NBSIR 75-733

An Evaluation of Proposed Safety Requirements for Infants' Pacifiers

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Final Report

Prepared for
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5401 Westbard Avenue
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U.S. DEPARTMENT OF COMMERCE, Rogers C.B. Morton, *Secretary*
John K. Tabor, *Under Secretary*
Dr. Betsy Ancker-Johnson, *Assistant Secretary for Science and Technology*

NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Acting Director*

An Evaluation of Proposed Safety Requirements for Infants' Pacifiers

The Consumer Product Safety Commission (CPSC) has prepared a revised working draft of a proposed regulation governing safety requirements for infants' pacifiers and related items. It is the intention of the CPSC to use this draft as the basis for proposing by 16CFR Part 1500.55, a regulation establishing safety requirements for pacifiers, and by 16CFR Part 1500.18(a)(8), a regulation to classify as banned hazardous substances those products which do not meet the requirements of 16CFR Part 1500.55.

Prior to publication of these proposed requirements the CPSC requested the Product Engineering Division to establish a program for the purpose of reviewing the Pacifier Regulation for appropriateness, feasibility, and ambiguities. In addition to a review, this program was to include a laboratory evaluation of the efficacy of various requirements and testing procedures included in the subject document.

For convenience the outline of the complete proposed Section 1500.55 is presented as an appendix to this report. In addition, this report contains figure 2 of the proposed regulation, which illustrates the methods for applying various tensile and bending forces to a pacifier. The following section of this report briefly describes those specific proposed requirements and testing procedures, which were subjected to laboratory evaluation.

Requirements and Test Procedures Evaluated

Although not specifically stated or obviously intended, the proposed requirements and test procedures in the regulation appear to have been written around the concept of a "classical" pacifier design: that is, one in which the nipple has an elongated tear-drop shape; is attached to the center of a flat, symmetrical, circular guard shield whose diameter is perpendicular to the major axis of the nipple; has an essentially circular open handle in which the horizontal plane of the fully extended handle, whether hinged or unhinged, is oriented in a plane perpendicular to that of the shield; and with the hinge line, if present, oriented parallel to major axes of both the shield and extended handle. Thus, in describing the direction of dimensional measurements, applied forces, and pacifier orientation, the terminology used in this report is intended to reflect the illustrated schematic diagrams and implied parameters presently included in the proposed draft regulation. The terms "horizontal" and "vertical", "upper" and "lower", apply to the directions and areas as they would relate to the pacifier when held in the mouth of a child standing on a level surface so that the major plane of the shield would be perpendicular to, and the major plane of the fully extended handle would be parallel to, the level surface.

Paragraph (b)(1) "Requirements for the guard shield" contains proposed minimum diameters for the width of the shield when measured along two principal perpendicular lines. The proposed dimensions vary depending on whether the shield is classified as non-flexible or flexible when tested in accordance with sub-paragraph (A) of (b)(1). It is proposed that the minimum diameter of a non-flexible shield be at least 3.8 cm (1 1/2 in), and that of a flexible shield, 4.3 cm (1 11/16 in). Section (A) of this paragraph sets forth the test procedure by which the shield flexibility is determined. Flexibility is determined by the resistance of the shield to being drawn at specific tensile forces through a test fixture which consists essentially of a flat, 0.64 cm (0.25 in) thick metal plate with a 3.65 cm (1 7/16 in) diameter orifice.

Paragraph (b)(2) proposes that no portion of the handle or any adjacent structure protrude more than 1.6 cm (5/8 in) from the face of the shield. The proposed test is conducted by applying to the fully extended handle, a vertical tensile force of 5 N (1 lb) at a point directly opposite to the attachment point of the handle to the shield. All measurements to determine compliance are made while the tensile force is being applied to the handle, and include the overall distance, projected as necessary, from the plane of the shield to a parallel plane passing tangentially along the outer edge of the handle. This is illustrated by force "a" in the attached figure 2 from the proposed regulation. Although the term "adjacent structure" was not identified, and there were no instructions on measuring such a component, for the purpose of the laboratory tests this term was arbitrarily assumed to include any component, other than the handle that was attached to the face of the shield on the handle side, as opposed to any insert or device, including the nipple, which projected from the face of the shield on the side to which the nipple was attached. Thus, if any adjacent structure (inserts in the case of the samples evaluated in this laboratory) appeared to extend beyond the projection distance of the handle during the time the test load was being applied to it, these structures were also measured to determine whether their projected distance exceeded the specified limits.

Paragraph (b)(3) is concerned with the presence of "Other Mechanical Hazards" as set forth in 16CFR Part 1500.18(a), both before and after the pacifier is tested.

Paragraph (b)(6) addresses the problem of structural integrity of the nipple and handle. The proposed test procedures are applicable to new pacifiers as well as those that have been subjected to a heat cycle deterioration test included as part of this paragraph. Basically these requirements imply that the term "structural integrity" is synonymous with the pacifier remaining intact after being subjected to the proposed test procedures.

