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FEDERAL TRADE COMMISSION

16 CFR Part 4

Appearances Before the Commission; Restrictions as to Former Members and Employees

AGENCY: Federal Trade Commission (FTC).

ACTION: Final rule.

SUMMARY: The Commission is amending its rule governing the appearances of former members and employees, Rule 4.1(b), to make it consistent with President Clinton's December 28, 2000 revocation of Executive Order 12834 (''Ethics Commitments by Executive Branch Appointees'').

EFFECTIVE DATE: These amendments are effective March 7, 2001.

FOR FURTHER INFORMATION CONTACT: Ira S. Kaye, 202–326–2426, or Shira Pavis Minton, 202–326–2479, Attorneys, Office of the General Counsel, FTC, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Commission is deleting the note following section (b)(1)(iv) of Commission Rule 4.1, 16 CFR 4.1, which currently states that former Commissioners and certain other ''senior'' employees may be subject to Executive Order 12834. That order formerly required that certain Executive Branch officials appointed on or after January 20, 1993, sign a pledge making particular post-employment ethics commitments. This amendment is necessary in order to reflect that, by Executive Order 13184 of December 28, 2000, President Clinton revoked Executive Order 12834.

This rule amendment relates solely to agency practice and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(a)(2), or to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2).

List of Subjects in 16 CFR part 4

Administrative practice and procedure.

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, chapter I, subchapter A, of the Code of Federal Regulations as follows:

PART 4—MISCELLANEOUS RULES

1. The authority citation for part 4 continues to read as follows:

Authority: Sec. 6, 38 Stat. 721; 15 U.S.C. 46.

§ 4.1 [Amended]

2. Section 4.1 is amended by removing the note that follows paragraph (b)(1)(iv).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–5507 Filed 3–6–01; 8:45 am]

BILLING CODE 6750–01–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Dive Sticks; Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a rule to ban certain dive sticks under the authority of the Federal Hazardous Substances Act.[1] Dive sticks are used for underwater activities, such as retrieval games and swimming instruction. They are typically made of rigid plastic and stand upright at the bottom of a swimming pool. Due to these characteristics, if a child jumps onto a dive stick in shallow water he or she may suffer severe injuries.

DATES: The rule will become effective on April 6, 2001.

FOR FURTHER INFORMATION CONTACT: Renae Rauchschwalbe, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0608, ext. 1362.

SUPPLEMENTARY INFORMATION:

A. Background

As of November 2000, the Commission is aware of nine confirmed impalement incidents involving dive sticks that were submerged and standing vertically. These incidents resulted in injuries to the perineal region of young children. The products were cylindrical batons, approximately 7⅞ to 8⅝ inches long and ⅞ to one inch in diameter. They were all constructed of rigid plastic.

In early 1999, when the Commission staff first learned of incidents involving dive sticks, the staff worked with product manufacturers to recall hazardous dive sticks. On June 24, 1999, the Commission announced that it had reached agreements with 15 manufacturers and importers to voluntarily recall their dive sticks. The recalls have removed most dive sticks from the market.[1,9] [2] However, because the hazard posed by dive sticks appeared to be inherent to the product and not related to any specific model or manufacturer, the Commission began a proceeding to ban all dive sticks with hazardous characteristics.

On July 16, 1999, the Commission issued an advance notice of proposed rulemaking (''ANPR'') announcing the Commission's intent to issue a rule addressing the risk of injury presented by dive sticks. 64 FR 38387 (1999). One alternative discussed in the ANPR was a rule declaring certain dive sticks to be banned hazardous substances.

On July 19, 2000, the Commission published a notice of proposed rulemaking (''NPR'') proposing to ban hazardous dive sticks. 65 FR 44703 (2000). The proposed rule stated that it would ban dive sticks that (1) are rigid; (2) submerge to the bottom of a pool of water; and (3) stand upright in water. The Commission proposed a performance test to determine the rigidity of a dive stick. Dive sticks that come to rest underwater at an angle greater than 45 degrees from vertical would be exempt under the proposed rule as would dive sticks that maintain a compressive force of less than 5-lbf under a prescribed performance test. The Commission has determined to

[1] Commissioner Mary Gall filed a separate statement which is available from the Office of the Secretary, Room 502, 4330 East-West Highway, Bethesda, Maryland.

[2] Numbers in brackets refer to documents listed at the end of this notice.

issue the proposed rule as a final standard without change.

The Commission received one comment on the proposed rule. That comment came from a student at Florida International University. He asked whether it would be safer to discontinue the sale of all dive sticks, both soft and rigid. Based on available medical literature, the Commission concludes that only rigid dive sticks pose the threat of impalement injuries to children. The Commission is not aware of any impalement incidents, reported to CPSC or in the medical literature, involving any flexible objects. Thus, the Commission believes that the rule, including the exemption for non-rigid dive sticks, will adequately protect the public.[11]

B. Statutory Authority

This proceeding is conducted pursuant to the Federal Hazardous Substances Act (''FHSA''), 15 U.S.C. 1261 *et seq.* Section 2(f)(1)(D) of the FHSA defines ''hazardous substance'' to include any toy or other article intended for use by children that the Commission determines, by regulation, presents an electrical, mechanical, or thermal hazard. 15 U.S.C. 1261(f)(1)(D). An article may present a mechanical hazard if its design or manufacture presents an unreasonable risk of personal injury or illness during normal use or when subjected to reasonably foreseeable damage or abuse. Among other things, a mechanical hazard could include a risk of injury or illness ''(3) from points or other protrusions, surfaces, edges, openings, or closures, * * * or (9) because of any other aspect of the article's design or manufacture.'' 15 U.S.C. 1261(s).

