CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Final Rule to Ban Small Balls Intended for Children Younger Than Three Years of Age and To Require Labeling of Certain Toys and Games

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The Child Safety Protection Act of 1994 (CSPA) amended the Federal Hazardous Substances Act (FHSA) by adding a new section 24 which, *inter alia,* imposes labeling requirements on certain balls, balloons, marbles, and certain toys and games intended for use by children three years of age and older. The amendment also bans certain balls intended for use by children younger than three years of age. Although the requirements imposed by the amendments are generally self-executing, the Commission is publishing this regulation to incorporate the requirements of the CSPA into the Code of Federal Regulations (CFR) and to interpret or clarify certain provisions of that legislation.

DATES: This regulation becomes effective on August 28, 1995 for products manufactured or imported into the United States.

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SUPPLEMENTARY INFORMATION:

A. Background

1. Previous Commission Actions

In 1979, the Commission issued regulations to ban toys and other articles which are intended for use by children younger than three years of age and which present an aspiration, ingestion, or choking hazard because of small parts. The small parts regulations are codified at 16 CFR 1500.18(a)(9) and Part 1501. Toys and children's articles subject to the regulations must be placed in a truncated cylinder with a diameter of 1.25 inches (31.7 mm.) and a depth ranging from 1 to 2.25 inches (25.4 mm to 57.1 mm). If the product or any independent or detachable component of the product fits entirely within the cylinder, it is banned. Additionally, a toy or children's article is banned if any component or piece of such a product becomes detached during ''use and abuse'' testing. The ''use and abuse'' tests are codified at 16 CFR 1500.50–1500.53.

The small parts regulations apply only to toys and articles intended for use by children younger than three years of age. Some products, including balloons, are excluded from the scope of these regulations because they cannot be manufactured to function as intended and still comply with the requirements of the regulations.

Previously, the Commission received information indicating that an average of seven children a year choke to death on balloons or parts of balloons. The agency also received reports of children younger than three choking on small toys or games, or the parts of such products, which were intended for children three years of age and older. For example, small balls and marbles are generally considered to be intended for such older children, but have been associated with choking fatalities involving children under three.

In some cases, choking incidents involving children younger than three years of age occurred after an adult purchased a product labeled to indicate that the article was suitable for children three years and older, but gave the article to a child younger than three. In such cases, it is possible that the purchaser believed that the labeling statement was not a safety message, but instead referred to the age at which the child could use or enjoy the product.

The origins of the CSPA rest in rulemaking activities in which the Commission engaged between 1988 and 1992. In 1988, the Commission published an advance notice of proposed rulemaking (ANPR) to initiate regulatory action to enlarge the dimensions of the cylinder used to evaluate whether toys or other articles intended for children under three contain small parts that could present a choking hazard. In 1990, the Commission terminated that proceeding. It determined that the use of the test cylinder specified in the existing small parts regulation had been effective in preventing choking deaths and injuries to children under three associated with toys intended for that age group. At the same time, however, the Commission published four ANPRs that, *inter alia,* solicited preliminary comment on proposals to require labeling on small balls, balloons, marbles, and toys and other articles with small parts intended for children aged three to approximately six. In 1991, after analyzing the comments received in response to the ANPRs, the Commission staff recommended that the Commission propose rules prescribing labeling under the FHSA for the products that later became the subject of the CSPA. The Commission, however, terminated all four proceedings because it felt that it could not make the findings required by the FHSA.

2. The Child Safety Protection Act

On June 16, 1994, Congress enacted the CSPA. The legislation establishes substantially the same labeling requirements for balloons, marbles, small balls, and toys and games containing small parts that the staff recommended in 1991. The primary purpose of the legislation is to warn purchasers of the potential hazards for children under three that products intended for older children may present. The CSPA prescribes labeling statements for balloons, for balls with a diameter of 1.75 inches or less (''small balls'') and marbles intended for children three years or over, and for toys or games that contain such items. The law also requires labeling for toys or games that contain small parts and that are intended for children at least three years old but not older than six. Under the CSPA, small balls intended for children under three are banned. The statute specifies the text of the required label statement for each of the enumerated products and requires that labeling appear on the principal display panel of product packages. For unpackaged, unlabeled items sold in bulk, any bin in which they are displayed, and any container for retail display or vending machine from which they are sold or dispensed must bear the required labeling. The law also directs the Commission to promulgate regulations to implement the statutory requirements.

