothers would be desirable. We have also, in our memo of February 18, 1977, recommended a change in the wording of the definition which would exclude nursing nipples.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

POTENTIAL ECONOMICS EFFECTS OF THE PACIFIER REGULATION

Bureau of Economic Analysis
Dale Ray
April 15, 1977

BEA:DRAY
April 15, 1977

Potential Economic Effects of the Pacifier Regulation

Introduction

The following is a brief description of the producers of, and the market for, pacifiers, and a discussion of the probable economic effects of the reproposed safety regulation (as published in the Federal Register on October 21, 1976). Our comments are based in part on information contained in our January 4, 1974 report. At that time, we expressed concern about certain effects on the industry, which had, in anticipation of the issuance of a final regulation in early 1973, incurred substantial retooling costs to meet the provisions of the October 18, 1972 proposal. We noted that serious effects might have resulted if substantial design-related changes in the proposed regulation were made so soon after the manufacturers had incurred these retooling costs, which included the costs associated with building, installing, and operating new molds. Most of the molds are probably still functional and may be for many more years with periodic maintenance.

It appears that our earlier concerns are not generally applicable to the current situation, though some significant effects of the regulation are expected. We have updated some of the information from our previous report, and included some observations on the current state of the industry and issues surrounding specific sections of the reproposal. Our information takes into account the industry's latest comments submitted since publication of the reproposal.

Industry and Market Characteristics

There are eight major pacifier manufacturers marketing primarily in the U.S., the production facilities of at least one or two of which are totally outside the U.S. These firms' products appear primarily under their own brand names or under those of exclusive distributors. Two of the largest companies, Lewis Woolf Griptight, Ltd. (distributed in the U.S. by Binky Baby Products Co., a division of Eagle Druggist Supply, Inc.) and Reliance Products Corp., appear to be the design, price and sales leaders in the industry.

There are also about 10 other foreign manufacturers whose products appear in the United States under various brand names other than their own. These firms' goods are imported and distributed by perhaps a dozen American companies. These American companies generally obtain unbranded, often unpackaged pacifiers from a variety of foreign and domestic makers or distributors. The goods are then packaged for resale to jobbers or retailers under the distributors' names (or the names of major retailers, if so agreed). Some retailers also purchase pacifiers directly from the manufacturers. Some of the domestic manufacturers fill out their lines with imports (the molds for which may be owned by the manufacturer or its agent abroad). Thus, it is possible to see the same pacifier being sold under more than one brand name.

The firms in this industry also produce or distribute other products, usually plastic juvenile goods such as rattles, teething rings, diaper pins, etc. These other products usually account for the majority of dollar sales. Most of the manufacturers are relatively small.

As we noted in our previous report, the baby products market tends to be fairly stable over time since the items are not subject to dramatic style changes, massive advertising campaigns or large shifts in demand. For example, one manufacturer's research indicates that most babies use pacifiers for about 1 1/2 years, and go through at least four per year. What little consumer advertising there is appears primarily in baby magazines; some advertising for orthodontic models also appears in magazines or trade journals of pediatrics and children's dentistry.

A composite of industry estimates places total annual pacifier sales at about 15 million units, at a retail value of $7-9 million. If "imports" are construed to include American distributors' brands which are actually manufactured abroad (but not to include those assembled and packaged here which use some foreign components), then imports could account for as much as 30-50% of total shipments. Imported pacifiers of the type involved in most of the complaints, however (i.e., very inexpensive, generally low-quality, multiple-piece), probably comprise a small percentage of the market.

A major trend in recent years has been toward the production of one-piece pacifiers of either rubber or plastic. These are considered to be "safer" by the industry because they cannot come apart.

As noted above, pacifiers and other baby products may go through one or several steps in the physical distribution process (e.g., from manufacturer to exporter to importer to jobber to retailer to consumer). Prices of pacifiers vary widely as a partial result. Though a standard range of markups is used in retail pricing, various discounts are used at previous levels of distribution depending on the state of the merchandise (bulk, packaged, distributor-labeled, etc.), the terms of sale, geographic location, and other trade-relations factors. Retail prices range from about 20-90¢ each, depending on style, quality, features, brand, guarantees, etc. Orthodontic pacifiers (so named for the special shape of the nipple) are generally the most expensive variety.

Economic Effects of the Regulation

Definitions

It appears that some types of teethers or gum soothers may be interpreted to fall under the definition of a pacifier as used in the reproposal. This would affect another $3-5 million in annual retail sales. These items are usually water or jelly-filled rings or other objects of various shapes and sizes which may be chilled and which are intended for the purpose of chewing or biting rather than sucking. Most do not have nipples, but some include them as an added feature. Most currently available teethers and gum soothers would probably fail the regulation's performance requirements, and would have to be discontinued or re-designed if included in the definition.

Nursing nipples for use with feeding bottles may also be included in the definition in the reproposal. It has been assumed that it is not the Commission's intention to regulate feeding nipples; inclusion in the definition as reproposed would essentially ban all nursing nipples.

Guard Requirements

It appears that all manufacturers will have to modify or replace their pacifier molds if the regulation is promulgated as it now stands. Compliance with the guard requirements may be accomplished in some cases by simply enlarging the holes in multi-cavity molds, providing this does not interfere with the water lines running between each cavity. For some firms with molds that cannot be drilled out, replacement may be the only alternative.

There are various kinds and sizes of molds in use. Minimum mold-modification costs range from about $2,000-$5,000 per mold. Changes in molds used for making flat guards will tend, on the average, to be in this minimum cost range, while changes in molds used for making convex guards may be somewhat more costly. Total mold-change costs may range up to $10,000 per mold, depending on the extent of the changes necessary. The cost of replacing an entire mold, including design, purchase, installation, and start-up costs may range from $20,000-$50,000 per mold, depending on its size (i.e., number of cavities) and complexity. Individual producers may have several molds.

Molds are generally used for many years, but require maintenance or overhauling on a periodic basis (one firm reports that it conducts major overhauls every two years; others go considerably longer between overhauls). The expense of overhauls depends on the extent of repairs needed. Industry representatives claim, however, that "normal" overhauls involve work of a much simpler nature (e.g., lubricating and polishing) than will changes to effect compliance with the regulation (e.g., drilling and grinding); thus, they would be much less expensive to perform. It is likely that at least one firm will be able to economize on mold-change costs because it is currently at the point of making large-scale mold changes anyway. This is not expected to be the case for most producers.

The enlargement of mold cavities to meet the guard requirements for some models may weaken some molds, necessitating more frequent maintenance or overhauling. The use of thicker or larger-diameter guards may also lead to a raw-material requirement increase of from 10-50% (depending on the model). This would increase manufacturers' total raw-material costs by some unknown but lesser percentage. Raw materials, however, account for a relatively small amount of total production costs compared to labor, packaging, and physical distribution costs. The use of larger or thicker guards would also tend to prolong cooling time in the molding process. This will tend to increase labor costs: injection and pressing may take only a few seconds; cooling may take 20-30 seconds, during which time some workers may be idle.

Ventilation Hole Requirement

Compliance with this requirement will also involve increased production costs to manufacturers, depending primarily on whether the pacifier is of one-piece or

multi-piece design. For inflexible (usually three-piece) pacifiers, ventilation holes are apparently relatively simple and inexpensive to punch in the guard. This is simplest for those pacifiers using flat guards. Those using curved guards may, in addition, have to be tumbled with an abrasive substance after molding to remove "flashing", or excess material around the edges of the holes which might otherwise pose a sharp-edge hazard. The cost of this extra operation should be quite small since producers apparently have the necessary facilities.

For flexible one-piece models the requirement can be met either by drilling holes in a separate operation after injection molding or by buying (or building) "cam-action" molds which combine multiple operations into one procedure. Cam-action molds are fairly expensive: it is not likely that manufacturers will use them to a wide extent.

Thus, it appears that the increased cost to manufacturers of complying with this requirement may be larger for one-piece pacifiers than for multiple-piece pacifiers. Most firms appear to produce both types, though some produce only one-piece models. We know of no major manufacturer producing only multiple-piece pacifiers, though some of the other foreign producers may do so.

Labeling Requirements

Pacifiers are usually packaged for retail sale in plastic bags or on shrink-wrapped cards that can be hung from hooks in a display. The marginal cost of labeling these packages as specified in the regulation is expected to be minimal, and is not expected to affect retail prices. Some rearrangement of current package labeling may be necessary, but the basic package concept and advertising messages will remain unaltered.

Overall Price Effects

The costs associated with production changes may result in some manufacturers increasing their prices of pacifiers to distributors. This would probably lead to a slight average price rise at the retail level. Some firms have indicated that their prices may go up by as much as 10-15%. This will probably not be the case in all firms: some have said that the costs of compliance will not be sufficiently large to motivate a price increase, given the price-competitive nature of the market. If the three or four largest sellers do not raise their prices, the rest of the industry will probably follow suit. This same phenomenon was observed when

the industry changed molds to meet the 1972 proposal: the costs were largely absorbed by the manufacturers, and not passed on to consumers in the form of retail pacifier price increases or lower quality merchandise. Thus, short-term contribution to gross profit margins for many pacifier models may decrease somewhat. These currently vary with the type of pacifier, the manufacturer, etc.

We estimate retail price increases for those models that undergo any increase to range between 2 and 10 cents per unit, depending on the model. This may be the result of new features on existing models, or the replacement of one model with another of the same basic design but of a different material, for example, to add guard rigidity. The total annual cost to consumers attributable to the regulation may be as much as $1.3 million. We regard this figure, however, as an upper limit: as noted above, there may, in fact, be no perceptible price rise.

For those firms which employ full-cost pricing methods, pacifier-related cost increases may be reflected not only in the price of pacifiers, but in the price of other baby products. Alternatively, prices of other baby products for which demand is perceived by the firm to be less price-elastic may rise to prevent pacifier prices, which are perceived to be fairly competitive, from rising. Prices of some pacifiers may also increase this year due to factors other than the regulation, such as labor or materials cost increases, etc.

Other Effects

Some pacifier models may be able to meet the regulation only after extensive modification or complete redesign. These may be dropped from production, or replaced with newer models that are more readily adaptable to the provisions of the regulation. At least one manufacturer, for whom gross profit margins on pacifiers are already claimed to be exceptionally low, may discontinue pacifier production if the regulation requires the purchase of new molds. The other manufacturers are expected to continue production.