Under section 2(q)(1)(A) of the FHSA, a toy, or other article intended for use by children, which is or contains a hazardous substance accessible by a child is a ''banned hazardous substance.'' 15 U.S.C. 1261(q)(1)(A).

Section 3(f) through 3(i) of the FHSA, 15 U.S.C. 1262(f)–(i), governs a proceeding to promulgate a regulation determining that a toy or other children's article presents an electrical, mechanical, or thermal hazard. As required by section 3(f), this proceeding began with an ANPR. 64 FR 38387 (1999). After considering the one comment submitted in response to the ANPR, the Commission issued a proposed rule and a preliminary regulatory analysis in accordance with section 3(h) of the FHSA. 65 FR 44703 (2000). The Commission then considered the comment received in response to the proposed rule and determined to issue a final rule and a final regulatory analysis. 15 U.S.C. 1262(i)(1).

Before the Commission can issue a final rule it must find (1) if an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to its costs; and (3) that the regulation imposes the least burdensome alternative that would adequately reduce the risk of injury. *Id.* 1261(i)(2).

C. The Product

Dive sticks are generally used in swimming pools for underwater retrieval activities, such as retrieval games and swimming instruction. They are made of rigid plastic. They are typically cylindrical in shape, ten inches or less in length with a diameter one inch or less, but some have novelty shapes such as shark silhouettes. They are or can be weighted so that when dropped into water they sink and stand upright on the bottom.

Before the June 1999 recall, retail prices usually ranged from $4 to $7 per set or about $1 per individual stick. Retail prices were almost always less than $10, even when sold with other products such as disks, rings, and snorkels. An estimated 4 to 5 million dive sticks were sold in both 1997 and 1998. Altogether, about 20 million dive sticks have been sold since 1990. Sales of dive sticks increased substantially during the 1990's. About 1 million households may have owned dive sticks during any given year.[8,12]

Before the June 1999 recalls, the CPSC staff identified at least 15 firms that manufactured or imported dive sticks into the United States. Most of the importers obtained their products from China, Hong Kong, or Taiwan. Because the product is inexpensive and simple to manufacture, it is relatively easy for firms to enter or leave the dive stick market. Therefore, firms that have not supplied dive sticks in the past, and were not part of the June 1999 recalls, could begin or renew producing or supplying dive sticks.[8,12]

D. The Risk of Injury

1. *Description of Injury.* Impalement injuries have occurred when a child accidently sat, fell or jumped buttocks-first into shallow water and landed on a dive stick. As discussed in the NPR, serious rectal or vaginal injuries can result. The severity of injuries depends on the degree of penetration by the object. The injuries could range from laceration of the rectum and sphincter, to puncture wounds and tears of the colon. Less serious injuries such as facial and eye injuries are also possible when a child attempts to retrieve a dive stick under the water.[2,10]

2. *Impalement Injury Data.* As of November 2000, the Commission is aware of nine confirmed impalement injuries involving submerged vertically-standing dive sticks. All the victims were children ranging in age from three to nine years old.[10]

Four females (ages 7 to 9) sustained injuries when the dive stick penetrated the vagina. Two males (ages 3 and 7) and two females (ages 5 and 6) suffered injuries when the dive stick penetrated the rectum. In the remaining incident, a female received external lacerations around the rectum after landing on a dive stick. Medical attention was sought after each incident, and six of the injuries required surgery to address multiple internal and external injuries.These nine incidents involved vertical-standing dive sticks. The products were cylindrical batons, approximately 7⅞ to 8⅝ inches long and ⅞ to one inch in diameter.[2,10]

Eight of the impalement injuries occurred in shallow depths of water. Of these, five occurred in small wading pools with water levels between 12 and 24 inches. Of the remaining three incidents, one occurred on the top step of a spa, one occurred in a pool measuring three feet in height with approximately 27 inches of water, and the final incident occurred in a bathtub with approximately 6 inches of water. The ninth incident reportedly took place in a pool; however, neither the type of pool nor the water depth is known.[2,10] [3]

The July 1999 ANPR provided summaries of impalement incidents reported at that time. The NPR published in July 2000 provided summaries of the three impalement injuries reported between publication of the ANPR and the NPR. One additional incident was not included in either the ANPR or the NPR. That incident involved a three-year-old boy who jumped or slid into a shallow pool and landed on an upright dive stick which penetrated his rectum. He suffered a 1½ inch puncture wound and tear in his bowels. Doctors performed a temporary colostomy and will have to reattach his intestines to his bowels once the puncture wound heals. The dive stick came in a package with a retrofit so that

[3] A tenth unconfirmed incident was reported to CPSC, but many details of the incident remain unclear.

the dive stick would not stand upright in the water. This retrofit was not attached to the product at the time of the incident.[10]

3. *Non-Impalement Injury Data.* In addition to genital and rectal injuries, the Commission received reports of four injuries to other body parts that occurred when the victim submerged onto the vertical-standing dive stick. As discussed in the NPR, the injuries occurred when the children attempted to retrieve the dive sticks from the bottom of the pool. The Commission has also received reports of 11 incidents of victims struck by a thrown dive stick. Five of these incidents were reported since the June 2000 briefing package. Seven females and four males were involved in the incidents. The victims ranged in age from 4 years old to 40 years old. One of the recent incidents involved a foam dive stick as opposed to the recalled dive sticks made of hard plastic. The foam dive stick was made of a foam cylinder with a weighted plastic end. The plastic end of the dive stick is the part that contacted the victim, resulting in a laceration to the scalp.[2,10]

E. The Ban

The Commission's rule will ban dive sticks with certain hazardous characteristics. Although voluntary recalls have removed most, if not all, of these products from the market for the present time, the Commission is concerned that, without a rule banning them, they could reappear on the market.