On July 1, 1994, the Commission published in the **Federal Register** a proposed rule (59 FR 33932). The proposed rule clarified and interpreted certain provisions of the CSPA. It included definitions of terms such as ''ball,'' ''small part,'' and ''descriptive material,'' and established criteria for determining the age of children for which a game or toy is intended. It also clarified the applicability of the type size and conspicuousness requirements of the regulation codified at 16 C.F.R. 1500.121 to the products that are subject to the CSPA. It further contained provisions to assure that labeling statements would appear prominently on product packages.

B. Response to Comments

In response to the proposed rule, the Commission received almost 300 comments, most from individual consumers. Major consumer groups supported many of the provisions of the

rule as written and recommended strengthening others. Many individual members of those organizations submitted comments supporting the rule as drafted. Approximately twenty manufacturers, trade associations, and firms that test toys commented on the proposed labeling requirements for toys and games, while other commenters addressed issues such as the applicability of the CSPA to writing and art materials and to balloons distributed by individual performers or sold individually. Other comments raised issues relating to labeling for unpackaged products sold or distributed in bulk or requested clarification of specific technical requirements established by the act or the proposed regulation. Comments on specific parts of the rule and the Commission's responses to the comments are discussed in the following paragraphs.

1. Relationship of the CSPA to Other Standards

Representatives of foreign toy manufacturers commented generally on the complications the legislation presents with regard to standardized labeling statements under the European toy safety directive and to the development and use of a graphic symbol to identify products that are hazardous to children under three. Inasmuch as Congress mandated in the CSPA the precise labeling requirements that products in the U.S. market must meet, the Commission has little ability to address these concerns. Thus, no changes have been made to the final rule concerning these issues.

2. Existing Policies With Respect to Labeling and Toys

A recurring question throughout the comments is the extent to which the Commission, in administering the CSPA, intends to apply its existing policies and interpretations with respect to labeling and toys generally. For example, commenters inquired whether they can combine the warning statements required for marbles and for games with small parts, if they produce a game that contains both items.

Under the general labeling provisions of 16 CFR 1500.127, the Commission permits information relating to a specific hazard associated with a hazardous substance to be combined with information relating to additional hazards if the resulting statement contains all the information needed to deal with each respective hazard. If the Commission followed its existing policies, the labeling for the game could be condensed to reflect the hazard associated with the small parts and the marble in one statement.

Similarly, under the Commission's small parts testing regulations, toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child are tested only in the assembled state, if the shelf package and assembly instructions prominently indicate that the article is intended to be assembled only by an adult. The effect of this exception is to exempt from the small parts test the hardware used to assemble the toy. If the Commission follows this policy with respect to the labeling required by the CSPA, products containing such hardware would also be exempt from the labeling requirements.

The majority of the Commission's policies applicable to toys have evolved over the last ten to fifteen years, while many of the labeling policies are twenty to thirty years old. All of the policies provide standardized points of reference, both for regulated industries as well as the Commission staff, and take into account the requirements of the law, the objective of protecting the public, and the practical realities of the commercial world.

To avoid the confusion associated with establishing differing requirements for similar toys and labels, in administering the labeling provisions of the CSPA, the Commission will generally apply its existing policies with respect to children's articles and hazardous substances labeling. This general rule will apply unless such a policy (1) conflicts with the express provisions of the CSPA; (2) is overridden by a policy decision of the Commission as expressed in the final rule or in subsequent guidance to the staff of the Commission; (3) is impractical in its application; or (4) could result in a diminution of the protection envisioned by the law. The Commission believes it unlikely, however, that either of the latter two exceptions will occur.