The publicity surrounding the development of the regulation and the uncertainty among wholesale and retail buyers of pacifiers has already begun to have an effect on the manufacturers: some firms have reported that orders either are being curtailed or are not being placed until the regulation is published and complying goods are available. Thus, substantial growth in pacifier sales before the regulation is promulgated is unlikely. This may lead to an excessive buildup of manufacturers' finished goods inventories to the extent promulgation is delayed.

Improved resistance to boiling and pulling (and therefore longer product life) will probably result from compliance with the structural integrity requirements of the regulation for some models. This would constitute an increase in the utility derived from the product by consumers. This may, however, have an adverse effect on sales, given a roughly constant birth rate, if replacement becomes necessary less often.

Effective Date

As we have noted in our February 8, 1977 memo, it is our understanding that the domestic manufacturers can comply with the regulation as reproposed within six months. Two extra months, or a total of eight months from the date of publication in the Federal Register, may be necessary for foreign producers to package and ship their goods to this country. A six to eight month effective date would not, however, allow for extensive production and market testing. Normal testing periods in the industry currently run about 6-12 months for new products or substantial product design changes. Some of this testing has been performed on a preliminary basis by some of the producers; one firm claims to have a model available which meets all the provisions of the reproposed regulation.

BEA 4/15/77

PACIFIER REGULATION: ENVIRONMENTAL ASSESSMENT

The reproposed pacifier regulation is intended to improve the safety of pacifiers by reducing the risk of choking. This is expected to be accomplished by certain structural and dimensional changes. The requirements of the regulation will result in some changes in production equipment, processes and costs, and possibly in retail price.

Examination of the possible effects reveals no significant environmental impact (see attached list of items considered). There may be a small increase in the use of raw materials and there will be some changes in production equipment, but neither of these will have any discernible effect on air and water quality, solid waste disposal, land use, energy use or other aspects of the environment. The probable economic effects of the regulation are discussed in BEA's report entitled, "Potential Economic Effects of the Pacifier Regulation."

No environmental impact statement is required.

ENVIRONMENTAL IMPACT: REPROPOSED PACIFIER REGULATION

Negative Declaration:

Pursuant to the National Environmental Policy Act and in accordance with the Council on Environmental Quality Guidelines and CPSC Policies and Procedures, an assessment of the reproposed Pacifier Regulation has been conducted by the Bureau of Economic Analysis.

The assessment concludes that no significant adverse effects on the environment are foreseen and therefore, no environmental impact statement need be prepared.

Walter R. Hobby, Director
Bureau of Economic Analysis

PACIFIER REGULATION

MATRIX 1: PRODUCTION

Possible Impacts	Assessed Impact Severity						
	Adverse Impact			Beneficial Impact			Negligible
Raw Materials	L	M	S	S	M	L	Impact
1a1 Availability							X
1a2 Land Use	◯						X
1a3 Associated Industries							X
1a4 Cost							X
1a5 Transportation Systems							X
1a6 Energy Requirements	◯						X
1a7 Health/Safety	◯	◯					X
1a8 Emissions							X
1a9 Employment	◯						X
1a10 Aesthetics							X
Processing							
1b1 New Technologies							X
1b2 Health/Safety	◯	◯					X
1b3 Employment	◯						X
1b4 Residuals							X
1b5 Cost		X	X				
1b6 Emissions							X
1b7 Related Industries							X
1b8 Energy Requirements							X
1b9 Time Delays/Advances	◯						X
1b10 Aesthetics							X
1b11 Location							X

◯ Level of severity of indicated impact that is likely to warrant filing of an Environmental Impact Statement

PACIFIER REGULATION

MATRIX 2: DISTRIBUTION

Possible Impacts	Assessed Impact Severity						
	Adverse Impact			Beneficial Impact			Negligible
Packaging	L	M	S	S	M	L	Impact
2a1 Weight/Space							X
2a2 Labor Force							X
2a3 Related Industries							X
2a4 Health/Safety	◯	◯					X
2a5 Cost			X				X
2a6 Energy Requirements	◯						X
Transportation							
2b1 Mode							X
2b2 Shipment Requirements							X
2b3 Labor Force							X
2b4 Cost							X
2b5 Health/Safety	◯	◯					X
2b6 Energy Requirements	◯						X
Outlets							
2c1 Marketing Techniques							X
2c2 Profit Margin			X				X
2c3 Stockpiles							X
2c4 Trade Balance							X

◯ Level of severity of indicated impact that is likely to warrant filing of an Environmental Impact Statement

PACIFIER REGULATION
MATRIX 3: CONSUMPTION

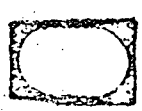
Possible Impacts	Assessed Impact Severity						
	Adverse Impact			Beneficial Impact			Negligible
Purchasing Patterns	L	M	S	S	M	L	Impact
3a1 Consumer Composition							X
3a2 Price		X	X				X
3a3 Longevity				X			
3a4 Utility							X
3a5 Foreign Consumption							X
3a6 Reduced Selection			X				
3a7 Aesthetics							X
Consumption or Use of Product							
3b1 Residuals/Emissions							X
3b2 Health/Safety				X			
3b3 Energy Requirement							X
3b4 Energy Form							X
3b5 Associated Industries							X
3b6 Number of uses/ alternative uses							X

Level of severity for indicated impact that is likely to warrant filing of an Environmental Impact Statement

PACIFIER REGULATION

MATRIX 4: DISPOSAL

Possible Impacts	Assessed Impact Severity						
	Adverse Impact			Beneficial Impact			Negligible
Solid Wastes	L	M	S	S	M	L	Impact
4a1 Litter	◯						X
4a2 Recyclable							X
4a3 Collection Cost							X
4a4 Labor Force							X
4a5 Pollutants	◯						X
Hazardous Wastes							
4b1 Hazardous/Toxic Wastes	◯	◯					X



Level of severity for indicated impact that is likely to warrant filing of an Environmental Impact Statement

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, Technical Analysis Division, OSCA
Through: Dale Miller, Director, BCMI DATE: 17 DEC 1976

FROM : Liz Jones, BCI

SUBJECT: Comments on November 20, 1976, Proposed Pacifier Regulation

We have reviewed the seven comments and have the following comments and/or questions:

Labeling

We continue to believe that the labeling concerning the use of string or ribbon is appropriate; however, we do agree with Mr. Schmitt of **Questor** Juvenile Products Co. and recommend that the labeling be altered to read as suggested by Mr. Schmitt.

Shield or Guard Dimensions

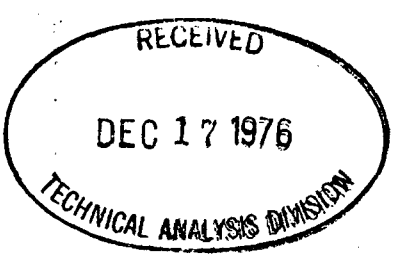
Several commentors contend that the shield or guard dimension requirements will cause the shield or guard of a flexible pacifier to interfer with a child's nose and make the pacifier practically useless and difficult to sell. One commentor also contends that the regulation as proposed would in essence "ban" pacifiers with a flexible guard or shield. If these statements are in fact true, we may be forcing a trend away from the one-piece flexible pacifier which would appear to be the safest type of pacifier currently available. What anthropometric and/or other data do we have to refute these statements? If such data is not available, we suggest a re-evaluation of the shield or guard dimension requirements.

The comment concerning the inconsistency between the proposed shield or guard dimension and the use of the small parts cylinder as the criteria for evaluating the size of a component which has been removed during use and abuse testing appears to be valid. What justification do we have for this inconsistency?

Ventilation Holes

1) Has OMD and/or BBS evaluated the potential for bacterial growth in the ventilation holes? If so, what are their findings.

2) To what extent will the ventilation holes weaken the structure of a rigid shield and/or increase the flexibility of a flexible shield? What data do we have to refute these contentions?



UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, TAD/OSCA
Through: Acting Assoc. Exec. Dir. for Compliance & Enforcement

DATE: 14 MAR 1977

Through: Director, Division of Inspection & Enforcement RCR

FROM : Liz Jones, BCMI

SUBJECT: Compliance Strategy for Pacifiers

The attached compliance strategy is provided for inclusion in the briefing package for the pacifier regulation.

Attachment

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

Proposed Compliance Strategy for Pacifiers

BEA has identified 23 firms engaged in the manufacture and/or distribution of pacifiers and has reported that most of these firms produce or sell more than one model or type of pacifier. BEA also reported that the pacifier industry is somewhat complex, in that a single firm may sell pacifiers that have been manufactured by the firm, imported by the firm and also bought from other domestic firms. These pacifiers may be sold under the firm's own brand name and/or under one or more of their customer's labels. In addition, the pacifiers may be sold to retailers, jobbers and/or distributors. Due to this complicated distribution system and the absence of product identification and record-keeping requirements, we anticipate some difficulties in tracking a banned pacifier once it has entered the distribution channels.

Industry Education

Due to the enforcement difficulties cited above, we see the need for extensive Commission effort to notify and educate the industry prior to the effective date of the regulation. Therefore, following the publication of the final regulation in the Federal Register all known pacifier firms will be invited to attend an industry seminar which will include a demonstration and discussion of the testing procedures specified in the regulation and will provide an opportunity to clarify any misunderstandings concerning the regulation. Due to the high concentration of the known industry in the New York area, we would anticipate holding the seminar in the New York Area Office. The seminar will be planned and conducted by BES and BCM with assistance from BIE and/or the training division, as needed.

CPSC Staff Training

An extensive training seminar for investigators does not appear to be necessary. However, we will provide guidance in the Pacifier Compliance Program for on-site screening evaluations.

Compliance Program

Following the effective date of the regulation, all known firms will be inspected to determine what action has and/or is being taken by the individual firms to assure compliance with the regulation. The regulation does not include a testing program; however, compliance with the majority of the requirements may be achieved by product design and a good quality control program. To confirm compliance however, representative samples of at least one pacifier model manufactured, imported and/or distributed by each firm will be collected for testing by the Commission. The manufacturing and/or importing lots of the pacifier model(s) selected for sampling will be identified and pacifiers will be randomly selected from each designated lot. In addition due to the large volume of imported pacifiers, a dock surveillance program will be initiated in cooperation with local U.S. Customs officials to sample pacifiers being imported by previously unidentified firms. The imported lots will not be held pending sample analysis; however, the responsible firm will be informed of the regulation and notified that a sample has been collected for compliance testing.