According to paragraph(b)(6)(a) the structural integrity of the nipple is determined by grasping the nipple end of the pacifier and applying a tensile force at a point on the handle opposite the face of the guard, in a direction parallel to the major axis of the nipple.

According to paragraph(b)(6)(b) the handle integrity is determined by clamping the shield and applying a tensile force in each of two directions. The pacifiers are tested by applying a tensile force at a point on the handle outermost from the shield, so that the force vector is perpendicular to the major plane of the handle and parallel to the plane of the shield, and in the case of hinged handles also perpendicular to the hinge line. In addition, a second test is conducted by applying the force at a point on the handle approximately midway between the point of attachment on the face of the shield and the outermost part of the handle, so that the force vector is parallel to the major planes of the handle, the shield, and the hinge line, if present.

The heat cycle deterioration test described in (b)(6)(c) involves subjecting the pacifiers to six consecutive five-minute periods in boiling water, with a five-minute cooling period at ambient room air temperature after each period in boiling water. Pacifiers subjected to this test are then required to comply with the structural integrity tests of (b)(6)(a) and (b)(6)(b).

Procedures

Procurement of Pacifiers

A total of ten types of pacifiers was purchased from four retail outlets. The pacifiers represented the products of eight manufacturers and one vendor. The manufacturer of sample J, obtained from the vendor, was not identified on the product label. For all practical purposes, however, it was identical to sample F, whose manufacturer was identifiable. A description of each type of pacifier is given in Table 1.

When this program was established the original intent had been to acquire a sufficient number of each sample so that at least ten specimens could be subjected to the structural integrity tests both before and after the heat cycle deterioration tests. It was obvious that determination for compliance to the proposed shield dimensions, paragraph (b)(1), would have no effect on subsequent tests. It was also believed that, if necessary, the test for shield flexibility (paragraph(b)(1)(A)) and compliance to protrustion requirements (paragraph (b)(2)) could be conducted on specimens later subjected to the structural integrity tests (paragraph(b)(6)) since the latter were much more severe and would not be expected to be unduly affected by the former test procedures. However, the number of available specimens ranged from nine to twenty, which resulted in a drastic reduction in the number of specimens available for the various tests.

Test Results

Samples A, G, H and I met all of the proposed requirements although there was some problem, discussed below, whether samples A, H and I should be classified as having flexible or non-flexible shields. Similarly there was a problem whether sample C, which passed all other tests, should be classified as safe or unsafe with respect to shield flexibility.

Paragraph (b)(1)

The shield dimensions were normally obtained by measuring the width along lines parallel and perpendicular to the plane of the handle, and passing through the center of the point of attachment of the nipple to the shield. Most of the shields had a visible mold parting line across the face in the parallel direction, which simplified measurement taking. The dimensions of the shields at least equaled or exceeded the proposed minimum dimensions when measured parallel to the plane of the handle. However, the dimensions of samples F, G and J were less than the proposed minimum when measured perpendicular to the handle plane. The "shield" on samples F and J, which were practically identical, was not the "classical" flat circular unit common in many pacifiers. Instead it had an elongated elliptical shape with the major axis parallel to the major horizontal plane of the handle. Sample G, identified by the manufacturer as an "orthodontic" type pacifier, had a uniquely designed nipple and a concave curvature along the edge of the shield. Apparently the nipple is designed so that the pacifier orients itself in the infant's mouth during sucking, with the curved portion of the shield resting on the upper lip, below the nose. Presumably this prevents any interference of the shield with nasal breathing. However, with sample G, if the dimensional measurements were made along two perpendicular lines oriented approximately 45° to the plane of the handle, an allowable procedure under current phrasing of the proposed regulation, it would comply with the minimum dimensional requirements. Sample A, and that of sample G, had similarly shaped nipples and shields; however, the shield dimensions were not symmetrical with respect to the centering of the nipple. When measured in the perpendicular direction, the lower portion of the shield of A was larger than the width of the shield as measured in the horizontal plane where the nipple was centered, so that the overall vertical dimension of the shield met the requirements of the proposed regulation.

Paragraph (b)(1)(A)

It is proposed that any pacifier capable of being pulled through the circular orifice of the test jig, described above, be considered to have failed this test, and presumably would be considered a banned hazardous substance, if the shield passed through the orifice under an applied tensile force of 9 N (2 lb) or less. It is also proposed that any pacifier shield which passed through the orifice when subjected

to a tensile force greater than 9N (2 lb), but less than 22.5 N (5 lb), be classified as flexible, and any pacifier shield which is not pulled through the orifice at an applied tensile force of 22.5 N (5 lb) be classified as non-flexible. Of the ten samples evaluated under the criteria proposed only samples F, G and J had flexible shields, and samples D and E had non-flexible shields.