The rule will ban dive sticks that (1) are rigid, (2) submerge to the bottom of a pool of water, and (3) stand upright in water. After considering the reported impalement injuries, the Commission believes that these are the essential characteristics that create the impalement hazard. Dive sticks and similar articles that do not have these characteristics, as well as dive rings and dive disks, are still allowed.

All dive stick impalement incidents and other rectal or vaginal impalement cases reported in the medical literature involved objects that were rigid. The staff is not aware of any impalement injuries to the perineum that involved a flexible object. In order to prevent serious injuries, the dive stick should be of sufficient flexibility that it would bend to a degree that prevents penetration when impact occurs with the perineal area. The staff developed a test to distinguish dive sticks that are sufficiently flexible so as to effectively limit the potential for serious impalement injury.

The Commission believes that it is appropriate to base a rigidity test on a fraction of the weight of a child who is first beginning to walk. Although the youngest child involved in a reported impalement incident was three years old, if a child can walk independently it is possible that he or she might be playing in a shallow body of water and fall onto a dive stick in the same manner that occurred in the impalement incidents. Children begin to walk on their own at about 11½ months. Therefore, the test uses the weight of a 10 to 12 month-old child. The weight of a 5th percentile 10 to 12 month-old child is 16.5 pounds (7.5 kg). The Commission believes that a failure criterion of 5-lbf (approximately ⅓ of the weight of a 10 to 12 month-old child) will provide a margin of safety to effectively limit the potential for a serious impalement injury.

The performance test applies a gradual compression load to the top of the dive stick for a period of 40 seconds. If the force reaches 5 lbf the dive stick is too rigid and fails the test. The Commission is aware that some manufacturers are developing dive sticks that are constructed of flexible material that would pass this test. The Commission believes that such flexible articles would not pose an impalement hazard.[5,7]

Commission staff tested samples of both rigid and flexible dive sticks. The flexible dive sticks began deflecting almost immediately. The maximum force remained under 5 lbf, which was achieved in under 10 seconds. When the compression load was applied for a total of 40 seconds, the dive stick bent significantly and the force readings dropped further from the recorded maximum force. In contrast to the flexible dive sticks, maximum force readings for rigid dive sticks exceeded 25-lbf in less than 3 seconds, with no noticeable bending.[7]

All confirmed impalement injuries occurred with dive sticks that had submerged to the bottom of a pool of water. It is unlikely that a child falling onto a dive stick floating on the water would suffer impalement. A floating dive stick is likely to move away before the child's body strikes the bottom of the pool.[3,6]

The vertical orientation of a submerged dive stick is a key factor in these impalement incidents. The Commission's Human Factors staff examined the reported incidents and concluded that when force is applied in line with the long axis of the dive sticks (as it is when a child lands on it in a vertical position), the sticks do not move. According to Human Factors, ''Because the stick is braced against the floor, the impact causes a relatively rapid deceleration of the body part which is struck, with the force of the impact concentrated on the small area at the end of the stick.'' The Human Factors staff believes that the potential for impalement injury declines as the angle of impact moves away from the vertical. However, the orientation of a child landing on a stick is variable, and impact at precisely the wrong angle may reorient the stick perpendicular to the bottom surface. Thus, slight deviations of the stick's position from vertical may not be adequate to avoid impalement. If the angle of the stick is sufficiently away from vertical, both impact in line with the axis and impact at an angle to the axis would tend to move the stick and limit the possibility of impalement. The Commission believes that a position at least 45 degrees from vertical would provide a sufficient safety margin to effectively limit the potential for impalement injuries.[3,6]

F. Alternatives

The Commission has considered other alternatives to reduce the risk of impalement injury related to dive sticks. However, as discussed below, the Commission does not believe that any of these would adequately reduce the risk of injury.

1. *Voluntary Recalls.* Before beginning this proceeding the Commission negotiated voluntary recalls with many companies that manufactured or imported dive sticks, and many other firms voluntarily removed their dive sticks from the market. One alternative to the banning rule is for the Commission to continue pursuing recalls on a case-by-case basis. However, it appears that the impalement hazard is present in all dive sticks that have the hazardous characteristics the staff has identified. The hazard is not limited to one particular model or brand. Therefore, a rule banning all dive sticks with the identified characteristics is more efficient. While the recalls have removed hazardous dive sticks from the market for now, proceeding with future recalls in the absence of a banning rule would allow hazardous dive sticks to return to the market until the Commission had a chance to act on the new dive sticks.[8,12]

2. *Voluntary Standard.* Currently, there is no applicable voluntary standard, nor was one submitted in response to the ANPR or the NPR. Moreover, because dive sticks are relatively inexpensive and easy to manufacture, compliance with a voluntary standard may be low.[8,12]

3. *Labeling.* One alternative to a banning rule would be to require cautionary labeling for dive sticks. Most dive sticks carry some warnings regarding small parts (in reference to the end caps); instructions to use only under the supervision of a competent swimmer, and/or warning against diving in shallow water. In order for a label warning of the impalement hazard to be fully effective, consumers must notice, read, and understand it, then comply with it 100% of the time. People are less likely to comply with a warning if the connection between the product and the injury potential is not clear, if they cannot imagine what the injury is, or if they do not fully understand how to avoid the hazard. As the impalement hazard presented by dive sticks is not apparent, the label would have to convey clearly that severe rectal or genital injuries can result if children jump into the water and land on the sticks. Further, a ''safe'' water depth would have to be identified to give consumers adequate information on which to base their purchasing decision.