A pacifier that fails to comply with the requirements of the regulation is a banned hazardous substance and subject to repurchase under the FHSA. If failures occur, the extent of the enforcement action (i.e. limited to one lot or all units of that model manufactured after the effective date of the regulation) will be determined on a case by case basis. This decision will be dependent upon the type of failure, the failure rate of the units tested, and the extent to which we can project total product failure.

This compliance strategy will require the following estimated field professional non-supervisory manhours:

*	Initial Inspections:	30 @ 11.4 MH =	342. MH
	Sample Collections: (including dock surveillance samples)	45 @ 5.1 MH =	229.5 MH
**	Follow-up Inspections:	5 @ 11.4 MH =	57.0 MH
**	Case Development	5 @ 36.0 MH =	180.0 MH
	TOTAL		808.5 MH

Fifteen of the 23 known firms are located within the New York Area Office; therefore, one or more investigators from another area office may need to be detailed to the New York Area Office during the inspectional phase of the program. The need for such a detail is of course dependent upon the total New York Area Office obligations during that time frame and the FY 78 Field Plan has not yet been prepared. In addition to the field time projected above, we would anticipate the need for an additional 100 to 500 field manhours per banned pacifier to monitor the repurchase.

The strategy will also require the following estimated headquarters professional non-supervisory manhours:

	BESL Sample Analysis:	45 @ 4.0 MH =	180.0 MH
***	BCM Case Processing:	2 @60.0 MH =	120.0 MH
	TOTAL		300.0 MH

When completed, the program will be evaluated to determine the need for future compliance activity in this product area. An over-view memorandum will also be prepared at that time and forwarded to the Commission.

---

* Allows for an additional 7 firms which may be identified through U.S. Customs or other sources.

** Based upon a projected non-compliance rate of 15%. A relatively high level of compliance is anticipated due to the extensive education program prior to the effective date of the regulation.

***BCM case processing includes only those cases that the Commission has voted to prosecute and is based upon a projected prosecution rate of 7 to 8%.

Consumer Information

BIE will initiate an information program directed toward retailers and consumers. The activity will include the development of a general Fact Sheet and a Technical Fact Sheet. These materials will be mailed, with a copy of the Federal Register notice of the regulation to large chain stores and national retail associations representing pharmacies, department stores, 5 and 10 cent stores, and/or supermarkets. The latter groups will be encouraged to provide the information to all member retailers and to encourage them to inturn disseminate the information concerning consumer awareness of proper use and to obtain written guarantees from their pacifier suppliers stating that the pacifiers being purchased comply with the regulation.

The information materials will also be disseminated to consumers and consumer groups through the routine distribution channels of each Area Office.

The combined industry education and consumer information programs will require an estimated .1 MY of headquarters time, $2,000 dollars in contact funds, $5,000 dollars in operating funds and a .2 MY of Area Office time.

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza
Technical Analysis Division, OSCA

DATE: April 25, 1977

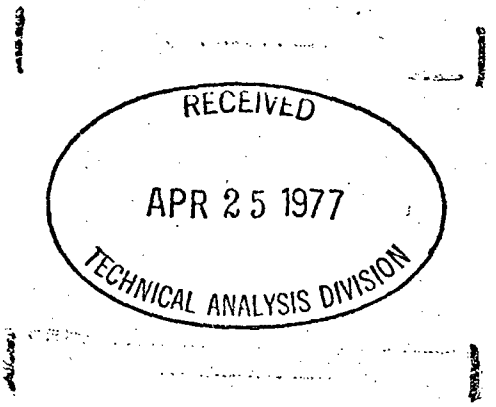
FROM : Bessie T. Draper, Acting Director
Bureau of Information and Education

SUBJECT: Final Pacifier Regulation

In follow-up to my memo of April 22, we have reviewed the commitments and resources with Elizabeth Jones, BCM.

Consequently, we would like to modify the last sentence of the March 14, 1977, memo from BCM as follows:

> The combined industry and consumer information programs will require .2 MY of headquarters time, $2,000 in contract funds, $8,600 in operating funds and .2 MY of Area Office time.



*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menze, Technical Analysis Division, OSCA DATE: March 25, 1977

FROM : Robert M. Hehir, Director, BBS R. M. Hehir 3/25/1977

SUBJECT: Comments on Infant Teethers

Attached are the Bureau's comments and views on the infant teether material submitted to the Commission by the Monroe County, New Jersey Health Department.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

MEMORANDUM

CONSUMER PRODUCT SAFETY COMMISSION

DATE: March 21, 1977

TO : R. M. Hehir, Director, BBS

FROM: S. Molinas, Ph.D., BBS S. Molinas 3/21/1977

SUBJECT: Comment on Infant Teethers - Item Submitted by Monroe County, N.Y. Health Department.

No action is indicated on the subject infant teethers (follow-up inquiry by W. Menza).

The firm (Reliance Products Corporation, Woonsocket, R.I.) voluntarily recalled the teethers referred to by the Monroe County Health Department in December of 1975. The contents of the teethers had also been reformulated in September 1975, and toxicological and bacteriological tests conducted on the reformulated product.

According to the firm, the results of the tests indicate the contents of the teethers do not constitute a health hazard.

The concern with the contents of the recalled teethers was: 1) the presence of bacteria (ranging from $\leq$ 1/ml to 30,000/ml (TNTC - too numerous to count) but no coliforms; and 2) the presence of 300 PPM of Quaternary Ammonium Compound.

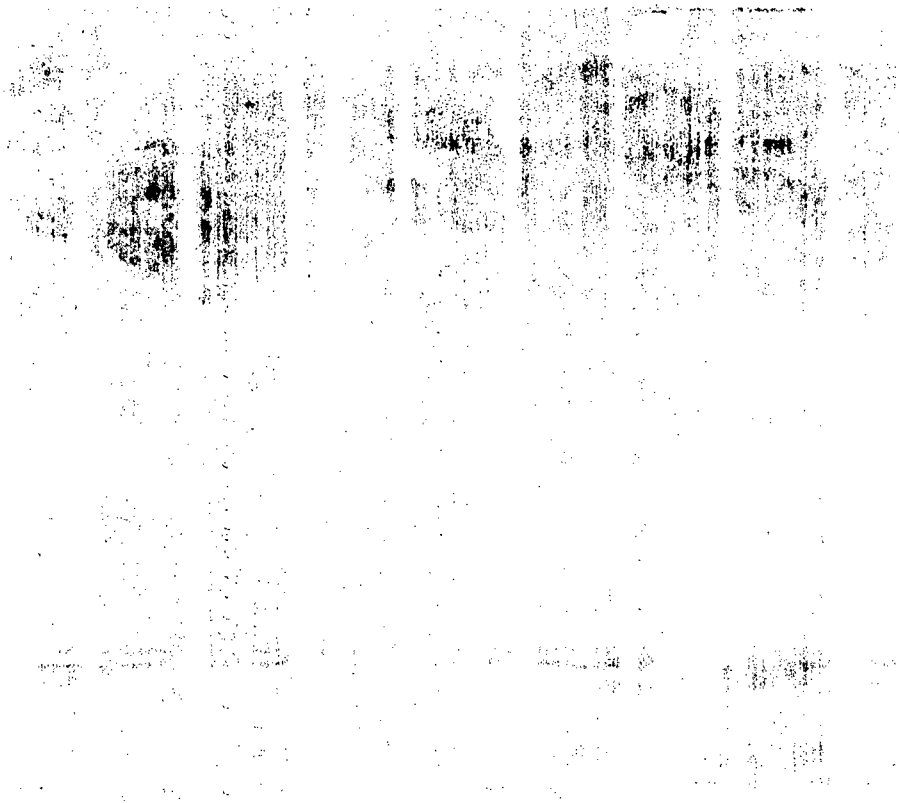
The primary concern of the Food and Drug Administration was the presence of the Quaternary Ammonium Compound (QAC), as indicated by FDA memo of 11/7/75: "Our medical advisors are concerned about the use of the Quaternary Ammonium Compound in the water since the ingestion can cause gastrointestinal irritations, convulsions, coma, respiratory distress and collapse."

The QAC used in the teether water as a bacteriostat, was a diluted version of Hyamine 2389 (a combination of methyl dodecyl benzyl trimethyl ammonium chloride and methyl dodecylxylene bis (trimethyl ammonium chloride). The oral LD_{50} for Hyamine 2389 is reported by the firm (Rohm and Haas) to be 389 ml/kg.

The product would not have been subject to the provisions of the FHSA on the basis of oral toxicity due to the presence of 300 PPM (0.03%) of the QAC. Additionally, the 33 ml of water in the teether would contain a total of 9.9 mg of the QAC.

The Commission (in 1975) was informed of the concerns of the Monroe County Health Department regarding the teethers, but referred the matter to the FDA as medical devices.

There may now be dual jurisdiction over pacifiers, and possibly teethers, between FDA and the Commission; however, it is my opinion that standards for the inner contents of such products (bacteriological and chemical content) should remain under the purview of the FDA.



NOTE: Additional information on these teething rings from the New York, Monroe County, Department of Health, is on file in Technical Analysis Division, OSCA.

MONROE COUNTY
DEPARTMENT OF HEALTH
111 WESTFALL ROAD, ROCHESTER, NEW YORK 14602

TELEPHONE 442-4000
AREA CODE 716

March 11, 1977

Elaine Besson
Office of the Executive Director
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

Dear Ms. Besson:

First off, please accept my apologies for not responding earlier to the Commission's request, made through Mrs. Judy Braiman, for information relative to experiences we have had with unsafe infant teethers and pacifiers.

Secondly, let me say that we in the Monroe County Department of Health commend the Commission on its plans to develop standards for teethers and pacifiers, and although our experience with these products is limited we strongly endorse the establishment of such standards.

Our chief concern is over potentially injurious liquid contents of teethers--from both bacteriological and chemical standpoints. This concern came as a result of an episode in 1975 in which first one mother, then another, reported to us that their infants had become ill after ingesting some of the liquid contents of a particular teether. Considerable field and laboratory work was carried out in a resulting investigation by us, the New York State Health Department and the U.S. Food and Drug Administration, that eventually led to a recall. I have made copies (enclosed) of documents involved in this episode, which I believe demonstrates need for standards relating to liquid contents of all teethers.

The only pertinent experience I can share with you is a recent compliance episode in which a pacifier, previously banned by the Commission, was apparently still in retail distribution locally. This led to a news release based on suggestions and advise from both the Commission and the New York State Health Department. Here, again, I have enclosed copies of supporting documents.

I hope this information is helpful. Please call me if you have any questions on the teether episode or if I can be of any further assistance.