If average values are the major concern then both samples B and C would be rated as safe, flexible pacifiers. However, one of the five specimens of sample B that were tested passed through the orifice of the test jig at a force of two pounds. Two of the five specimens of sample C were pulled through the fixture at forces of less than two pounds, and a third at a force of two pounds. Thus, with these four specimens, the criterion in the proposed regulations that the shield must resist a pull force of 2 pounds was not met, and these individual specimens would be classed as banned hazardous substances.

With respect to paragraph (b)(2), four of the pacifiers failed to meet the proposed requirements for protrusions when the tests were conducted in accordance with the arbitrary assumptions, discussed above, surmised from the proposed regulations. When the 5 N (1 lb) tensile force was applied to the hinged handle of sample E, the handle was within the proposed maximum allowable distance from the shield, but the rigid plastic insert protruded beyond the proposed maximum dimension. Sample D also failed to meet these requirements, but for a different reason. The handle and nipple insert were molded as a single piece from a rigid plastic. A hinge is produced in this unit during the molding process by simply reducing the thickness of the plastic across the width of the "stem" connecting the handle and insert. In the plastics industry this type of construction is referred to as an integral molded in hinge. When the handle on this pacifier is tested (that is, bent for the first time) by application of the weight, portions of it extend beyond the proposed 1.6 cm (5/8 in) limit. However, after the handle is bent several times through a 180° arc, the pacifier readily passes this test. Samples F and J failed this proposed requirement because the handles, designed to be used as a teething ring, were made of a relatively thick plastic, and filled with gelatin.

With regard to paragraph (b)(3), none of the pacifiers evaluated appeared to be capable of producing a mechanical hazard when tested in accordance with the proposed regulation. A potential small parts hazard existed in the case of sample E, unless it were assumed that the onset of any distortion or separation of components as a result of immersion in boiling water, would induce the parent to discard the pacifier. Otherwise, ease of removal of the nipple from a heat distorted sample could result in an aspiration or ingestion hazard, as defined in the proposed small parts regulation promulgated as 21CFR 191.9a, FR 2179, January 22, 1973. In the case of this sample heat

induced distortion was initiated during the first heat deterioration cycle, and became progressively worse with each additional cycle. Because these specimens were not tested until the six boiling water cycles had been completed, it was not possible to determine the actual number of cycles that the pacifiers could withstand before onset of failure of the structural integrity tests.

With respect to paragraph (b)(6)(a), only sample B was considered to have failed the test for structural integrity in the new, or "as received", condition, which requires that the pacifier remain intact when the nipple is subjected to a 44 N (10 lb) tensile force. Four of the five specimens tested did not meet the proposed requirement. Specimens of this sample which were subjected to the heat deterioration tests of (b)(6)(c) prior to these tests, met the requirements for structural integrity of the nipple. This phenomenon could be attributable to several factors; e.g., the rigid plastic insert possibly expanded due to absorption of water. The sterilized pacifiers could then be expected to fail in the same manner as the unsterilized specimens, if they were allowed to recondition for a minimum of 96 hours at 23°C and 50% R.H. after each five-minute boiling cycle. Three specimens of sample E failed the nipple test after the heat deterioration tests, and the other two of the five specimens tested failed because they came apart when subjected to the boiling water. Failure was due to gross thermal distortion of the rigid plastic components. This sample was labeled by the manufacturer as being boilable.

In evaluating the effects of the proposed test parameters on handle integrity, set forth in paragraph (b)(6)(b), the following failures were observed. All of the specimens of sample B failed all of the test requirements for handle integrity both before and after being subjected to the heat deterioration tests. In the case of sample D, two of five specimens failed prior to boiling and three of five specimens failed after boiling when subjected to a tensile force applied at the midpoint between the shield and outermost point of the handle, in the direction parallel to both the major plane of the shield and of the handle. Two of the five specimens of sample E failed before boiling when the tensile force was applied parallel to the major planes of both the shield and the handle. When boiled, components of two of the five specimens tested from sample E separated and could not be tested, while the remaining three specimens failed the handle test when tested with both directional tensile forces.

Samples F and J were not boilable. The plastic material used in their construction softened, and partially melted and distorted during the first boiling water cycle. Consequently, they were not subjected to the complete series of boiling water cycles and subsequent integrity tests.

Comments on Test Procedures

General

The proposed regulation is entitled "Certain Pacifiers and Other Similar Articles"; however, it is addressed strictly to the definition of, and tests for, pacifiers. "Similar Articles" are not even defined in a general way.