A label that meets these criteria could have a significant impact at the point of purchase, but would need to be reinforced with an on-product warning. It would be difficult, however, to develop a label that is highly noticeable and easy to read because of the small and typically curved surface area of the dive stick. Moreover, a label may not last the life of the product because it is used in water. In contrast, the effectiveness of banning hazardous dive sticks is not in question, because the impalement hazard would be minimized or eliminated.[3, 8, 12]

4. *Change in Scope.* A final alternative considered was to modify the scope of the rule so that it would apply only to pre-weighted dive sticks. However, it is easy to add weight to certain unweighted dive sticks by filling them with water, sand or similar materials so that they too can stand vertically at the bottom of a pool. Because such unweighted dive sticks can pose the same risk as pre-weighted ones, the Commission is including them in the rule.

G. Final Regulatory Analysis

1. Introduction

The Commission has determined to ban dive sticks with certain hazardous characteristics. Section 3(i) of the FHSA requires the Commission to prepare a final regulatory analysis containing (1) a description of the potential benefits and costs of the rule, including any benefits or costs that cannot be quantified in monetary terms and the identification of those likely to be affected; (2) a description of alternatives considered by the Commission, a discussion of their costs and benefits, and a brief explanation of why they were not chosen; and (3) a discussion of any significant issues raised by comments on the preliminary regulatory analysis published with the proposed rule. 15 U.S.C. 1261(i). The following discussion addresses these requirements.

2. Potential Benefits of a Rule Banning Certain Dive Sticks

When used in shallow water, rigid dive sticks that stand upright in water can cause serious impalement injuries to the perineum. The CPSC is aware of eight confirmed impalement injuries that occurred prior to the 1999 recall. A ninth injury occurred in April 2000. However, because the recall of dive sticks had an unknown impact on the number of dive sticks in use, this analysis of the societal costs of dive stick injuries is limited to the eight occurring from 1990 through 1999.[4] All victims received medical attention after the injury and at least five required surgery. In one case a temporary colostomy was performed. The CPSC is aware of 17 non-impalement injuries associated with dive sticks. Four of these incidents involved submerged dive sticks and resulted in lacerations that required stitches or surgical glue to close. Although the rule is not directly aimed at reducing these injuries, some of these injuries may have been prevented by the rule.

The reduction in the societal costs of injuries represents the societal benefits of a ban on certain dive sticks. Based on estimates from the CPSC's Injury Cost Model, the costs of impalement injuries, such as those from dive sticks, may range from about $9,000 for injuries that do not require hospitalization to about $100,000 for injuries that require hospitalization. These estimates are based on the costs of injuries involving punctures or lacerations to the victims' lower trunk or pubic region for children 5 to 9 years-of-age (the age range of the known victims). These cost estimates include the cost of medical treatment, pain and suffering, lost work time (including that lost by parents and caregivers), and legal and liability costs.

If we assume that the only cases that required hospitalization were the 5 incidents that required surgery, the total societal costs of the known incidents are about $527,000 (5 cases × $100,000 and 3 cases × $9,000) or an average of $52,700 a year since 1990. This is a low estimate of the total societal cost because it is based only on the cases known to CPSC. There may have been other injuries of which CPSC is not aware.

A useful measure for analytical purposes is the annual average injury cost per dive stick. This estimate is derived by dividing the average annual societal costs of injuries by the average number of dive sticks in use each year. As discussed earlier, the average number of dive sticks in use each year from 1990 to 1999 ranged from about 3 million units (assuming a 1 year product life) to about 5.5 million units (assuming a 4 year product life). Therefore, the annual societal costs of dive stick injuries may range from about one cent per dive stick in use ($52,700 ÷ 5.5 million) to 2 cents per dive stick in use ($52,700 ÷ 3 million).

Since dive sticks may last from one to four years, the societal costs of injuries per dive stick over the entire life of the dive stick range from about 2 cents ($0.02 × 1 year) to about 4 cents ($.01 × 4 years). Since the benefit of a ban on certain dive sticks is the reduction in the societal cost of the injuries, the benefits of a ban that eliminates these injuries is about 2 to 4 cents per banned dive stick removed from or prevented from entering the market.

The average total annual cost of dive stick injuries of $52,700 is based on known injury cases from 1990 to 1999. However, as noted earlier, dive stick sales increased from less than 1 million per year to about 5 million. If rigid dive sticks that stand upright in water had not been recalled and their annual sales had leveled off at about 5 million units annually (the sales volume in the late 1990s), the product population model indicates that the number of dive sticks in use would have reached 8 to 20 million units within the next few years. Since we estimated that the societal cost of injuries per dive stick in use was about 1 to 2 cents, this indicates that the annual cost of dive stick impalement injuries would have reached approximately $160,000 ($0.02 × 8 million) to $200,000 ($0.01 × 20 million) per year had these dive sticks not been recalled.