Sincerely,

John Van Buren
Health Information Officer

JVB/dls
cc. Mrs. Braiman
Mr. Fisher

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

November 25, 1975

Mr. Leslie Fisher
Adviser for Product Safety
New York State Department of Health
Empire State Plaza
14th Floor
Albany, New York 12237

Dear Mr. Fisher:

As you requested in your telephone conversation with Mr. Dan R. Beardsley of this office, 11/24/75, I am enclosing a copy of the comments the Bureau of Medical Devices and Diagnostic Products made on review of Establishment Inspection Reports and Sample Analysis of Teethers, from Reliance Products Corporation and Mark Stevens, Inc.

Sincerely yours,

Muriel Gelles

Muriel M. Gelles
Division of Compliance
Bureau of Medical Devices and
Diagnostic Products

Enclosure:
11/7/75 memo BOS-DO

Note Attached comments subject to updating L.F

(facsimile)

BOSTON DISTRICT
COMPLIANCE BRANCH, HFR-1140
ATTN: B.W. SEMIS, COMPLIANCE OFFICER

November 7, 1975

Division of Compliance, HFK-100

Mfr: Reliance Products Corp
106 Mason Street
Woonsocket, Rhode Island 02895

Review of BIR's, Both Firms
Sample 76-05-285, Teething Ring

Detbr: Mark Stevens, Inc.
400 Founders Ave
Woonsocket, Rhode Island 02895

We have completed our review of the above-referenced BIR's and the worksheets for sample 76-05-285. Scientific personnel within the Bureau consider the presence of both the Quaternary Ammonium Compound and the gram negative bacteria in the water-filled teethers to be a potential health hazard, should the contents be accidentally ingested by an infant.

We suggest you advise Reliance Products Corporation of the fact that we consider the water-filled teethers to be adulterated because of the presence of bacteria in the water, and misbranded since the statement "Filled with Pure Water" is false and misleading because the product contains approximately 300 ppm quaternary ammonium compound. Our medical advisors are concerned about the use of the Quaternary Ammonium Compound in the water since its ingestion can cause gastrointestinal irritations, convulsions, coma, respiratory distress and collapse. You should determine what further action the firm plans on taking with respect to the product currently in commerce. Should the firm not voluntarily elect to remove it from commerce, the Bureau is in position to support an FDA initiated recall or other regulatory action.

We consider the action by Mark Stevens Incorporated to be a voluntary recall. The firm should be advised of this, complete Appendix A information should be secured, and an R&R submitted to HFK-100.

Lee C. Matthews

Enclosure:
cc this memo

cc RFDD, Region I

HFK-100 (Shaw, Pre-Recall File)
HFO-110
HFK-1 R/F
HFA-226

Init HEButts 11/7/75

LCMatthews:js d/t 11/6/75

DISCUSSION DRAFT IA
11/26/75

Cc. Jack Van Bur
John Campan
see p. 3
Letter

corr. are my notes
R. Burton

Meeting Between

New York State Department of Health
and
Reliance Products Corporation
Woonsocket, Rhode Island
at
New York State Department of Health
Empire State Plaza, Tower Building, Albany

November 28, 1975

To explore whether their baby teethers pose an "unreasonable" risk for children, the degree of that risk, and possible remedial action by the State of New York.

Background and Summary

On ~~September~~ August 11, 1975 the Monroe County Health Department, following a report from the Poison Control Center of Strong Memorial Hospital, contacted the New York State Department of Health, Home Product Safety Program, to report that a 5-month-old child had bitten through a plastic ring teether, swallowed some of the liquid contents and immediately regurgitated. No other symptoms were noted.

The Advisor for Product Safety promptly reported the episode orally to the Consumer Product Safety Commission (which under PL 92-573 has the authority to receive complaints of possible "substantial" hazards and to investigate them). In addition, he called the Reliance Products Corporation's President to alert the company to the condition for possible information and assistance. At that point in time, he was specific to mention that perhaps a health problem existed and the information was being shared with the company for their review. With the assistance of the Advisor for Product Safety, Monroe County Health Department immediately wrote the Reliance Products Corporation, the U.S. Food and Drug Administration, the Consumer Product Safety Commission and the New York State Health Department's Product Safety Program citing its findings. (Attachments 1, 2, 3)

The letters from the county health department described the product involved, the sequence of events in the episode, a quantitative microbiological analysis of the contents of 5 similar teethers by the County Health Department. The total acidity was considered to be moderately high, (attachment 1). Additional laboratory data are available from Monroe County and will be discussed.

Two questions were posed during these discussions:

1. Is the plastic polyvinyl chloride (i.e. it might be associated with a carcinogenisis)?

2. What were the ingredients in the liquid to result in such a high acidity and was that related liquid associated with the episode?

From FDA we learned that potable drinking water only limits coliforms and we learned, in discussions with the company, that the chemicals present in the teether included chlorine bleach (a sanitizer), quaternary ammonia ("killmore" sanitizer), and the water from the Woonsocket City water supply.

The resulting acidity, therefore, could be associated with the sanitizing chemicals (which, in fact, actually neutralize the sanitizing effect of each other), and, according to key toxicological references could be associated with the vomiting of the child. ① we have no explanation for pH level ② Surfactant effects | labelling - water filled safe - sanitary

After the consultation with Monroe County Health Department and our State Health Department laboratories, we advised the company that QAC ammonia compounds can be considered to be moderate to very toxic, and that the risk to a young child might be even greater because of his age and stage of development.

By September 5, 1975, the Consomer Product Safety Commission had suggested that this particular product was probably in the realm of Food and Drug Administration's law and subsequently they shared the information with the Bureau

of Medical Devices FDA, Washington.

About the same period of time the Monroe County Health Department in response to media inquiries stated they were investigating that they were not sure of the degree or nature of risk but were asking for additional reports of similar episodes. Thereafter, the county health department did receive one additional report of a 7-month-old boy had vomited intermittently for the previous 18 hours and the pediatrician cited the problem as probably a viral type illness that would "run its course". However, shortly after she spoke to the pediatrician, the mother saw the article in the local newspaper about the problem and checked the suspected illness with the associated injestion of the fluid of the teething ring. The ring was the same product manufactured by Reliance Products Corporation and the product was exposed only the previous evening for the first time. (Attachment 4)

The Reliance Products Corporation was continually in contact with this Department and updated as to the findings of the Monroe County Health Department and to our referral to the Food and Drug Administration. They decided upon their first contact with us, to cease production and distribution of their product and study the condition. Later, they did not feel that the situation was a "health issue" but a "problem."

A toxicological consultant for the Monroe County Health Department stated that the concentration of quaternary ammonia in the teethers could, in fact, affect the mucus membrane of a young child and vomiting was a distinct risk, especially to a small child, that the product may be mislabeled and the company might consider other ways to sanitize which did not present a possible risk to a child.

Reliance Corporation mentioned that they had hired consultants (ADL) to evaluate the whole chemical and bacteriological system of the product's production. (Attachment 5)

On September 12, one of the independent distributors of the product had advised all its stores and that the product be returned to the warehouse immediately.

The Food and Drug Administration conducted a detailed inspection of the facilities on October 1, 1975 and gathered samples for testing. We received an oral communication from FDA on November 21, 1975 that irritation, collapse, convulsions, respiratory stress can, in the opinion of the FDA medical staff, might occur from the swallowing of this product. The FDA Boston Office had visited the company and the company had apparently refused to conduct a retail recall of the items.

Additional federal action will probably occur. Meanwhile, the Department cites the need to control any "unreasonable health risk" in New York State and plans to issue a release in cooperation with the company, if possible, and if necessary consider appropriate legal action. The company, however, requested today's meeting with the Department.

UNITED STATES GOVERNMENT

Memorandum

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

TO : Charles Casper, Director, SCAT
Attention: William Menza, SCAT

THRU : Robert Bledsoe, Director, SCAD 5-5-77

FROM : Delores Barros, Attorney, SCAD

DATE: May 4, 1977

SUBJECT: Final Regulation for Pacifiers

Attached is a draft of the final regulation for pacifiers. This draft incorporates the bureaus and offices latest suggested changes.

*U.S. GOVERNMENT PRINTING OFFICE: 1974 733-533/3604 1-3

Delores Barros, SCAD
May 4, 1977

Title 16--Commercial Practices

Chapter II--Consumer Product Safety Commission

Subchapter C--Federal Hazardous Substances Act Regulations

Part 1500--Hazardous Substances and Articles; Administration and Enforcement Regulations

Part 1511--Requirements for Pacifiers

Banning of Hazardous Articles and Establishment of Safety Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: This document prescribes a regulation (16 CFR Part 1511) for the safety requirements of pacifiers and a regulation (16 CFR 1500.18 (a)(8)) banning from interstate commerce pacifiers not meeting such safety requirements.

EFFECTIVE DATE: (insert date that is 240 days after publication of this notice).

FOR FURTHER INFORMATION, CONTACT: William Menza, Office of Standards Coordination and Appraisal, 5401 Westbard Avenue, Bethesda, Maryland 20207, (301-492-6470).

SUPPLEMENTARY INFORMATION:

In the FEDERAL REGISTER of October 20, 1976 (41 FR 46347), the Consumer Product Safety Commission (CPSC) proposed for public comment a regulation (16 CFR Part 1511) prescribing safety requirements for pacifiers and a regulation (16 CFR 1500.18(a)(8)) banning from interstate commerce pacifiers not meeting such safety requirements.

The Commission proposed banning and safety requirements for hazardous pacifiers pursuant to section 2(f)(1)(D) of the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261). Section 2(f)(1)(D) provides for the classification of any toy or other article intended for use by children as a hazardous substance upon a determination by regulation, in accordance with section 3(e)(1) of the FHSA (15 U.S.C. 1262), that it presents a mechanical hazard. In addition, section 2(q)(1)(A) of FHSA provides that such toy or article be termed a banned hazardous substance.

The need for this regulation was demonstrated by injury data and death reports. Eight deaths, and seven choking incidents which did not result in death, associated with pacifiers were reported between 1970 and 1975. They were mentioned in the October 20, 1976, proposal. Two of the deaths were due to choking and six to strangulation. Since that time, it has been determined that there were two additional choking deaths which were not indicated in the October 1976 proposal.

DISCUSSION OF MAJOR COMMENTS

The proposal of October 20, 1976, invited interested persons to submit comments on or before November 19, 1976. A total of 10 comments were received: seven from manufacturers (6 domestic and one foreign), one from a retailer, one from a domestic manufacturer's association and one from a foreign Trade Commission.