3. Upper Age Limit

a. Toys and Games

The CSPA establishes labeling requirements for any toy or game that includes a small part and that is intended for use by children who are at least three years old but not older than six. The law permits the Commission to establish an alternative age to the upper limit of six years, but that alternative limit ''may not be less than five years of age.'' 15 U.S.C. 1278(a)(1). In the proposed rule, the Commission declined to establish an alternative upper age limit. As explained below, the final rule adopts an upper age limit of less than six years.

Consumer advocates supported maintaining the upper age limit at six years, arguing that, in the absence of compelling evidence to the contrary, the upper age limit specified in the statute should control. Several industry commenters, however, objected to applying the labeling requirements to toys or games intended for use by children under seven years of age (i.e while they are six years old). These commenters argued that this upper age limit departed from the original 1991 staff recommendation that the Commission require labeling on toys or games intended for children aged from 36 months up to, but not including, 60 months. Most of these commenters suggested that the Commission select an alternative upper age limit of not more than five years, although some suggested that the Commission adopt the upper age limit in the original staff recommendation.

Other commenters argued that the upper age limit of six is inconsistent with the Commissions's Guidelines for Relating Children's Ages to Toy Characteristics which the Commission uses to evaluate toys or other articles intended for use by children. According to these commenters, the inconsistency arises because the guidelines differentiate products intended for children aged 37 through 72 months from those intended for children 73 through 96 months old. The commenters contended that, if manufacturers complied with the labeling requirements and also followed the guidelines, the practical effect of applying the labeling to products intended for children under the age of seven would be to require labeling for products intended for children between the ages of 73 and 96 months.

At the outset, neither the CSPA nor its legislative history contain an explanation of the reason for the statutory upper age limit of six years or for the floor of five years on the alternative age limit. The text of the legislation, however, expressly forecloses using the original staff recommendation to label toys and games intended for children up to, but not including, 60 months of age as the alternative upper age limit. Similarly, any alleged inconsistency between the Commission age grading guidelines and the labeling requirements of the CSPA arises because the statute itself establishes a presumptive upper age limit of six years for labeling that does not coincide with the age divisions in the guidelines. The Commission is, of

course, bound to follow the requirements of the law.

The original staff recommendation did not suggest labeling products for children five years of age or older because available data did not support the need to extend the labeling requirements to products intended for that age group. That recommendation therefore does not itself provide a basis for specifying a specific alternative upper age between five and seven years. However, the Commission believes that the rationale for the original proposal—that the products most likely to present a threat to children under three are toys and games intended for three and four year olds, and that the skills, levels of development and play interests of children five years of age and older differ significantly from those of such younger children—is valid. Thus, the Commission believes that establishing an upper age limit lower than six would not significantly compromise the safety of children under three.

An upper age limit of 5 years (e.g., under 60 months and one day) would most closely approximate the objectives of the original staff recommendation. However, since there is no clearly defined line between toys intended for four year olds and those intended for five years olds, drawing a distinction in the rule in effect based on the day after a child reaches his or her fifth year could create problems for manufacturers in complying with the law. In contrast, an upper age limit of less than 6 years (less than 73 months) would be consistent with the Commission's Guidelines for Relating Children's Ages to Toy Characteristics. Those established guidelines recognize a break between toys and games intended for children 37 months through 72 months old (less than 6 years old), and those intended for children 73 (6 years old) through 96 months.