Dimensions

Considering that four of the ten samples, A, F, and G,and J, evaluated did not have the "classical" flat, circular shield, but passed the minimum requirement for resistance to the two-pound pull test in the flexibility test jig, it seems reasonable to reassess the dimensional requirements. The proposed dimensions could be retained to cover shields that were essentially symmetrical along two perpendicular lines. However, it may be necessary in other cases for the shield to meet the minimum dimension in only one direction. This assumes that the rationale on which the orifice size of the test fixture is based and the requirement that the pacifier resist a two-pound pull test, is sound. If an exception is granted for non-symmetrical shields, it still may be necessary to retain a minimum size along the minor axis of the shield. In addition, the dimensional requirements for this type of shield could be made more stringent by raising the minimum size of the major shield axis, for example, by adding an additional 1.6 mm (1/16 in) to the proposed requirements for flexible and non-flexible shields. In all cases, it would be judicious to increase the severity of the test by specifically requiring in paragraph (b)(1)(A), that the pacifier nipple be inserted through the orifice such that the major axis of the nipple project through the center of the orifice. Based on known variations in pacifier design, it does not presently appear that incorporation of these changes in the regulation would increase the possibility of an unsafe product being marketed.

At present the phraseology of the dimensional measurements is unclear. Obviously the intent was that the two perpendicular lines pass through the center of the face of a circular shield, where they would be perpendicular at their midpoints, but this is not specified in the regulation. A triangle can be measured by two perpendicular lines, one along its base and one from the base to the apex.

Flexibility Test Procedure

The procedures in paragraph (b)(1)(A) are unclear, appear to be transposed with respect to the chronological order of testing, and do not adequately describe the time duration of the applied force. It is recommended that the nipple be subjected to the two-pound test for a period of 10 seconds, and assuming that the specimen remains intact and that the shield has not passed through the orifice, the force be increased to five pounds for an additional 10 seconds, or until the shield is pulled through.

To be consistent with other sections of the Regulations pertaining to childrens' products, the method of loading should be as follows: apply the force slowly over a period not to exceed five seconds and then maintain the force for an additional ten seconds. The reason for slowly loading the specimen is to prevent it from being subjected to an impact force, a more severe test condition.

With respect to flexible shields, the CPSC should determine whether the average value of a series of specimens within a sample should be used, or the individual test value should be used. For example, in testing sample C the five force values required to pull the shield through the orifice were 1.0, 1.5, 2.0, 3.5, and 3.5 pounds. The average value, 2.3 pounds, would indicate that this sample be classified as a safe pacifier with a flexible shield, but the individual values would indicate that it could be classified as a banned hazardous substance under the proposed regulations. Similar classification problems exist in determining whether a shield is flexible or non-flexible. If all of the specimens within a sample require a force between two and five pounds to pull the shield through the test orifice, then an approximate average value can be obtained and may be used to classify the shield as flexible. A true average value of the pull force can only be obtained, in this case, if the rate used to increase the test load from two to five pounds is constant for all specimens tested. Variations in the rate of loading between specimens will result in approximate individual force values. In addition, true values obtained on a group of specimens loaded at one rate could be expected to differ from those loaded at a different rate. In general, the more rapid the rate of loading, the higher the expected force required to pull the shield through the orifice. Similarly, if all of the specimens from a sample resist an applied force of 5 pounds for ten seconds, they would be classified as non-flexible by the proposed criteria. The major classification problem concerns those cases where some specimens resist the five pound force for ten seconds, and other specimens of the same sample either are pulled through by the five-pound force under ten seconds, or are pulled through before the full five-pound force is obtained, i.e., while the applied force is still increasing. Such behavior was noted for samples A, H and I. To discriminate between flexible and non-flexible shields, one NBS staff member proposed that the applied force be continually increased until the shield was pulled through the orifice, and to compute the average values using these forces. This procedure, although valid, precludes the use of dead-weight loading, a relatively inexpensive procedure for these tests. In addition, greater accuracy would require the use of test equipment capable of providing a constant speed of loading. Neither would it resolve the type of problem, described above, for specimens behaving like those of sample C, where the applied load was steadily increasing rather than held at two pounds for ten seconds as recommended in this report.

If the CPSC determines that no specimen within a sample shall fail the two-pound test, or that if one or more specimens resist the two-pound force and are pulled through the test orifice at less than five pounds that they shall be classified as flexible shields, then it may be necessary to discuss sampling procedures in detail. Examples of the various

types of procedures that can be used are presented in Military Standard for Sampling Procedures and Tables for Inspection by Attributes (MIL-STD-105). Sampling is usually predicated on the number of units within a lot of material. A "lot" can be defined in several ways; for example, all units produced from one batch of plastic, all units produced in the same cavity of a mold, all units packed and shipped to a single destination. Presently it does not appear necessary to include the definition of a lot in the regulation. However, this may become necessary if comments received after publication of this proposal indicate confusion as to meaning.

Handle or Ring Protrusions

The rationale behind the requirement given in paragraph (b)(2) is elusive. It implies that the handle must either be hinged or be quite flexible, with respect to the proposed test. This aspect may be challenged with respect to allowable design restrictions and to the types of materials that can be used.