The benefits of eliminating dive stick injuries most directly affect households with children, since all victims have been 9 years old or younger. However, since medical costs are generally pooled through insurance, and some of the benefits include a reduction in lost worktime of caregivers, the monetary benefits of the proposed rule would be diffused through society as a whole.

[4] An estimate of the number of dive sticks in use in needed to estimate the pre-regulatory risk of injury that will be addressed by the regulation.

3. Potential Costs of the Rule

Rigid dive sticks that stand upright were removed from the U.S. market in 1999 when the Commission recalled dive sticks. Since then, when the CPSC has become aware of a rigid dive stick that stands upright being available in this country, the staff has taken action under the authority of section 15 of the FHSA to remove the dive stick from the market. The rule being issued now promulgates a ban on these dive sticks and establishes a performance standard for dive sticks. The performance standard establishes criteria for distinguishing dive sticks that are unlikely to pose impalement risks (and so are not banned) from dive sticks that may impose impalement risks (and therefore, are banned).

Manufacturers that produced the banned dive sticks (or that continue to produce these dive sticks for sale in other countries) will incur some costs to modify their products to conform to the requirements of the rule. The CPSC staff believes that the modifications can be made with minimal impact on tooling and other production processes. For example, some manufacturers may be able to continue to use the same molds that they used for rigid dive sticks, but with a softer or more flexible plastic. Other manufacturers may be able to use the same material as before but adjust the center of gravity of the dive sticks so that they do not stand upright in water. Consequently, it seems reasonably likely that when the incremental cost of the changes are spread over large production runs, the cost will be no more than the benefits—2 to 4 cents per dive stick manufactured.[5]

The ban on rigid dive sticks that stand upright may reduce consumer utility if consumers prefer the banned dive sticks to the substitute products (*i.e.*, dive sticks that do not stand upright, flexible dive sticks, dive rings, dive disks, and so on). However, because these substitute products serve essentially the same purposes and would cost about the same,[6] the negative impact on consumer utility, if any, is unlikely to be significant.

4. Alternatives Considered

The Commission considered several alternatives to issuing this rule to ban certain dive sticks. These included (1) taking no action and relying on a voluntary standard or section 15 actions, (2) a labeling only requirement, and (3) changing the scope of the products subject to the ban.

(a) *Taking No Action and Relying on a Voluntary Standard or Section 15 Activities.* The Office of Compliance has successfully negotiated recalls with many of the firms that manufactured or imported the dive sticks. Other firms for which recalls were not negotiated have voluntarily ceased distributing these dive sticks. However, since it is relatively easy for firms to enter this market, new firms could begin selling non-complying dive sticks in the absence of a standard. CPSC is aware of at least one firm that was not involved in the June 1999 recall but was distributing dive sticks after June 1999.

The Commission could continue to use its Section 15 authority to recall hazardous dive sticks when they are found instead of banning them outright. However, this approach would require the CPSC staff to make a determination that a product was hazardous each time a new dive stick was introduced to the market. Additionally, without a standard, potentially hazardous products would be available to consumers while CPSC staff were making this determination.

There is no voluntary standard for dive sticks that addresses the impalement hazard, nor was a proposed standard submitted in response to the NPR. Even if one were developed, it would be difficult to enforce since dive sticks are relatively easy to manufacture and new firms could easily begin distributing the product. Therefore, compliance with a voluntary standard may be low.

(b) *Labeling Only Requirement.* The staff explored the possibility of a warning label instead of a ban. However, according to the Commission's Human Factors staff, a warning label is the least effective approach to reducing the number of injuries. A label that is highly visible and clearly communicates the hazard could have a significant impact at the point of purchase. However, a label on the package would not remain with the product after the sale, and because the product is intended for use in the water, it is likely that any label attached to the product itself would not last the life of the product. Moreover, the surface area on a dive stick is not conducive to designing an effective warning label.

(c) *Changing the Scope.* The scope of the rule could be modified so that it applies only to pre-weighted dive sticks. However, the staff found that consumers could weight some unweighted dive sticks so that they stood vertically in water. These products would then present exactly the same impalement hazard as the pre-weighted dive sticks.

5. Significant Issues Raised by Comments on Preliminary Regulatory Analysis

The Commission did not receive any comments concerning the preliminary regulatory analysis.

H. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (''RFA''), when an agency issues a proposed rule it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities. 5 U.S.C. 605(b). For the reasons discussed below, the Commission made this certification in the NPR.

Although most of the firms that manufactured or imported dive sticks are small businesses, staff analysis suggests that the rule is unlikely to have a significant effect on any businesses, large or small. Most manufacturers removed their dive sticks from the market in response to the 1999 recalls. Some manufacturers have already taken steps to redesign their products. If the redesigned products conform to the rule, the manufacturers would not incur any additional costs. In addition, as discussed above, the costs of the rule are likely to be small. Finally, dive sticks probably account for only a small percentage of any individual firm's sales. Several dive stick manufacturers market various types of pool or other toys. Others have additional product lines such as pool supplies and equipment. Additionally, most of the firms that manufactured or imported dive sticks also distribute similar toys (such as dive rings and disks and certain dive eggs that do not rest vertically on the bottom) that would not be covered by the ban. If firms stopped producing and selling dive sticks, sales of these substitute products may increase, offsetting any loss due to a ban on dive sticks.[8,12]

[5] Manufacturers that enter the dive stick market after the rule goes into effect may not incur any additional costs associated with ''redesigning'' dive sticks because they would design their products from the start to comply with the rule's requirements.