The Commission has therefore lowered the upper age limit to apply to toys or games intended for use by children who are less than six years old. In addition to the reasons discussed above, the Commission believes that limiting the scope of the labeling requirement will more closely focus prospective purchasers on the potential hazards of those toys and games intended for older children that are most likely to be purchased for younger children. Moreover, many toys intended for children six years of age are also intended for children seven and eight years of age. While the great majority of these products are unlikely to be purchased for children under three, labeling all of these products could dilute the effectiveness of the labeling on products intended for children from three up to six years of age that are most likely to be purchased for younger children.

b. ''Younger Than Seven Years''

The preamble to the proposed rule points out that products intended for children of a specific age are generally recognized by consumers as being suitable for all children of that age. Thus, a toy labeled for use by children six years old is typically viewed as being appropriate for use by children who have just turned six, as well as for use by those approaching their seventh birthday. The proposed rule interpreted the term ''intended for use by children who are * * * not older than six years'' in the CSPA to mean that the labeling requirements apply to toys or games intended for children under seven years of age.

Several commenters disagreed with this approach. Some contended it was inconsistent with the Commission's age grading guidelines. Others, relying on the statutory upper age limit of six years, suggested that the interpretation in the proposed rule would lead manufacturers who currently label products for children age six and up in accordance with industry standard practice to revise the age recommendations to seven and up.

None of the commenters provided a basis for changing the interpretation. This approach is the same as that of the Commission's small parts regulation which applies to products intended for children under three years of age. Moreover, applying the labeling requirements to products intended for use by children who have not yet reached a specific age—in this case, six—is consistent with the analytical approach of the Commission's age grading guidelines. For example, a child does not attain the age of six years until the completion of the last day of his or her seventy-second month (i.e., is beginning the seventy-third month). Thus, the upper end of 72 months in the age grouping of 37 to 72 months specified in the guidelines, in effect, applies to articles intended for children who are in the midst of their fifth year but have not yet reached their sixth year, i.e. are under six years of age. The Commission, therefore, declines to modify the final rule in the manner requested by the commenters.

4. Prominence and Conspicuousness of Labeling

Under the CSPA, precautionary labeling statements must be displayed in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed material on a product package, on any accompanying descriptive material, on any bin or container for retail display from which the product is sold, and on any vending machine from which it is dispensed. The act also requires that the labeling statements be displayed ''in a manner consistent with part 1500 of title 16, Code of Federal Regulations.'' 15 U.S.C. 1278(c)(1)(B). Title 16, Part 1500.121, contains the Commission's policies and interpretations implementing section 2(p)(2) of the FHSA which requires that precautionary labeling for hazardous substances appear prominently and conspicuously. The proposed rule incorporated by reference those policies and interpretations, with modifications designed to accommodate specific provisions of the CSPA and the general differences between toy labels and hazardous substance labels.

No commenter objected to incorporating the provisions of 16 CFR 1500.121 by reference in the proposed rule. Consumer advocates favored publishing the proposed requirements in final without change. Several industry commenters, however, objected to specific provisions in the proposed rule modifying 16 CFR 1500.121. Those objections and the Commission's response are discussed below.

a. ''Color-Blocking''

To assure that the labeling statements required by the CSPA appear prominently and conspicuously, the proposed rule solicited comments on the desirability of ''color-blocking'' those statements. Color-blocking would require the statements to appear on a background different from the color of the background of the area of the package on which it appears, from the color of any printed matter in proximity to the required statements, and, if the package were a see-through package, from the color of the article contained in the package. As the proposed rule explained, the packages of products subject to the CSPA generally contain many visual messages, some in printed product descriptions and depictions, others in see-through features that display actual products. All of these features have the potential to obscure labeling statements which, if they generally followed the provisions of 16 CFR 1500.121, would otherwise be regarded as conspicuous.

Several commenters objected to the ''color-blocking'' proposal, contending that it is more stringent than the current conspicuousness requirements contained in 16 CFR 1500.121. They also contended that requiring color-

blocking would unnecessarily increase the size of blister packaging used for small products and hinder tri-lingual labeling under the North American Free Trade Agreement (NAFTA). The commenters argued that applying the existing provisions of 16 CFR 1500.121 to products subject to CSPA labeling would be adequate to assure that the labels are conspicuous.