Considering only the requirements of paragraph (b)(2), there appears to be no mechanical hazard involved in the cases of samples F and J. These two samples were made of relatively flexible and rather soft materials, but because of their physical dimensions, failed to pass the test requirement, which appeared to have been designed for the purpose of evaluating rigid materials. Neither does there appear to be a particular hazard associated with the type of design used in the production of sample D. If protrusions exceeding 5/8 in (1.6 cm) are considered to be mechanical hazards, then the failure of sample E is basically due to design. In all of these cases, with the probable exception of sample E, it seems obvious that the proposed requirements of this paragraph could impose arbitrary design limitations on the manufacturers. The limitations could potentially lead to the development of less safe products. A child with one or more partially or fully developed incisors could reasonably be expected to be capable of biting through a thin, rubbery material more easily than a thicker one, where the former would pass this proposed requirement and the latter fail it.

Other Mechanical Hazards

Paragraph (b)(3) should be addressed more specifically to the problem of mechanical hazards not only before testing, but also after testing in accordance with paragraph (b)(1), (b)(2), and (b)(6), as a minimum. When considering mechanical hazards there is some concern that there are no dimensional requirements for the handle, which a child may put into his mouth or into his eye, for example. Neither is there a requirement that the nipple not exceed a certain length. Small or unusually shaped handles and long nipples could reasonably be expected to induce gagging or vomiting, and as such should be classified as mechanical hazards due to the fact that physical dimensions would be involved.

Structural Integrity Tests

In paragraph (b)(6)(a) the method of grasping the nipple for the structural integrity test is not explicit. It simply states: "Hold the nipple end of the pacifier . . ." In the cases of samples B, D and E, all have rigid inserts used to attach the handles to the nipples. These inserts extend into the nipple beyond the face of the shield. The way the test requirement is worded does not preclude grasping the nipple near the shield in such a manner as to allow the insert to also be grasped by the test clamp. This procedure would probably defeat the purpose of the test. However, a simple statement prohibiting inclusion of the insert in the test clamp may not solve the problem; for example, sample H is a one-piece pacifier which includes the nipple, shield, and handle. Apparently as a means of preventing nipple collapse, this sample contains a separate insert molded from a semi-rigid plastic, whose shape can best be described as similar to that of a button-head rivet, which when inserted into the nipple, extends from the shield to the outer end of the nipple. With this particular sample, it is virtually impossible to grasp adequately the nipple without also including the end of the insert.

In conducting the tests described in paragraph (b)(6)(c) it was noted that some pacifiers tended to float due to either the type of construction, the apparent density of the materials used, or the turbulence of the boiling water. It is suggested that this paragraph be reworded to require total immersion of the pacifier in the boiling water. Although this might require attachment of a counterweight to the specimen it should increase the severity of the test for those samples which float, or which at times will be partially exposed to air. Total immersion may not be equivalent to normal use modes, but it is doubtful that any parent would be so fastidious as to boil a pacifier for a total of thirty minutes in any given hour.

The title of paragraph (b)(6)(c) should be changed to: "Resistance to boiling water", or the like, since this would be more descriptive of the actual test.

It seems likely that this test requirement may be the most controversial of all. A manufacturer, faced with the necessity of testing many specimens per week, may have a legitimate complaint about the test procedure. However, the consumer advocate may justifiably claim that the test is not typical of normal use. The authors believe that the test procedure is adequate for quality control for boilable pacifiers such as those exemplified by sample E, but may not be applicable to pacifiers such as those similar to samples F and J. If a manufacturer labels a pacifier as "boilable", it should pass this test. Although is is believed that sterilizability may not be necessary for all types of "pacifiers and similar articles", there obviously will be a certain amount of psychological "comfort" to the parent of a very young child, e.g. four months of age or less, to know at the time of purchase that the pacifier is "boilable" or "sterilizable".

Other Comments Regarding The Proposed Regulation

Samples F and J, which apparently were made by the same manufacturer failed to survive the first cycle of the heat deterioration test of paragraph (b)(6)(c). This seemed to be rather unfortunate. These two samples met the definition of a pacifier as set forth in the regulation, in that they had a nipple, a shield, and a handle. However, the handle of these pacifiers was actually intended to be used as a teething ring. These pacifiers were filled with gelatin and intended to be chilled before use, a practice which tends to alleviate teething pains. By the time a child is old enough to need a teething ring, perhaps at the age of four to six months, it seems logical that most parents, even with their first child, would have become somewhat lax with respect to the sterility syndrome.

The plastics used to produce these two samples were analyzed by infrared spectrographic techniques, and both were found to consist of an ethylene-vinyl acetate copolymer. This material is ideal for the intended use. It exhibits the softness and flexibility of plasticized poly(vinyl chloride) (PVC) without requiring the use of extractable additives, removal of which can lead to embrittlement. It has excellent low temperature impact properties, and superior aging resistance compared to plasticized PVC, and some rubber compounds. When manufactured under appropriate conditions, it is FDA-approved for contact with foodstuffs. Its only inherent fault with respect to meeting the requirements of the Pacifier Regulation is that it melts or softens in the general range of 65° to 90°C (150° to 185°F). It not only is not amenable to boiling, but could be borderline for withstanding the normal temperatures of a household dishwasher. Perhaps this type of product, although categorized by the definitions in paragraph (a) of the proposed regulation as a pacifier, might really be better classified as one of those elusive "Similar Articles" referred to in the title of the Regulation.