The major criticisms concerned the definition of a pacifier, the guard or shield requirements, particularly the requirement for ventilation holes, and the cautionary labeling statement.

The principal issues and criticisms raised in the comments and the Commission's response to these points are as follows:

A. § 1511.2 Definitions. One commentor suggested that the definition of a pacifier be reworded to exclude products that have a nipple but do not have a guard or shield. The Commission does not agree since such a change might allow the sale of products that can present the hazards the pacifier regulation is designed to prevent.

To clarify the exclusion of nipples intended for dispensing liquids from bottles the Commission has changed the definition of a pacifier as follows.

"A pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid and usually includes a guard or shield and a handle or ring.

B. § 1511.3 Guard or shield requirements. Several commentors criticized the proposed requirements for guards or shields. The commentors stated (1) that the diameter of the opening in the test fixture in figure 1(a) is too large, (2) that the regulations should define the minimum area measurements and widths of shields, since large oval or eliptical shields could slide through a circular fixture, and (3) that the testing of pacifiers in the most adverse orientation is excessively rigorous..

The Commission finds that the fixture opening diameter is not excessively large since its size is based on sample measurements of

children's mouths taken by the Maryland State Department of Health and Mental Hygiene. The Commission believes that a reduction in the dimensional requirements to those recommended by the commentors may not be adequate in preventing entry of the pacifier into a child's mouth and would not reduce or eliminate the risk of injury or death by asphyxiation. However, the most adverse orientation requirement may be unnecessarily stringent. Tests of pacifiers performed by the Commission's staff showed that many pacifiers with non-circular shields of a generous size could not comply with the proposed requirement. These same pacifiers, when centered on the opening of the fixture would comply. Lack of injury data on these pacifiers indicates that presently they do not present an unreasonable risk of injury. Therefore, the regulation has been changed so that the nipple of the pacifier is centered in the opening of the fixture. Such a change would permit the sale of pacifiers which had a simple bar at right angles to the nipple axis provided that the bar was larger than the diameter of the opening. In the opinion of the Commission such a bar would not be an effective substitute for a guard or shield. To prohibit the use of such a bar the Commission has modified the opening in the guard or shield test fixture to include slots on either side of the circular opening. The resulting configuration, shown in figure 1(a) of the regulation below, is similar to an existing requirement in a Canadian regulation for pacifiers. To relieve manufacturers and distributors from the burden of complying with two regulations with essentially similar requirements, the Commission

has reduced the diameter of the circular opening from 1.70 inches to 1.68 inches (an insignificant amount). With similar fixture opening dimensions in the two regulations the Commission believes that compliance efforts in the U.S. and Canada could mutually support each other.

One commentor asked that the test force of 2 pounds be reduced to 1 pound because children are not as strong as adults and cannot develop the suction which adults attain. Although the suction of adults was initially used in determining this force, a fatality moved the Commission to consider the force that could develop if a child should fall or roll over with a pacifier in it's mouth. The weight of the child's head resting partially on the pacifier can reasonably be expected to develop a force of 2 pounds. Therefore, the Commission finds that a 2 pound force is necessary to allow for a margin of safety.

Two commentors said that the 43 mm dimensional requirement would force pacifier guards or shields to be so large that they could cover a child's nostrils and impair breathing. The Commission is aware of pacifiers currently on the market that meet the dimensional requirements of the proposed guard or shield test and is not aware of any complaints or reports of injuries involving these pacifiers.

One commentor felt that there is an inconsistency between the guard or shield requirements and the small parts test. The guard or shield requirement is designed to prevent impaction of the entire pacifier in the child's mouth. The use of the small parts test is intended to

insure that if a pacifier should break, the parts would not be readily aspirated, ingested or cause choking.

C. § 1511.3(b) Ventilation holes. Commentors on this proposed requirement said that (1) it has no merit, (2) it is unhygienic, (3) it will prevent sucking, (4) it will weaken the shield, and (5) it will provide holes by which to attach strings to fasten the pacifier around a child's neck. One commentor recommended that other means of providing air flow, like "V" or "U" notches, be permitted and another suggested that if there had to be holes, 4 holes would assure alignment with breathing passages.

The Commission's medical staff states that the purpose of the ventilation holes are to (1) provide an auxiliary pathway for air to the lungs including the insertion of a nasal catheter and (2) provide a means to remove a pacifier impacted in the throat.

On the criticisms of this requirement, the Commission points out that at least 2 holes are required. If one is closed by throat tissue, the second hole could still be open to provide an auxiliary air passage or to facilitate removal of the pacifier. Dirt and bacteria trapped in the holes should prove no more harmful than dirt and bacteria found on the pacifier surface or in junctions, as between the nipple and shield of a multipiece pacifier. This dirt and bacteria should be removed regardless of where it is on the pacifier; surface, junctions, or ventilation holes. As for the comment that the ventilation holes would prevent sucking, the Commission points out that the nipple and not the

shield is sucked on by the child. The Commission's Bureau of Engineering Sciences laboratory punched or drilled ventilation holes in several shields to see if they would weaken the shield, and found that the strength of the shield was not measureably affected. Required cautionary labeling should minimize consumers using the holes to tie a pacifier around a child's neck.

For these reasons the Commission finds that the ventilation holes as proposed are necessary to prevent or eliminate unreasonable risk of injury and should be required. As for the suggestion for "V" or "U" notches the Commission believes that permitting an infinite variety of holes and notches could delay emergency personnel searching for openings in which to insert a nasal catheter to assist breathing or a hook to facilitate removal of the pacifier. In regard to the suggestion for 4 holes to assure alignment with breathing passages, the Commission believes that 2 holes will adequately accomplish the intended purpose but has not precluded the use of 4 holes.

D. § 1511.4 Protrusion test. The comments on this requirement were that it is: (1) unnecessary, (2) unclear, and (3) that the allowed protrusion dimension be increased from 16 to 18 millimeters. One commentor felt that this requirement is necessary. The Commission believes this requirement is necessary to prevent pacifiers from being forceably pushed into a child's throat by a child rolling face down on a firm surface, while sucking on a pacifier. Therefore, the Commission finds that increasing the permissable protrusion from 16 to 18 mm would

only decrease the margin of safety. However, the Commission finds that the wording of the test procedure in this requirement of the proposal may be unclear. Accordingly, § 1511.4 below has been changed to clarify that during the test, flexible or hinged handles are allowed to buckle or freely rotate during the application of the plane surface. A further change has also been made to clarify the distance to be measured when testing a pacifier with a curved shield, as follows: "Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple." This clarifies the test.

One commentor said that a nipple length of no longer than 30 mm should be required. The Commission has no hazard information or medical information at this time to require that the nipple length be no longer than 30 mm.

E. § 1511.6 Ribbons, strings, cords etc. The Commission's staff noted that the wording of this requirement is ambiguous. It tends to qualify the length of the ribbon, string or cord when its intention is to prohibit such attachments to a pacifier. Therefore, the Commission has changed the wording of this section to read as follows:

> "A pacifier shall not be sold or distributed with any ribbon, string, cord, chain or ribbon-like attachments."

F. § 1511.7 Structural integrity tests. A commentor said that the boiling test time should be no less than 5 minutes, and another said it

should be reduced to 3 minutes. A third commentor said he was in agreement with the proposed test requirements. The boiling test time of 5 minutes is based on common household practice to sterilize pacifiers. Accordingly, the Commission has not changed the time for boiling in the heat cycle deterioration test.

The Commission draws attention to the change in the Small Parts Gage shown in figure 2 of the regulation below. Previous publications of this gage in a proposed regulation for small parts, a voluntary toy standard, and a foreign pacifier regulation used linear dimensions for diameter and depths with no tolerances. For consistency the method of dimensioning this gage in the regulation below has been changed. The Commission points out that the dimensions of the gage used for compliance testing shall be no greater than those shown in figure 2.

Federal energy conservation guidelines, published subsequent to the date of the proposal dictated a change to the temperature range specified for room temperature in the heat cycle deterioration test. The Commission has therefore changed the temperature range to 60° to 80° F (16° to 27° C) to allow testing in a typical laboratory winter or summer without violating Federal energy conservation guidelines.

G. § 1511.7 Labeling. Some commentors stated that this requirement was not necessary or that it should be worded differently. Several different warning statements were suggested. Of those suggested the Commission agrees that the wording: WARNING-DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING--IT MAY PRESENT A STRANG-

ULATION DANGER is a more appropriate label than that previously proposed since it is the ribbon or string that creates the strangulation danger and not the pacifier. Accordingly, § 1511.7 has been changed to adopt this suggested labeling requirement.

H. § 1500.18(a)(8) Effective date. Some commentors suggested that domestic manufacturers could comply with the proposed regulation within six months.

The Commission agrees that domestic manufacturers can make the changes to comply with the proposed regulation within 6 months but finds that it would take importers 1 or 2 months longer than domestic manufacturers to comply because of the added time for transoceanic shipping. The Commission therefore believes that the effective date of the regulation should be 240 days after publication.

ECONOMIC IMPACT ANALYSIS

The Commission estimates that some 15 million pacifiers are sold annually in the U.S. Most if not all new production will have to be modified to meet the regulation.

Substantial retooling costs may be incurred by some manufacturers to comply with the guard and ventilation hole requirements. These costs are primarily those associated with modification or replacement of injection molding equipment.

The Commission estimates that retail prices of some pacifier models may rise from 2 to 10 cents each. For other models, retail prices will

probably not show any increase. Some models of pacifiers may be discontinued, or replaced with other models which can more easily meet the regulation. One manufacturer has indicated that, should major mold changes be required, it may discontinue all pacifier production. It also appears that some wholesale and retail buyers intend to delay buying pacifiers until the regulation is published and complying merchandise is available.

METRIC CONVERSION

Domestic pacifier manufacturers generally produce other children's products. For consistency with previous CPSC regulations for children's products which acknowledge the current measurement practice of the industry, compliance tests prescribed by the regulation below shall be conducted by the Commission staff using the English units of measurement. The metric approximations are provided in the regulation for convenience and information only.

EFFECTIVE DATE

The effective date will be _____ [240 days from publication of a final regulation establishing safety requirements for pacifiers] introduced into interstate commerce after that date. For purposes of the regulation, introduction into interstate is defined for imported or domestically manufactured pacifier as follows: A pacifier manufactured outside the United States is introduced into interstate commerce when it is first brought within the U.S. port of _____

entry. A pacifier manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262) and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a); 86 Stat. 1231; 15 U.S.C. 2079(a)), a new paragraph (a)(8) is added to section 1500.18 and a new Part 1511 is added to Title 16, Chapter II, as follows:

§ 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:

* * * * *

(8) Any pacifier that does not meet the requirements of 16 CFR Part 1511 and that is introduced into interstate commerce after _____

[insert date that is 240 days after date of publication in the FEDERAL REGISTER].