The CSPA requires that the labels it prescribes must be displayed conspicuously in a manner consistent with part 1500 of title 16 of the Code of Federal Regulations. The law does not require that the conspicuousness requirements for the labels of toys and games be identical to any similar requirement in the existing regulations. Accordingly, while the proposed regulation incorporated certain provisions of 16 CFR 1500.121, it also contained variations that take into account the requirements of the legislation itself and the lithography and design features of packages for toys and games. The ''color-blocking'' proposal was one variation.

The conspicuousness of a labeling statement depends on a variety of factors, including the location of the statement on the package and the types of printed material in proximity to it. While ''color-blocking'' is one technique to assure that labeling is conspicuous, the Commission believes that the use of this method in all cases may be unnecessary to accomplish the objectives of the CSPA. As is discussed below, two provisions of the existing conspicuousness regulations provide adequate assurance that labels required by the CSPA will be conspicuous without requiring the use of color-blocking.

The Commission's existing policy in 16 CFR 1500.121(b)(2)(ii) requires that labeling statements that appear on a principal display panel be blocked together within a square or rectangular area with or without a border. The statements must be separated on all sides from other printed or graphic matter by a space no smaller than the minimum allowable height of the type size for precautionary labeling other than signal words and statements of principal hazard (e.g. the statement ''Not for children under three yrs.'' in the CSPA). If not separated by that distance, the labeling statements must be surrounded by a border line. With regard to other cautionary material, 16 CFR 1500.121(d)(2) specifies that the label design, the use of vignettes, or the proximity of other labeling or lettering shall not be such that any cautionary labeling statement is obscured or rendered inconspicuous.

The Commission has revised the final regulation to eliminate the requirement for color-blocking. Instead, the labeling must also conform to the spacing/borderline requirements of 16 CFR 1500.121(b)(2)(ii) for principal display panel labeling. This means that, if a border line is used, it must be rectangular or square in shape. If no border line is used, other printed or graphic material should be separated from the cautionary labeling statements in a manner that makes the precautionary statements appear in a square or rectangular area. If other printed or graphic material appears on less than four sides of the cautionary material, the other printed or graphic material on any side should be laid out in a manner that creates the appearance of a vertical or horizontal line of separation, as appropriate, between that material and the cautionary labeling.

The Commission believes that the latter measures will adequately assure the conspicuousness of labeling for almost every product subject to the CSPA. Recognizing, however, that it is impossible to anticipate the design or lithography of every package, the final regulation includes a provision similar to that of 16 CFR 1500.121(d)(2) relating to interference with precautionary labeling by label design, the proximity of other labeling, or vignettes. The practical effect of this provision is that all labeling mandated by the CSPA must appear on a solid background, although the color of that background need not differ from the background color of the rest of the package label as long as the precautionary statements appear conspicuously. The inclusion of this provision will also permit the Commission to take action, should the spacing/borderline provisions be inadequate in a specific case to make the labeling required by the CSPA conspicuous.

b. Principal Display Panel/Multiple Type Sizes

The proposed rule established minimum type sizes for the various labeling statements required by the CSPA based upon the area of the display panel upon which those statements appear. For smaller packages with display panels of less than 100 square inches, the regulation followed the type size charts of Table 1 of 16 CFR 1500.121(c)(2) which generally apply to the labels of hazardous substances packaged in containers up to one gallon in volume. For larger packages, the regulation followed the minimum lettering heights of 16 CFR 1505.3(d)(2) which apply to labels on packages for electrically operated toys.

1. *See-Through Features:* Several commenters requested clarification of the definition and the measurement of the area of principal display panels. A number argued that the measurement of the area of the principal display panel should exclude the area of see-through features, contending that including this area in the measurement would result in labels that are too large. The Commission declines to accept this recommendation.