Comments Based on Overall Review of the Regulation

Throughout the regulation metric units are used, followed by parenthetical English units. The English units are specific, the metric units approximate. Usually the first units listed are the determinants with respect to whether a product passes or fails a test. We would recommend that the order of entry be reversed with indications that the English units are the determinants. Although this concept is contrary to NBS recommended practices, we would point out that your regulations should be consistent. For example, the regulations on Use and Abuse Tests for Toys promulgated as 16CFR Part 1500.50 through 1500.53, FR 1480, January 7, 1975, specifically addresses the fact that English units are to take precedence where any conflict is involved.

In paragraph (b)(1)(A), a discussion of the two-pound pull test contains the phrase "passage of the pacifier". This should be changed to "passage of the pacifier shield". The present wording is imprecise. It could be interpreted to mean that a pacifier would not be considered to have failed unless the entire product passed through the orifice at a force of two pounds or less. This test is for shield flexibility, not

pacifier swallowability. Presumably if the shield is flexible enough to be sucked into an infant's mouth, regardless of the size or rigidity of the handle, the resultant deeper insertion of the nipple into the mouth or throat could be a potential hazard if choking, gagging, or vomiting occurs.

The description of the handle integrity tests is not very clear, nor is the referenced schematic diagram showing the direction of test. It is not clear, for example, whether the forces applied to the handle, in each of the two directions, are to be applied individually or simultaneously. Nor is it clear from the diagram whether the force applied parallel to the major planes of the shield and handle, at the apparent midpoint between the point of attachment and the outermost edge, is a tensile force or a compressive force. In the case of most of the pacifiers evaluated, a compressive force applied to the handle would be much less severe than a tensile force. In conducting the tests in this laboratory, the handles were individually tested in each direction, using a tensile pull force. There is some confusion also with respect to the applied force parallel to the plane of the shield, in paragraph (b)(6)(b)(2).

General

The problem surrounding the usage of average values, where appropriate, versus "no single failure" must be resolved and spelled out in the proposed regulation. Specifically, this applies to the areas involving shield flexibility and the structural integrity of the nipple and handle. The same concept also affects the determination of whether a shield is flexible or non-flexible.

In the case of protrusions, the problems may center around the insert rather than the handle. For example, it may not be as important to base these dimensions on measurements between shield and the outermost edge of the handle (where the test weight is attached), as the distance that a rigid insert protrudes from the face of the shield. An approach to the solution of this problem is to exempt from this requirement any material having a durometer hardness below a specified value.

Noticeable odors were detected when the individual blister packs containing samples A, H and I were opened. These three samples also exhibited varying degrees of surface tackiness. A cursory, qualitative chemical analysis indicated that all three samples had been made of poly(vinyl chloride). Infrared spectrographic analysis of material removed by hot methanol extraction indicated the presence of dioctyl phthalate in all three samples. The odors undoubtedly were due to entrapped vapors of this plasticizer and to its presence on the surfaces of the products, as an exudate. The latter would also account for apparent surface tackiness, which can usually be removed readily by washing in warm, soapy water.

It is recommended, with respect to paragraph (b)(5), that a qualitative statement of the thermal resistance be required on all pacifier labels, using terms such as boilable, sterilizable, cleanse in warm soapy water, not boilable, etc. It is also recommended that labels contain the statement: "Not Sterile", when appropriate.

Other Overall Review of the Regulation

At the request of this laboratory, the staff of the Human Factors Section, Product Systems Analysis Division, was requested to review the regulation. These comments are included in this report as Appendix B.