[6] Dive rings appeared to retail for approximately the same price per package as dive sticks, but there are generally fewer dive rings per package than dive sticks. For example, packages of dive sticks often contained 6 dive sticks; packages of dive rings seldom contain more than 4 rings. The retail prices of dive disks appear to be roughly equal to the retail prices of dive sticks. Modified dive sticks (that are either not rigid or that do not stand upright) retail for close to the prices of the banned dive sticks.

I. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission assessed the possible environmental effects associated with the rule banning certain dive sticks.

The Commission's regulations state that rules providing design or performance requirements for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.[8,12]

J. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state the preemptive effect, if any, of new regulations.

The FHSA provides that, generally, if the Commission issues a banning rule under section 2(q) of the FHSA to protect against a risk of illness or injury associated with a hazardous substance, ''no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.'' 15 U.S.C. 1261n(b)(1)(B). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the FHSA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the FHSA requirement for the hazardous substance for the Federal, State or local government's own use. 15 U.S.C. 1261n(b)(2).

Thus, with the exceptions noted above, the rule banning certain dive sticks would preempt non-identical state or local requirements applicable to dive sticks designed to protect against the same risk of injury.

The Commission has also evaluated this rule in light of the principles stated in Executive Order 13132 concerning federalism, even though that Order does not apply to independent regulatory agencies such as CPSC. The Commission does not expect that the rule will have any substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among various levels of government.

K. Effective Date

The rule will become effective 30 days from publication in the **Federal Register** and will apply to dive sticks entering the chain of distribution on or after that date. As stated in the NPR, the Commission believes a 30-day effective date is appropriate because (1) due to the 1999 recalls, few, if any, hazardous dive sticks should be currently on the market; (2) redesigning products to comply with the rule should be fairly simple; and (3) substitute products are readily available.[1,8,9]

L. Commission Findings

For the Commission to issue a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). Accordingly, the Commission makes the following findings.

Voluntary standard. The FHSA requires the Commission to make certain findings concerning compliance with and adequacy of a voluntary standard if a relevant voluntary standard has been adopted and implemented. *Id.* The Commission is not aware of any voluntary standards addressing the risk of injury posed by dive sticks. Therefore, no findings concerning voluntary standards are necessary.

Relationship of benefits to costs. The FHSA requires the Commission to find that the benefits expected from a regulation bear a reasonable relationship to its costs. *Id.* The Commission estimates the potential benefits of removing hazardous dive sticks from the market to be 2 to 4 cents per dive stick. With the availability of substitutes and the expected low cost of modifying dive sticks to conform to the rule, the Commission anticipates that necessary changes will be minimal. The Commission estimates that the costs of the rule will be no more than 2 to 4 cents per dive stick. Thus, the Commission finds that there is a reasonable relationship between the expected benefits of the rule and its costs.

Least burdensome requirement. The FHSA requires the Commission to find that a regulation imposes the least burdensome alternative that would adequately reduce the risk of injury. 15 U.S.C. 1262(i)(2). The Commission considered pursuing voluntary recalls, following a voluntary standard, requiring labeling or changing the scope of the rule. A banning rule would be more effective than case-by-case recalls because the impalement hazard affects all dive sticks, not a specific brand or model. Awaiting recalls would allow these hazardous items on the market until the Commission obtained recalls. As explained above, no applicable voluntary standard exists, and compliance may be low if one did. Although labeling could help reduce the risk of injuries from dive sticks, it would be less effective than a banning rule. It may be difficult for a label to convey the necessary information at the time of use. Modifying the scope so that the rule would only apply to pre-weighted dive sticks would continue to permit hazardous items because the unweighted dive sticks can easily be weighted to stand vertically at the bottom of the water. Thus, the Commission finds that a ban of dive sticks with the hazardous characteristics it has identified is the least burdensome alternative that would adequately reduce the risk of injury.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, and Toys.

Conclusion

For the reasons stated above, the Commission concludes that the dive sticks described in this rule are hazardous substances under section 2(f)(1)(D) of the FHSA. They are intended for children and present a mechanical hazard because their design or manufacture presents an unreasonable risk of injury. 15 U.S.C. 1261(s). Therefore, the Commission amends title 16 of the Code of Federal Regulations as follows:

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

1. The authority for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261–1278.

2. Section 1500.18 is amended to add a new paragraph (a)(18) to read as follows:

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

(a) * * *

(18)(i) Dive sticks, and other similar articles, that are used in swimming pools or other water environments for such activities as underwater retrieval games or swimming instruction, and which, when placed in the water, submerge and rest at the bottom of the pool. This includes products that are pre-weighted to sink to the bottom and products that are designed to allow the user to adjust the weight. Dive sticks and similar articles that come to rest underwater at an angle greater than 45 degrees from vertical when measured under the test at § 1500.86(a)(7) and dive sticks and similar articles that maintain a compressive force of less than 5-lbf under the test at § 1500.86(a)(8) are exempt from this banning rule. Articles that have a continuous circular shape, such as dive rings and dive disks are also exempt.