The Commission's existing policies require that the area of a see-through feature be included in measuring the area of a principal display panel. This is because see-through features are incorporated into packages to permit consumers to see the item for sale in conjunction with the labeling that accompanies the item. Such a feature often includes background graphics designed to promote specific attributes of the item that is visible through the feature or to show the item in an action setting. Like written descriptions or printed depictions of the products that generally appear on the packages of toys or games, see-through features communicate to prospective purchasers details about the products contained therein. Accordingly, the Commission views see-through features as functioning as part of the label of the product. To assure that the precautionary statements required by the CSPA are conspicuous and that a see-through feature does not direct a prospective purchaser's attention away from those statements, the area of the see-through feature is included in computing the area of the principal display panel to determine the proper type size.

The Commission, however, distinguishes packages with see-through features from peg-board packages consisting of a cardboard header with an attached plastic bag containing the item for sale. In the latter instance, all of the graphic material typically appears on the cardboard header separated from the item, making the header the principal display panel of the package. If a manufacturer chooses to place precautionary labeling on the header, the area of the surface of the header designed to face outward at retail controls the type size of the labeling. If, however, a manufacturer chooses to place precautionary labeling on the plastic bag, the bag itself becomes part of the principal display panel and its area is included along with that of the header in determining the appropriate type size. For peg board packages consisting of a header and a plastic bag which contains multiple individually packaged products, some of which may

require labeling, labeling each individual package that contains a product requiring labeling is sufficient to comply with the law, as long as the label is visible through the outer bag and is conspicuous. The type size of the statement would be based on the area of the individual bag containing the item, rather than on the area of the outer plastic bag.

2. *Vending Machine Display Panels:* Representatives of vending machine interests questioned what the principal display panel of a vending machine is, noting that, generally, labeling may appear either on the glass or clear plastic container of the machine or on a display card intended to be inserted in a holder in the machine. The commenters suggested that, if the machine has a display card that contains graphic material, the card itself constitutes the principal display panel. In the absence of such a card, the front of the container would be the principal display panel. The type size of the required labeling statements would depend on the area of the surface treated as the principal display panel. The Commission agrees that this approach is appropriate and has revised the final regulation accordingly.

3. *Type Size for Large Packages:* Some commenters objected to the use of letter sizes specified in the electrical toy regulation for large packages. The commenters contended that the type sizes prescribed for packages with an area in excess of 30 square inches (approximately the size of a gallon container) in 16 CFR 1500.121(c)(2) are adequate for larger packages, including those with an area in excess of 400 square inches. One commenter argued that the larger type sizes prescribed in the proposed regulation are inappropriate for products subject to the CSPA which, unlike electrical toys, do not present a hazard to the intended user. That commenter also submitted mock-up labels which purported to represent how the labels would actually appear if they complied with the larger type size requirements of the proposed regulation. It also submitted other mock-up labels purporting to demonstrate that the use of smaller type size on large packages could still result in conspicuous labels. As was argued with color-blocking, other commenters contended that the use of larger type sizes would increase the size of blister packaging for small products and would hinder tri-lingual labeling under NAFTA.

The Commission believes that the commenters' objections and concerns are unfounded and has adopted the proposed type size requirements in the final rule. Labeling cannot be effective unless it attracts the attention of consumers. Both 16 CFR 1500.121 and the labeling provisions of the electrical toy regulation follow the established principle that scaling the size of type to the display panel area on which it appears is essential to accomplish this objective. The type size requirements of 16 CFR 1500.121 are designed to accommodate the relatively small packages used for products such as household cleaners. The electrical toy regulation, which has been in effect for over twenty years, expressly addresses the issue of the size of labeling for larger packages similar to those in which many products covered by the CSPA are marketed. The commenters did not adequately explain why the Commission should accede to smaller type sizes for products in large packages which could, in many cases, make labeling statements required by the CSPA inconspicuous. The Commission notes that the commenters' attempt to distinguish the electrical toy labeling requirements from those required by the CSPA on the basis of hazard to the intended user is not persuasive. The labeling required by the electrical toy regulation states in part ''CAUTION—ELECTRIC TOY: Not recommended for children under _____ years of age * * *'', a statement which has substantially the same purpose as the labels prescribed by the CSPA.