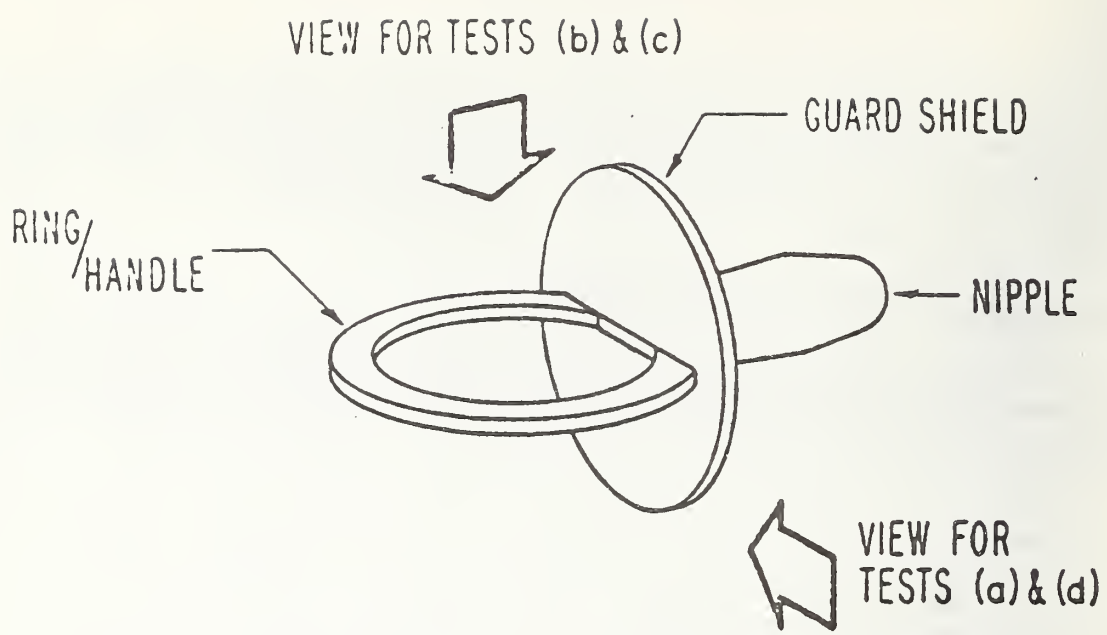

FIG 2 (a thru d) - PACIFIER TENSILE & BENDING TEST DIAGRAMS

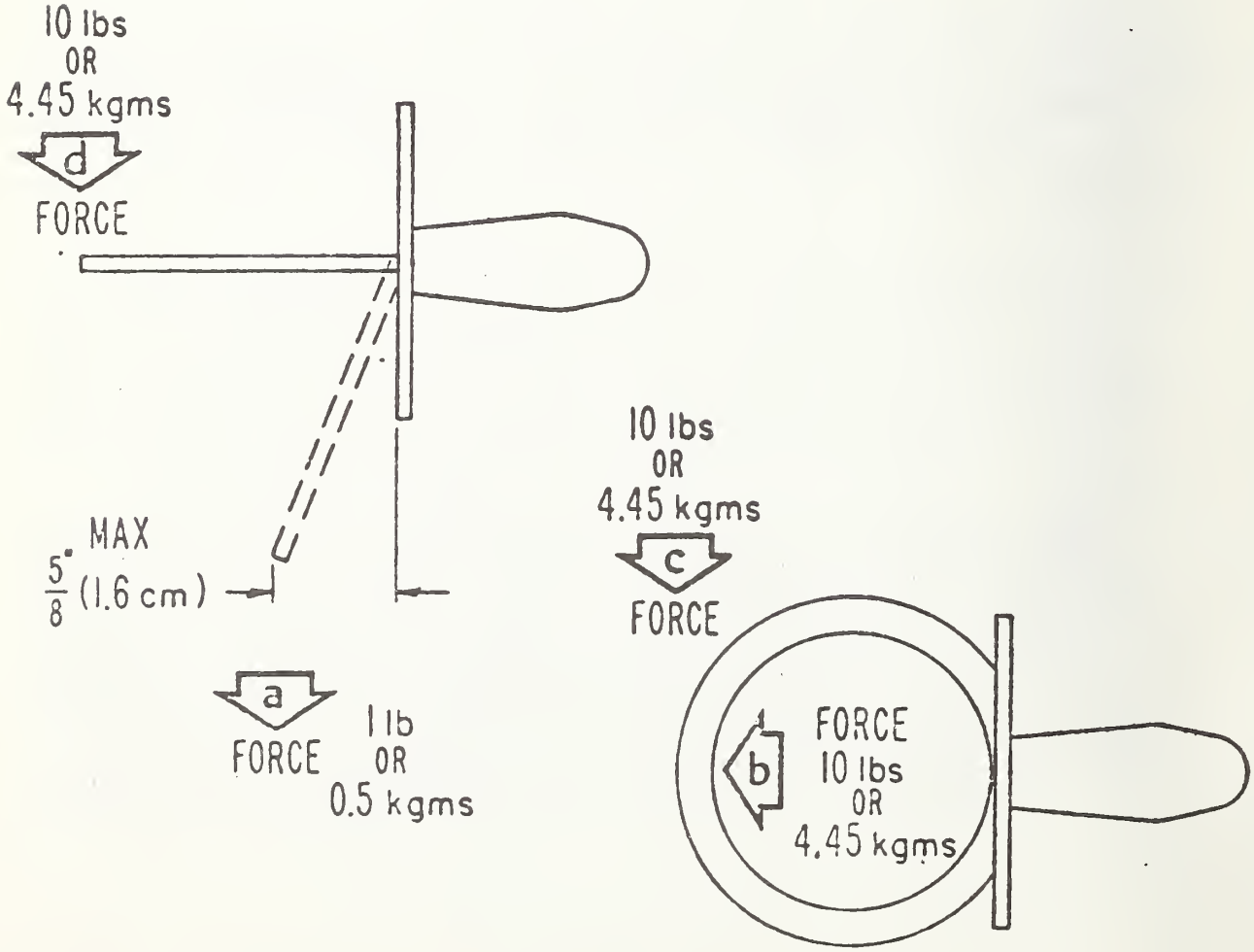

Table 1. Identification of Pacifiers

NBS Sample Code	Number of Pacifier Components	Number of Specimens Tested	Apparent Material of Construction a/
A	1	5	PVC
B	3	5	Rub (H, N); RP (I)
C	1	5	PVC
D	4	5	Rub (N); RP (H,S); Rub (thimble insert)
E	5	5	Rub (N); RP (H, S, I) Rub (thimble insert)
F	1	3	EVA
G	1	3	PVC
H	2 b/	3	PVC; PVC (I)
I	1	5	PVC
J	1	5	EVA

a/ PVC = poly(vinyl chloride)
Rub = vulcanized natural or synthetic rubber
RP = rigid plastic, probably a rubber-modified polystyrene
EVA = ethylene-vinyl acetate copolymer
H = handle
N = nipple
I = insert

b/ Nipple, shield and handle were molded in one piece; insert served as a nipple "filler".

Appendix A

Outline of Proposed 16CFR Part 1500.55

S1500.55 - Requirements and test methods for pacifiers

(a) Definitions

(1) Pacifier

(2) Guard or shield

(3) Handle or ring

(b) Requirements

*(1) Guard shield

(i) non-flexible

(ii) flexible

(A) flexibility determination

*(2) Handle or ring

*(3) Other mechanical hazards

(4) Ribbon or string

(5) Labeling

(a) Display carton

(b) Individual package

*(6) Structural Integrity

(a) Nipple

(b) Handle

(1) unhinged

(2) hinged

(c) Heat cycle deterioration

(*) Indicates those paragraphs containing dimensional and performance requirements evaluated in the laboratory studies.

Appendix B

Date: April 23, 1975

To: Mr. Karl Plitt
Chief, Product Systems Section

From: John Fechter JF
Through: Robert J. Cunitz, Acting Chief RJC
Human Factors Section

Subject: Draft of the Pacifier Standard

I have completed the review you requested of the proposed pacifier standard. My comments address potential oversights in the standard, and reflect material discussed with Harriet Baker in March. I conducted no empirical tests.

1. Toxicants - Neither the introduction to the problem nor restrictions in the standard mention poisoning or toxic substances. It seems obvious that products intended to be kept in the mouth and/or possibly ingested should be free of such substances. The standard should either include a reference to appropriate FDA regulations regarding poisonous substances or should include similar tests for them.

2. Ingestion - Infants and children are likely to swallow small parts and/or pieces of pacifiers. Pieces or parts which cannot pass easily through the digestive system should be prohibited (e.g., hooks, sharp angles, or pieces under tension). All parts should be rounded and smooth, and should not be affected by chemicals normally found in the digestive system.