(ii)(A) *Findings.* In order for the Commission to issue a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). These findings are discussed in paragraphs (a)(18)(ii)(B) through (D) of this section.

(B) *Voluntary standard.* No findings concerning compliance with and adequacy of a voluntary standard are necessary because no relevant voluntary standard addressing the risk of injury posed by dive sticks has been adopted and implemented.

(C) *Relationship of benefits to costs.* The Commission estimates the potential benefits of removing hazardous dive sticks from the market to be 2 to 4 cents per dive stick. With the availability of substitutes and the expected low cost of modifying dive sticks to conform to the rule, the Commission anticipates that necessary changes will be minimal. The Commission estimates that the costs of the rule will be no more than 2 to 4 cents per dive stick. Thus, the Commission finds that there is a reasonable relationship between the expected benefits of the rule and its costs.

(D) *Least burdensome requirement.* The Commission considered pursuing voluntary recalls, following a voluntary standard, requiring labeling or changing the scope of the rule. A banning rule would be more effective than case-by-case recalls because the impalement hazard affects all dive sticks, not a specific brand or model. Awaiting recalls would allow these hazardous items on the market until the Commission obtained recalls. No applicable voluntary standard exists, and compliance may be low if one did. Although labeling could help reduce the risk of injuries from dive sticks, it would be less effective than a banning rule. It may be difficult for a label to convey the necessary information at the time of use. Modifying the scope so that the rule would only apply to pre-weighted dive sticks would continue to permit hazardous items because the unweighted dive sticks can easily be weighted to stand vertically at the bottom of the water. Thus, the Commission finds that a ban of dive sticks with the hazardous characteristics it has identified is the least burdensome alternative that would adequately reduce the risk of injury.

* * * * *

3. Section 1500.86 is amended to add new paragraphs (a)(7) and (8) to read as follows:

§ 1500.86 Exemptions from classification as a banned toy or other banned article for use by children.

(a) * * *

(7) Dive sticks and similar articles described in § 1500.18(a)(18) that come to rest at the bottom of a container of water in a position in which the long axis of the article is greater than 45 degrees from vertical when measured in accordance with the following test method:

(i) Test equipment.

(A) A container that is filled with tap water to a depth at least 3 inches [76 mm] greater than the longest dimension of the dive stick. The container shall:

(*1*) Be sufficiently wide to allow the dive stick to lie along the bottom with its long axis in a horizontal position,

(*2*) Have clear side walls to permit observation of the dive stick under water, and

(*3*) Be placed on a level surface and have a flat bottom.

(B) A protractor or other suitable angle measurement device that has an indicator for 45 degrees from vertical.

(ii) Testing procedure

(A) If the dive stick is sold such that the consumer is required to attach an additional component(s) to the dive stick, then the product shall be tested both with and without the attachment(s).

(B) From just above the water surface, drop the dive stick into the container.

(C) Let the dive stick sink and come to rest at the bottom of the container. If the dive stick is designed so that the weight can be adjusted by adding water or other substance, adjust the weight so that the dive stick sinks and comes to rest with its long axis positioned as close to vertical as possible.

(D) Align the angle measurement device alongside the dive stick underwater and wait for the dive stick to come to rest if there is any water disturbance. Determine whether the long axis of the dive stick is greater than or less than 45 degrees from vertical.

(8) Dive sticks and similar articles described in § 1500.18(a)(18) in which the maximum force measured in the following test method is less than 5–lbf [22N]. The test shall be conducted in the ambient environment of the laboratory and not under water.

(i) Test equipment.

(A) A compression rig that has a force gauge or equivalent device that is calibrated for force measurements within a minimum range of 0 to 5 lbf [0–22 N] and with an accuracy of ±0.1 lbf [±0.44 N] or better. The test rig shall have a system to guide this force application in the vertical direction and shall have a means to adjust the rate of load application.

(B) Compression disk—the loading device that is attached to the force gauge shall be a rigid metal disk with a minimum diameter of 1.125 inches [29 mm].

(C) Vise or other clamping device.

(ii) Testing procedure

(A) Position the bottom of the dive stick in the clamping device so that the longest axis of the dive stick is vertical. The bottom end of the dive stick is the end that sinks to the bottom of a pool of water. Secure the bottom of the dive stick in the clamp such that the clamping mechanism covers no more than the bottom ½ inch [13 mm] of the dive stick.

(B) Apply a downward force at a rate of 0.05 in/sec (±0.01 in/sec) [1.3 mm.sec ±0.3 mm/sec] at the top of the dive stick with the compression disk positioned so that the plane of the disk contact surface is perpendicular to the long axis of the dive stick.

(C) Apply the load for a period of 40 seconds or until the maximum recorded force exceeds 5-lbf [22 N].

(D) Record the maximum force that was measured during the test.

Dated: March 1, 2001.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. Briefing memorandum from Ronald Medford, AED, Office of Hazard Identification and Reduction and Scott Heh, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Dive Sticks,'' June 8, 2000.

2. Memorandum from Debra Sweet, Directorate for Epidemiology, to Scott Heh, Project Manager, ''Injury Data Related to Dive Sticks,'' March 21, 2000.

3. Memorandum from Catherine A. Sedney, Division of Human Factors, to Scott

Heh, Project Manager, ''Human Factors Assessment of Dive Sticks,'' April 10, 2000.