With respect to the ''mock-up'' labels submitted by one commenter, the proposed regulation only specified the minimum height of the letters in a precautionary labeling statement. However, the conspicuousness of a label statement also depends on the style of type used, as well on the ratio of the height of the letters in the statement to their width and the spacing between the letters. The ''mock-up'' labels that the commenter submitted to demonstrate that the type size in the proposed rule for packages with a display panel in excess of 100 square inches was ''too large'' used a heavy, bold-faced type, with an approximate two-to-one height-to-width ratio for the letters, and normal spacing between the letters. In contrast, the labeling requirements of 16 CFR 1500.121(c)(3), incorporated by reference in the proposed rule, only require that the height-to-width ratio not exceed three to one, and are silent on type style and letter spacing. Thus, while a manufacturer is free to use a label similar to the ''mock-up'' labels presented by the commenter, the regulation does not require it, nor would following the provisions of the proposed rule with respect to large packages necessarily produce the result displayed by the mock-up labels that the commenter viewed as undesirable.

The same commenter also submitted other mock-up labels purporting to demonstrate that the use of smaller type size on large packages could still result in conspicuous labels. Again, in addition to letter height, type style, height-to-width ratio, and spacing all play a major role in making labels conspicuous. The Commission agrees that certain combinations of these factors coupled with sharply contrasting colors may tend to make smaller type more conspicuous. However, in the absence of requirements in the regulations specifying type style, spacing, etc., there is no assurance that the use of smaller type will result in a conspicuous label.

With respect to the allegation that the type sizes specified in the rule for large packages will require that the size of blister packaging for small products be increased, those type sizes have, for years, been accepted as striking a reasonable balance to assure that warnings are conspicuous while providing ample space for other graphic material. In the Commission's view, while changes in lithography may be required to meet the requirements of the CSPA, there is no evidence that compliance will require increasing package sizes.

4. *Blister Cards:* One commenter suggested that the Commission permit blister cards to be labeled either on the front of the card or the back, reasoning that parents are just as likely to read the information on the back of the card as they are the information on the front. The Commission declines to accept this suggestion. The law requires that the principal display panel—the front of a blister card—be labeled. Moreover, the intent of the CSPA is to provide point-of-purchase warnings. There is no evidence that parents will read the back of a blister card prior to purchase. Moreover, in the case of articles like dolls or toy cars which are generally not accompanied by instructions, the Commission believes it unlikely that purchasers will read the back of the card at all.

c. *Multiple Label Statements*

Several commenters expressed concern that the proposed rule would require a toy or game that contained multiple articles subject to the labeling requirements of the CSPA to bear the complete text of each label specified in the act addressing the hazard associated with each article. The proposed regulation did not address this issue. For clarity, the Commission has revised

the final regulation to incorporate a provision similar to 16 CFR 1500.127(b) which permits labeling information relating to multiple hazards to be condensed as long as the resulting statement contains all of the information necessary to deal with the specific hazard presented by each article. The Commission notes, however, that the message contained in the balloon label specified in the CSPA differs substantially from those in the labels for balls, marbles, and toys and games with small parts. Therefore, the label of a package that contains a balloon and another item subject to the CSPA may only have a combined signal word and statement of hazard. The remaining statements required by the act with respect to each of the products in the package must appear on the label of the package.

d. *Label Justification, Layout and Spacing*

The proposed rule required that labels required by the CSPA appear in the same format and layout as that prescribed in the legislation itself. Several commenters objected to this requirement, noting the Senate Report on the legislation would have permitted labels to vary from the precise format specified in the law. One commenter questioned whether the statutory format requirements included margin justification.

The requirement in the proposed rule was based on the precision with which the law identifies the text and format of the various labeling statements. The rule construed that precision as an express indication of how Congress intended those statements to appear on package labels. However, when taken in conjunction with the Congressional mandate that the Commission's regulations for the conspicuousness of labeling required by the CSPA be consistent with 16 CFR 1500.121, the Commission believes that a more valid reading of the legislation would treat the format and layout of the various labeling statements in the law as exemplary, rather than mandatory.