3. Strangulation - Proposed instructions warn "first users" about the potential for strangulation if ribbons, strings or cord are used to hang pacifiers around a child's neck. I suggest that this specification be added: no closed loop or eye be allowed which can be used as a string attachment point. If such a loop or eye is allowed, it should break open under the weight of a 3-month-old infant.

4. Vomiting - The length of the nipple or other pacifier parts intended to be inside the child's mouth and throat should not be so long that reflex vomiting or choking is induced. The maximum length allowed depends on the child's size. I do not know of data which would specify the appropriate pacifier length for a given child size, but pediatricians should be able to provide such information.

5. Sterilization - People may try to sterilize pacifiers by methods other than boiling. Pacifiers should withstand exposure to alcohol and other sterilizing solutions without deteriorating or becoming toxic.

6. Broken parts - The standard makes no reference to jagged edges or sharp points which can be produced by children chewing on hard-plastic pacifiers. Since this chewing or shearing is expected product use, especially if the children are teething, additional tests should be added to consider shearing and chewing forces.

7. Suffocation - Flexible guards present a potential suffocation hazard if they cover and seal the nostrils.

8. Aspiration - The proposed standard does not test for or prohibit pacifiers whose parts can be breathed into the lungs or lodge in the airway.

9. Orthodontal problems - The standard should consider poor occlusion as a consumer hazard if it can be caused by improper pacifier design. Pacifiers A and G are supposedly designed to avoid problems of poor occlusion caused by thumb-sucking or long-term pacifier use. If data exist to support such a contention, improper designs should be prohibited.

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7. AUTHOR(S): Samuel D. Toner, Harriet A. Baker

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16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)

This report is concerned with a review of a regulation proposed by the Consumer Product Safety Commission on the safety of infants' pacifiers. In addition, the results of a laboratory evaluation of the efficacy of various requirements and testing procedures are given.

17. KEY WORDS (six to twelve entries; alphabetical order, capitalize only the first letter of the first key word unless a proper name; separated by semicolons)

Consumer products, CPSC proposed regulation; pacifiers; product safety; safety requirements; safety testing

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