* * * * *

PART 1511--REQUIREMENTS FOR PACIFIERS

Sec.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262.

§ 1511.1 Scope of Part 1511.

This Part 1511 sets forth the requirements whereby pacifiers (as defined in § 1511.2(a)) are not banned articles under § 1500.18(a)(8) of this chapter.

§ 1511.2 Definitions.

(a) A "pacifier" is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facili-

tate a baby's obtaining fluid and usually includes a guard or shield and a handle or ring.

(b) "Guard or shield" means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth.

(c) "Handle or ring" means the structure usually located adjacent to the guard or shield used for holding or grasping the pacifier. A hinged handle or ring is one that is free to pivot about an axis parallel to the plane of the guard or shield.

§ 1511.3 Guard or shield performance requirements.

(a) Place the pacifier in the opening of the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier is centered in the opening and protrudes through the back of the fixture as shown in Figure 1(b). For pacifiers with non-circular guards or shields, align the major axis of the guard or shield with the major axis of the opening in the fixture. Apply a tensile force to the pacifier nipple in the direction shown. The force shall be gradually applied within a period of 5 seconds and maintained at a maximum of 2.0 pounds (8.9 newtons) for an additional 10 seconds. Any pacifier which can be completely drawn through an opening with dimensions no greater than those of Figure 1(a) by such a force shall fail the test in this part.

(b) Ventilation holes. The pacifier guard or shield shall contain at least two holes symmetrically located and each being at least 0.20

inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier guard or shield.

§ 1511.4 Protrusions.

(a) Protrusion limitation. No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16mm) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) Protrusion test. Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be gradually applied to any protrusion from the guard or shield with a force up to, but not exceeding 2.0 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple.

§ 1511.5 Structural integrity tests.

(a) Nipple. Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force in any possible direction. The force shall be gradually applied within a period of 5 seconds and maintained at a maximum of 10.0 pounds (44.5 newtons) for an additional 10 seconds.

(b) Handle or ring. Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force shall be gradually applied within a period of 5 seconds and maintained at a maximum of 10.0 pounds (44.5 newtons) for an additional 10 seconds.

(c) Heat cycle deterioration. All pacifiers shall be subject to the following tests: Submerge the pacifier in boiling water for 5 minutes and then remove the pacifier and allow it to cool for 5 minutes in room temperature air, 60° to 80°F (16° to 27° C). After the cooling period, resubmerge the pacifier in the boiling water for 5 minutes. The process shall be repeated for a total of 6 boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and section 1511.3.

(d) Small parts. Any components or fragments which are released as a result of the tests specified in (a), (b) and (c) shall be placed in the truncated cylinder shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

§ 1511.6 Ribbons, strings, cords, etc.

A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, or ribbonlike attachments.

§ 1511.7 Labeling.

(a) As required by (b) and (c) below, pacifiers shall be labeled with the statement: "WARNING--DO NOT TIE PACIFIER AROUND CHILD'S NECK WITH ANY KIND OF RIBBON OR STRING--IT MAY PRESENT A STRANGULATION DANGER."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

§ 1511.8 Metric references.

For purposes of compliance with the test procedure prescribed by this § 1500.46, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

Dated: _____, 1977.

SADYE E. DUNN,
Secretary, Consumer Product
Safety Commission.

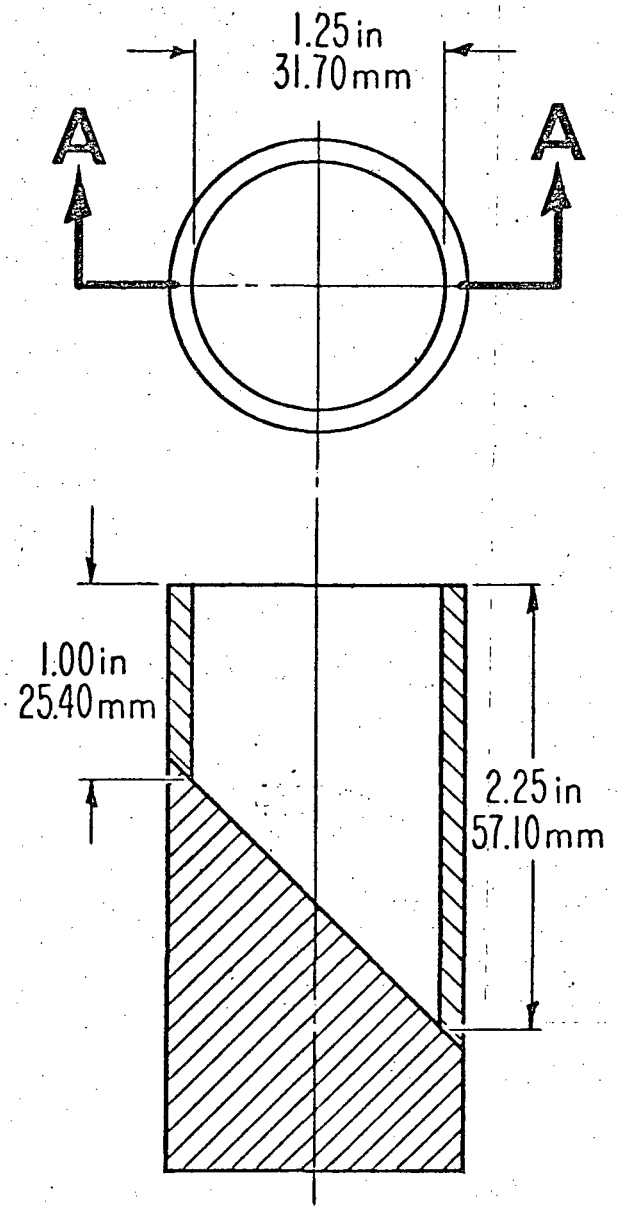


FIG 2-SMALL PARTS GAGE

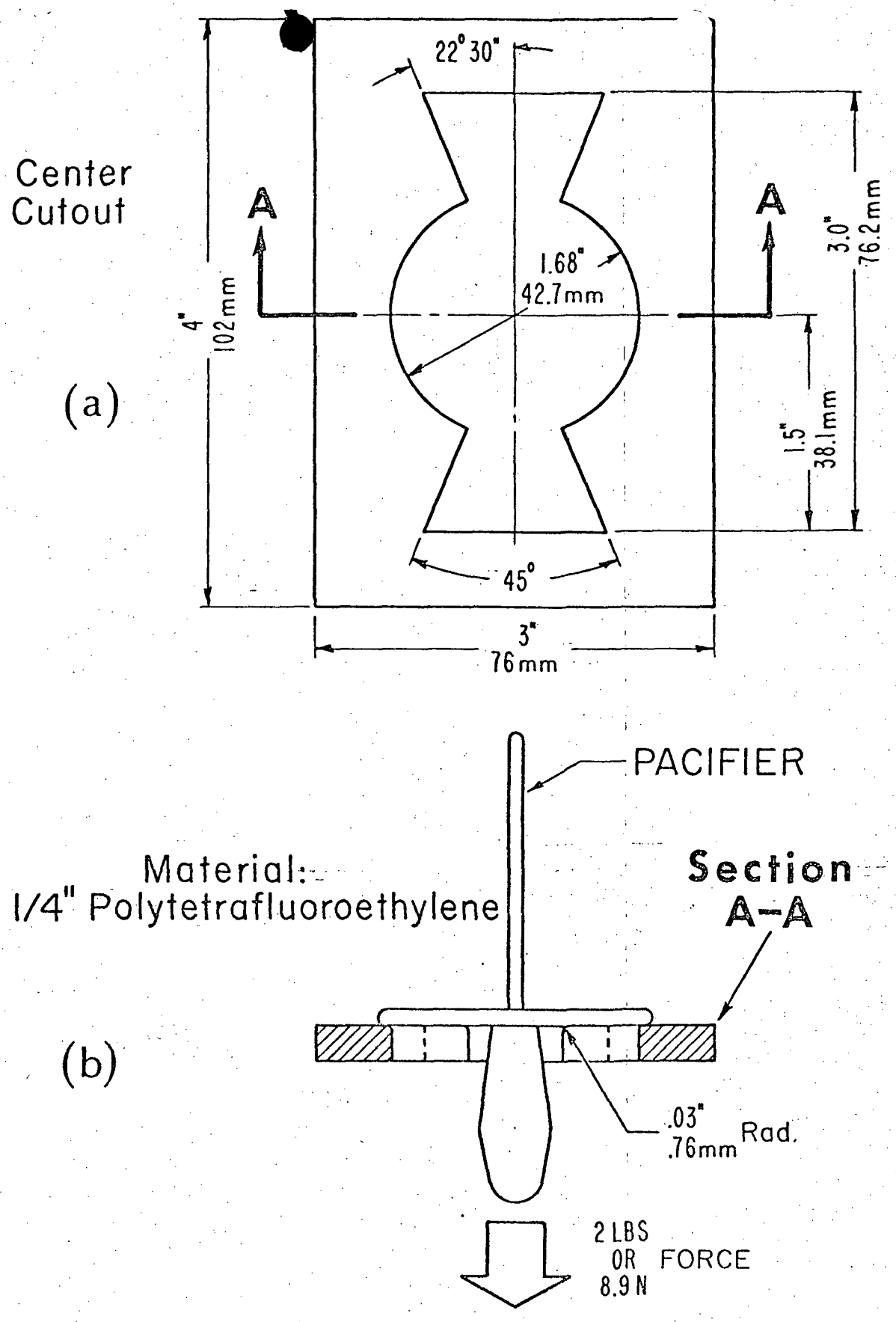


FIG 1 - PACIFIER TEST FIXTURE

FR NOTICE- 10-20-76
COMMENTS DUE- 11-19-76

UNITED STATES GOVERNMENT

Memorandum

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

TO : OFFICE OF STANDARDS COORDINATION & APPRAISAL
OFFICE OF THE GENERAL COUNSEL

DATE: 12-9-76

FROM: CATHY RASBERRY, OFFICE OF THE SECRETARY

SUBJECT: REFERRAL OF OFFICIAL COMMENTS

16 CFR Parts 1500, 1511

Hazardous Pacifiers Ban
Revised Proposal

ATTACHED ARE COMMENTS ON THE CH3-76

PLEASE LOG AND HANDLE AS APPROPRIATE. (L) INDICATES LATE COMMENT

Comments By Date Of Receipt

COMMENT	DATE	CORRESPONDENT	SIGNED BY
CH3-76-10(L)	12-8-76	Toy Mfg., of America,Inc., AAron Locker Counsel, N.Y.	Aaron Locker

HP3-76-10 RM

LAW OFFICES
AARON LOCKER
ONE PENN PLAZA
NEW YORK, N.Y. 10001

AARON LOCKER
THEODORE M. GREENBERG
GERTRUDE BERELSON

(212) 594-7000
TWX 710-581-2884

December 3, 1976

Sadye E. Dunn, Secretary
Consumer Product Safety Commission
Washington, D. C. 20207

Re: Reproposed Pacifier Regulation

Dear Ms. Dunn:

We represent Toy Manufacturers of America, Inc. (TMA), a trade association consisting of domestic manufacturers and importers of toys whose members account for approximately 85% by volume of all toys sold in the United States. Our members include most of the manufacturers and distributors of pacifiers in the United States.