4. Comment Received in Response to the ANPR, Steve Hutchison, Department of Fair Trading, NSW Consumer Protection Agency, Australia, dated August 30, 1999.

5. Memorandum from Scott Heh, Project Manager, to File, ''Banning Definition and Test Methods for Dive Sticks,'' May 3, 2000.

6. Memorandum from Catherine A. Sedney, Division of Human Factors, to Scott Heh, Project Manager, ''Prevention of Impalement Injuries: Specification of the Position of Dive Sticks in Water,'' January 27, 2000.

7. Memorandum from Suad Nakamura, Ph.D., Physiologist, Division of Health Sciences, and Scott Heh, Mechanical Engineer, Directorate for Engineering Sciences, to File, ''Development of an Exemption for Non-rigid Dive Sticks,'' May 3, 2000.

8. Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis, to Scott Heh, Project Manager, ''Preliminary Regulatory Analysis: Dive Sticks,'' May 18, 2000.

9. Briefing memorandum from Ronald Medford, AED, Office of Hazard Identification and Reduction and Scott Heh, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Dive Sticks,'' February 15, 2001.

10. Memorandum from Debra Sweet, Directorate for Epidemiology, to Scott Heh, Project Manager, ''Injury Data Related to Dive Sticks,'' January 30, 2001.

11. Memorandum from Scott Heh, Project Manager, to File, ''Comment Responding to the NPR on Dive Sticks,'' January 24, 2001.

12. Memorandum from Robert Franklin, Economist, Directorate for Economic Analysis, to Scott Heh, Project Manager, ''Final Regulatory Analysis: Dive Sticks,'' February 14, 2001.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 00F–0812]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Dimethyl Dicarbonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for a more descriptive term, in place of ''inhibitor of yeast,'' for the safe use of dimethyl dicarbonate (DMDC). The more descriptive term is ''microbial control agent.'' This document also involves adding related limitations to our regulations on dimethyl dicarbonate. This action is in response to a petition filed by Bayer Co.

DATES: This rule is effective March 7, 2001. Submit written objections and requests for a hearing by April 6, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of March 7, 2000 (65 FR 12014), FDA announced that a food additive petition (FAP 0A4718) had been filed by Bayer Co., c/o McKenna & Cuneo LLP, 1900 K St. NW., Washington, DC 20006–1108. The petition proposed to amend the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFR 172.133) both to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice and to provide for a more descriptive term in place of ''inhibitor of yeast,'' for the safe use of DMDC.

In a notice published in the **Federal Register** of September 27, 2000 (65 FR 58091), FDA announced that it was amending the filing notice of March 7, 2000, to clarify that the proposed amendment to provide for a more descriptive term in place of ''inhibitor of yeast,'' for the safe use of DMDC will also involve adding related limitations to § 172.133. In the September 27, 2000, notice, FDA also announced that the petitioner's additional request, to amend the food additive regulations to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice, was converted to a food-contact substance notice (FCN 0035) (21 U.S.C. 348(h)(5)). Subsequently, this request was withdrawn from the petition as of the effective date of FCN 0035 (June 9, 2000).

DMDC is currently listed in § 172.133 for use as a yeast inhibitor in wine, dealcoholized wine, and low alcohol wine (53 FR 41325, October 21, 1988; and 58 FR 6088, January 26, 1993); in ready-to-drink teas (59 FR 5317, February 4, 1994); in carbonated or noncarbonated, nonjuice-containing flavored or unflavored beverages containing added electrolytes (61 FR 26786, May 29, 1996); and in carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent (61 FR 26786, May 29, 1996). In addition, there is an effective notification for the use of DMDC as a microbial control agent in noncarbonated juice beverages containing up to and including 100 percent juice (FCN 0035, June 9, 2000).

II. Evaluation of Safety

DMDC is used in the beverage industry for supplemental microbial control in beverages during the final stages of filling. It is added to beverages, whose viable microorganism load was previously reduced by other technologies, immediately prior to bottling, canning, or other forms of final packaging. To ensure its safe use, the agency set the maximum amount of DMDC that may be added to food at 250 parts per million (ppm). DMDC is currently approved under § 172.133(b)(1) and (b)(2) as an inhibitor of yeast in various beverages under normal circumstances of bottling or canning where the viable yeast count has been reduced to 500 per milliliter (mL) or less by current good manufacturing practices. DMDC is also approved under § 172.133(b)(3) and (b)(4) as an inhibitor of yeast in additional beverages. During its review of the subject petition, FDA found that restrictions given in paragraphs (b)(1) and (b)(2) were inadvertently omitted from paragraphs (b)(3) and (b)(4).

Bayer Co. petitioned the agency to change the term ''inhibitor of yeast'' to ''microbial control agent'' to better describe the actual functional effect of DMDC (at levels up to 250 ppm) in beverages during the final stages of filling. In support of the more descriptive term ''microbial control agent,'' the petitioner provided studies of the effect of DMDC (at levels up to 250 ppm) on various yeast strains and on *Escherichia coli* 0157:H7 in several noncarbonated juice beverages.

In its review of the proposed use of the term ''microbial control agent,'' the agency evaluated the information submitted with FAP 0A4718, as well as previously submitted information. FDA has determined that DMDC is effective in microbial control for beverages under normal circumstances of bottling, canning, and other forms of final packaging where the viable microorganism load has been reduced to 500 microorganisms/mL or less by current technologies.