TMA offers the following comments with respect to the proposed pacifier regulation:

1. We have reviewed the injury record which led to the reproposal of the regulation. Every injury or death, with one exception, was due to a pacifier made of two or three parts, one or more of which came apart from the others. The one exception was the LaCibeles case which involved a pacifier which did not conform to the proposed 1972 regulation. This pacifier had a shield measuring only 38 millimeters. The 1972 regulations require a 43 millimeter shield. In other words, not one recorded injury or death occurred with a one-piece flexible pacifier which conformed to the proposed 1972 regulation.

2. The one-piece pacifier is the safest possible pacifier developed so far. The test fixture provisions would eliminate this pacifier. For example: A good pacifier must have a flexible, not hard nipple. In order to make such a nipple and mold the pacifier in one piece, a certain amount of flexibility is inherent in the manufacture of the product. Under these circumstances, no reasonable size shield could pass the test provided. To make the shield of the pacifier larger would interfere with a child's breathing through his nose. Suffocation could occur if the child was lying on its stomach. Babies cannot turn themselves over for weeks and even months after birth. They are, however, given pacifiers in that period.

3. The proposed regulation requires a test fixture with a hole diameter of 1.70". We feel that a fixture diameter of 43mm is adequate to insure flexible shield pacifiers would not be ingested and a 1.25" diameter test hole for rigid shield pacifiers. A shield much larger than 1.70", which would be necessary to pass the proposed regulation test, will create the danger of closing off the breathing passage through the nostrils. The nasal passage must be used for breathing when a pacifier is in an infant's mouth and blockage of the nares makes use of a pacifier impossible.

4. Again, not a single death or injury has been known or recorded to have occurred with a one-piece 43 millimeter shield pacifier since the passage of the 1972 regulations. This is a safety record that must be recognized and acknowledged.

5. With reference to the holes in the shield, a common sense evaluation would show that their purpose would not be accomplished. The size of a baby's pharynx would necessarily crush the shield in order to get it into that size aperture. The holes would then be blocked. Holes in the shield also make the shield more vulnerable to crushing and bending (or breaking in the case of hard plastic). Instead of making the product more safe, it would create exactly the reverse effect. To further negate the inclusion of holes in the shield, it is not possible from an engineering standpoint to mold these holes in a one-piece pacifier. Insistence on this regulation would take the safest possible pacifier off the market. No medical evidence has been presented by way of justification of the requirement that holes be placed in the shields.

6. The two holes of 0.20" would cause increased flexibility on a flexible shield pacifier and increase the danger of bending and, therefore, the danger of ingestion.

7. The two holes could facilitate breathing after impaction only under the most ideal conditions with the holes positioned in a specific alignment with the breathing passage.

8. Open holes in either shield would make cleaning more difficult, especially when used outside the household where boiling would not be available, and therefore, provide an ideal location for the growth of bacteria, mold and other micro-organisms. These micro-organisms would be in contact with the infants' lips during pacifier usage. Saliva from the infants' mouth, collecting in the holes, would provide an ideal medium for the micr-organism growth.

9. Since there is no inherent danger in the use of a pacifier

itself, but only in the misuse by adding an additional item (i.e. ribbon, string, cord) a warning label is not necessary. There have been reported deaths through the misuse of ribbon or string, so I would suggest a voluntary effort by manufacturers of pacifiers to incorporate the message to consumers on the rear of the package.

"Caution - Do not tie pacifier around child's neck."

or

"It is dangerous to tie a pacifier around child's neck."

The pacifier industry is not large, according to data from the Bureau of Economic Analysis. It consists of ten firms manufacturing pacifiers with a total retail value of between $5 million and $7 million annually.

The regulation as proposed would eliminate the sale of all pacifiers currently on the market.

Very truly yours,

Aaron Locker

AL:crl

FR NOTICE- 10-20-76
COMMENTS DUE- 11-19-76

UNITED STATES GOVERNMENT

Memorandum

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

TO : OFFICE OF STANDARDS COORDINATION & APPRAISAL
OFFICE OF THE GENERAL COUNSEL

DATE: 11-29-76

FROM: CATHY RASBERRY, OFFICE OF THE SECRETARY

16 CFR Parts 1500, 1511

SUBJECT: REFERRAL OF OFFICIAL COMMENTS

Hazardous Pacifiers Ban
Revised Proposal

ATTACHED ARE COMMENTS ON THE CH3-76

PLEASE LOG AND HANDLE AS APPROPRIATE.

Comments By Date Of Receipt

COMMENT	DATE	CORRESPONDENT	SIGNED BY
CH3-76-8	11-26-76	Austrian Trade Commission in The U.S., N.Y.,N.Y.	Peter Schwartz, Deputy Trade Commissioner
CH3-76-9	11-29-76	Giant Food, Inc. Washington,D.C.	Odonna Mathews Product Safety Officer

CH3-76-8

RECEIVED
OFFICE OF THE SECRETARY

Nov 26 11 08 AM '76

CONSUMER PRODUCT
SAFETY COMMISSION

AUSTRIAN TRADE COMMISSION
IN THE UNITED STATES

845 THIRD AVENUE
21ST FLOOR
NEW YORK, N. Y. 10022

TEL., (212) 421-5250
CABLE, AUSTROTRAD
TELEX, 422 967 ATD

REGISTERED, SPECIAL DELIVERY

Mr. Sadye Dunn
Secretary, Consumer Product
Safety Commission
Washington, D.C. 20207

19 November 1976

Dear Mr. Dunn:

Reference is made to the revised proposals regarding the ban of hazardous Pacifiers, published by the Consumer Product Safety Commission in the Federal Register of October 20,1976.

On behalf of the Austrian manufacturer and exporter, Roehrig & Co., Murlingengasse 54, A 1122 Vienna,whose product will be marketed under the trade name "MAM", we herewith submit comments regarding this proposal. The MAM-product was designed and researched by the manufacturer in cooperation with orthodontists and professional designers.

Mr. Ernst W. Beranek, the author of the submitted comments is Professor of Industrial Design at the Vienna College for Applied Art.

In order to give you a more descriptive view on the MAM pacifiers we respectfully submit sales literature and plan to follow up with samples of the MAM pacifiers after receipt from Vienna.

We are looking forward to hearing from you .

Very truly yours,

Peter Schwarz
DEPUTY TRADE COMMISSIONER

Enclosures
PS:ck

*Samples Send to Don Early

-A13-76-8

Institut für Industrial Design

Hochschule für angewandte Kunst – Wien 1
Kopalplatz 2, A-1010 · Tel. 72 11 29, 72 21 91

Vienna, 1976 11 11

To the

Secretary, Consumer Product Safety Commission

Washington, D.C. 20207 USA

Gentlemen,

We have recieved your proposed rules concerning requirements for pacifiers and would like to submit the following comments.

During the last two years we have developed a new pacifier with scientific methods. We consulted medical doctors, nurses, plastics technologists and designers during the reasarch as well as the stages product design. We noticed that your regulations cover most of the problem areas which we encountered as critical points in pacifiers. We do believe to have solved theses Problems in our new design and would therefore like the submit our proposals fpr your consideration. Although our design meets the requirements specified we would like the propose the following amendements to the proposed rules.

ad § 1511.2/Definitions (a)

It should be noted that a pacifier may have a handle or ring but does not necessarily need one. Our model has neither one because we want to prevent the attachment of a ribbon or string.

ad § 1511.3/Guard or shield performance requirements (a)

We have some objections to the form and dimension of the "pacifier test fixture".

1. Our medical research has proven that the diameter of 43 mm for a circular shield is too big because it would actually reach or partly cover the nose of the infant. We therefore suggest a test fixture with an opening of 40 mm ø which coincides with the Scandinavian safety regulations.
2. The circular test fixture is not appropriate for oval or elliptic shield forms because even very large shields could slide through the circular opening diagonally while, in our view, providing the same safety. Consequently we believe the regulations should define area measurements of the shield rather than merely a diameter (the minimum width of the shield however should not be less than 31,7 mm according to figure 2 test cylinder).

Institut für Industrial Design

Hochschule für angewandte Kunst – Wien 1
Kopalplatz 2, A-1010 · Tel. 72 11 29, 72 21 91

ad § 1511.3/Ventilation holes (b)

We do not believe that ventilation can be achieved by holes only. There are a number of possible design solutions, for example to have V- or U- shaped segments cut out from the circumference of the shield. Also, the ventilation holes might encourage to apply strings or ribbons to the pacifier.
Our shield has an 8 - shaped form which guarantees sufficient air flow even in an oval or round tube or hose which more or less reflects the natural situation in the throut. Therefore we recommend to specify the minimum area providing sufficient air flow.

ad § 1511.7/Labeling (a,b,c)

In our view the "WARNING . . . . . " statement should only be compulsory on pacifier models encouraging the attachment of strings or ribbons such as models with rings or holes. In our case, for example, we believe that our design is safe in its use and this labeling is not applicable.

We hope to have made a useful conrtibution and are looking forward to hearing from you,

sincerely yours,

Prof. Ernst W. Beranek

These are the convincing MAM® product advantages

Voilà les avantages incontestables de MAM®

1) Advantage of Symmetry

MAM pacifiers are symmetric and therefore problem-free in application, they cannot be inserted wrongly. Asymmetrically formed pacifiers only fit properly one way. What mother has nowadays time continually to control correct pacifier position.

1) L'avantage de la symétrie

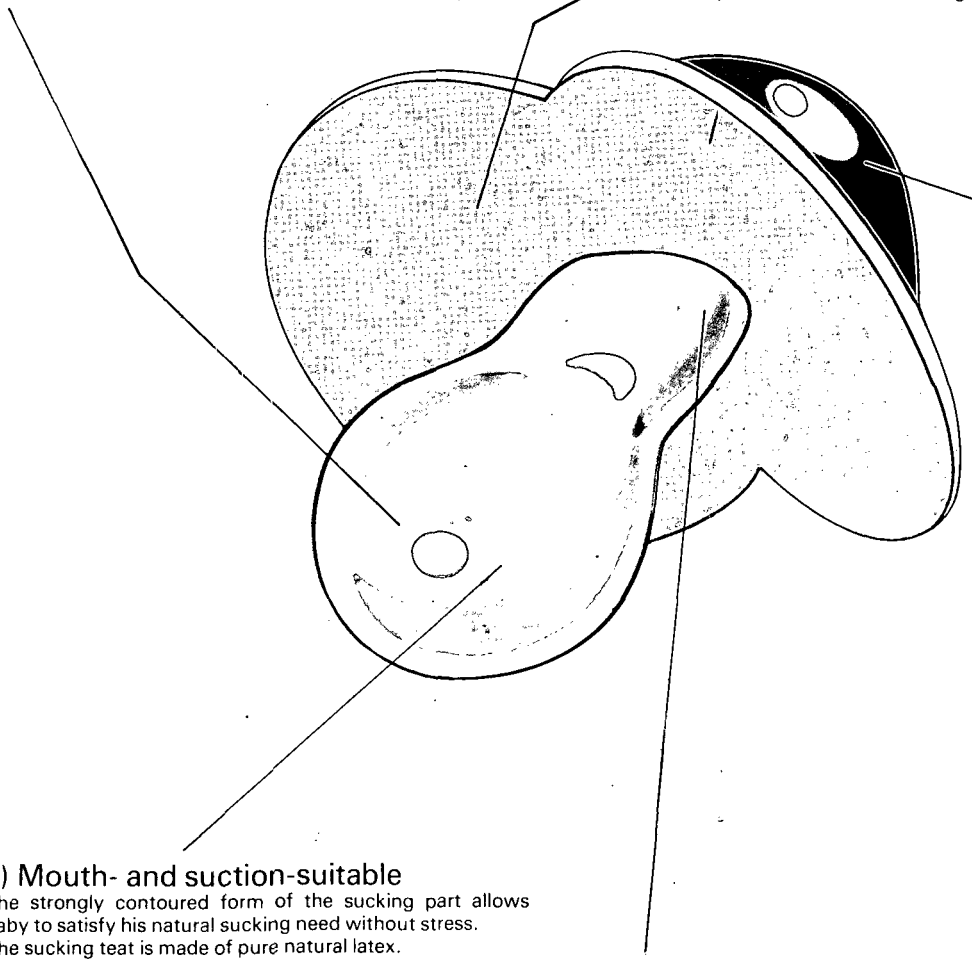
MAM, la sucette qui calme le bébé, est symétrique et pour cette raison facile à employer, parce qu'elle est toujours bien placée dans la bouche. Les sucettes asymétriques ne sont appropriées que lorsqu'elles sont utilisées correctement — et quelle maman a le temps de toujours contrôler si la sucette est vraiment bien placée?

4) Shield in conformity with the lips

With the MAM pacifier the shield is concave and adapted to the lip, thus partly limiting mouth-breathing by the child and supporting breathing through the nose. The size of the shield prevents any danger of swallowing.

4) disque de protection conforme aux lèvres

Le disque de protection de la sucette MAM est concave et sa forme correspond aux lèvres, l'enfant respire moins par la bouche et la respiration nasale est encouragée. Les dimensions du disque permettent d'éviter le danger de déglutition.



5) Also suitable for stomach position

There is no projecting ring with the MAM-pacifier, allowing the use of the pacifier comfortably when baby is lying on its stomach.
A further advantage is that the pacifier does not drop from the mouth as easily.

5) elle tient même quand le bébé est couché sur le ventre

Nous avons conçu la sucette MAM qui calme le bébé sans anneau en poignée de sorte que le bébé peut l'avoir dans la bouche même s'il est couché sur le ventre. Cela a l'avantage qu'elle tombe moins facilement de la bouche.

2) Mouth- and suction-suitable

The strongly contoured form of the sucking part allows baby to satisfy his natural sucking need without stress.
The sucking teat is made of pure natural latex.

2) conforme à la bouche et aux mouvements de suction

La forme aux contours clairs et l'élasticité de la tétine permettent à l'enfant de sucer sans se fatiguer. La tétine est bien sûr en latex naturel pur.

3) Sucking part without hard plastic insert

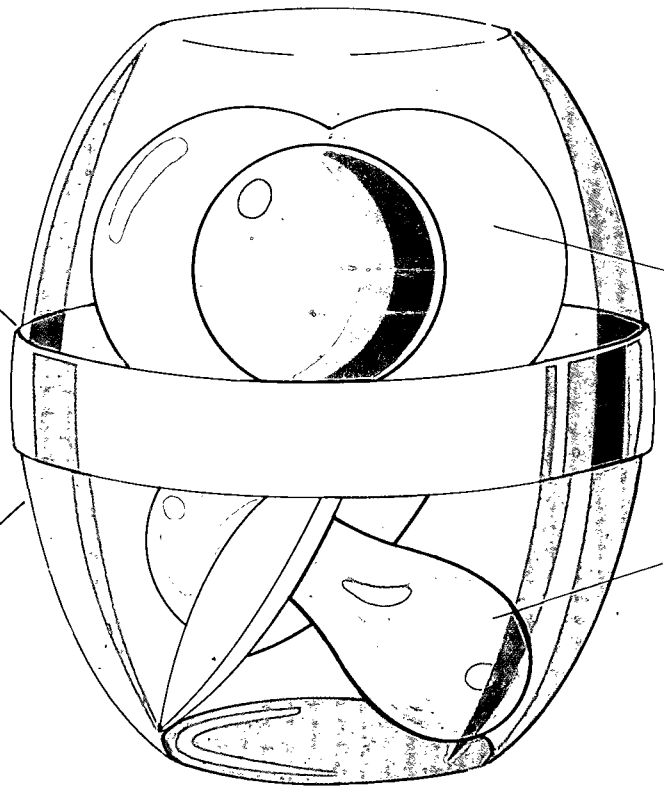
With past pacifiers a hard plastic extension of the grip extended into the sucking part.
This not the case with MAM — the whole sucking part up to the shield is soft and compressible.

3) tétine sans élément plastique dur

Dans les sucettes ordinaires une partie de la poignée dure pénètre dans la tétine. Il n'en est pas ainsi pour MAM — toute la tétine est molle et comprimable.

Research and development work for MAM took two years. MAM is now ready for marketing success.

Après deux ans de travaux de recherche et de développement MAM mérite tout le succès possible sur le marché.



6) Hygienic Box
Every mother's problem "Where to put the Pacifier?" is solved. MAM pacifiers are supplied in a hygienic box for problem- and dirtfree pacifier storage.

6) box hygiénique
Le problème qui se pose à toutes les mamans — « que faire de la sucette » — est résolu. La sucette MAM peut être rangée dans le box hygiénique qui la protège de saletés.

8) 1 sale = 2 pacifiers
The MAM-sales unit consists of 2 pacifiers, so that one sale equals the purchase of 2 pacifiers.

8) 1 achat = 2 sucettes
L'unité de production MAM comprend deux sucettes de sorte qu'en un seul acte d'achat deux sucettes sont acquises.

7) Display-favorable package
MAM brings convincing proof of attractive and sales-promoting pacifier-packaging. With its strong sales impulse MAM brings life to the pacifier shelf.

7) emballage particulièrement approprié au display
MAM prouve une fois pour toutes que même des sucettes peuvent être emballées d'une manière attrayante et efficace pour la vente. Cet attrait à l'achat de MAM anime le rayon des sucettes.

MAM®

- based on newest medico-scientific research
- a functional and well-designed product
- with sales-supporting display effect and built-in purchase appeal
- est basé sur les connaissances médicales et scientifiques les plus récentes.
- est d'une conception plaisante et conforme à sa fonction.
- se prête très bien à un display efficace et à la commercialisation.

Producer:
Röhrig & Co.
Murlingengasse 54
A-1120 Vienna
AUSTRIA
phone: (02 22) 83 24 36
cables: Röhrigplastik Wien
Distributor for Austria:
Austro-Hahn, Salzburg

Producteur: Röhrig et Cie.
Murlingengasse 54, A 1120 Vienna, Autriche
Tél.: (02 22) 83 24 36
télégramme: Röhrigplastik Wien
Diffusion en Autriche par Austro Hahn Salzburg

CH3-76-9

rm

GIANT FOOD INC. BOX 1804 · WASHINGTON, D.C. 20013

ESTHER PETERSON
CONSUMER ADVISOR

November 24, 1976

Ms. Sayde E. Dunn, Secretary
Consumer Product Safety Commission
Washington, D. C. 20207

Comments re: Consumer Product Safety Commission Hazardous Pacifiers Ban, Proposed Regulation, October 20, 1976, Federal Register

Dear Ms. Dunn:

We at Giant Food Inc. are writing in support of the proposed regulation on pacifiers as stated in the October 20, 1976 Federal Register. In addition, we believe that the regulation would reduce the possibility of strangulation and small parts hazards that can occur with such children's products. The proposed test methods can be duplicated in our Quality Assurance Labaoratory and therefore incorporated in our toy testing program.

We question whether or not the ventilation holes, as stated in Section 1511.3, are adequate to provide an emergency oxygen supply and a rapid means of removing the pacifier from a child's throat. We wonder if there is any evidence to substantiate this requirement. If CPSC decides there is adequate evidence, we suggest that the Commission consider requiring four holes, or another quantity greater than two, to be located symmetrically on the pacifier shield. The greater number should not interfere with the stability of the shield in any way.

Regarding Section 1511.7, an addition should be added to indicate that the warning statement should be displayed on the front panel in at least 3/16-inch type. This is to insure that consumers will easily be able to read such an important caution statement.

We urge the Commission to act promptly in analyzing the proposal and revising it where necessary, and we appreciate the opportunity to communicate with the CPSC on this issue.

Sincerely,

Odonna Mathews

Odonna Mathews
Product Safety Officer

OM/sz