While the label format set forth in the law is more than adequate to meet the Commission's existing conspicuousness regulations, it does not take into account variations in packaging design and lithography that the Commission can expect to encounter for products subject to the CSPA. On balance, the existing policies implementing the labeling requirements of the FHSA have proven adequate to ensure that labels are prominent and conspicuous. Thus, the Commission has revised the proposed rule to delete the requirement that manufacturers follow the precise format in the statute and instead will follow its existing labeling policies with respect to format and layout. The Commission however notes that one existing policy states that labeling statements shall appear blocked together within a square or rectangular area. This means that the labeling statements required by the act must appear on at least two lines. Since the resolution of the overall issue of format also resolves the question of margin justification, no response to that comment is necessary.

5. Descriptive Material

The CSPA requires the statutory warnings to appear on descriptive material accompanying a product that requires labeling under the act. The proposed regulation defined the term ''descriptive material'' as ''any instruction (whether written or otherwise) for the use of the product, any depiction of the product, and any promotional material, advertisement, or other written literature that describes any function, use, warnings, user population, or other characteristic of the product, including its suitability for use with or relationship to other games, products, or toys.'' The proposed regulation also noted that descriptive material ''accompanies'' a product when it is packaged with the product or is intended to be distributed with the product at the time of sale or delivery to the purchaser. As is discussed below, the final rule retains much of the definition, but clarifies that catalogs and marketing materials that describe products other than a regulated product generally need not be labeled.

a. Meaning of ''Accompanies''

Several commenters expressed concern that the definition of the term ''descriptive material'' in the proposed regulation might require multiple labels on product packages such as blister cards that, for example, contain instructions for use or recommended age labeling on the back of the cards. As the discussion of the term ''accompanies'' in the proposed rule indicates, the Commission believes that Congress intended labeling requirements for descriptive material to apply to material separate from the package of the article itself, such as an instruction sheet. The final regulation clarifies this point.

Another commenter questioned whether material such as mail order catalogs or newspaper advertisements depicting items subject to the CSPA are required to bear the required warning statements. The act only requires descriptive material which accompanies a regulated product to be labeled. According to the proposed regulation, descriptive material ''accompanies'' a product when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. A catalog or advertisement that does not meet either of these criteria would not require labeling.

b. Instructions for Use

Several commenters contended that the definition of the term ''descriptive material'' in the proposed rule was too expansive. Some requested that the definition be limited to material containing instructions for use.

Section 2(n)(2) of the FHSA expressly requires that labeling required by the act appear ''* * * on all accompanying literature where there are instructions for use, written or otherwise.'' Inasmuch as the CSPA follows the general labeling scheme of the FHSA, the Commission believes that the use of the term ''descriptive material'' without the limitation contained in section 2(n) indicates a Congressional intention that CSPA labeling not be limited to material containing instructions for use. Accordingly, the Commission declines to adopt the revision requested by the commenter to limit the labeling requirements to written material containing instructions for use.

The Commission notes that the great majority of material that accompanies the products subject to the CSPA contains instructions for use, either with or without other descriptions. Moreover, each discrete piece of material accompanying a regulated product need only have one label. Thus, if a piece of accompanying literature contained, for example, instructions for use, a statement of the age of the children for whom an item is intended, and a depiction of the product, only one precautionary statement would be required. Therefore, the Commission believes that defining the term ''descriptive material'' broadly to include the variety of ways that accompanying material can describe or depict a regulated product should have little practical effect.

c. Catalogs and Marketing Materials

Many industry commenters contended that catalogs and marketing materials depicting other products, as well as the regulated products that such materials accompany, should be exempt from the labeling requirements. Under their rationale, the purpose of such catalogs is to focus the attention of the purchaser on the other products rather

than on the regulated product he or she has just purchased.

First, the law only applies to descriptive material that accompanies a product that requires labeling. A catalog that accompanies an unregulated product need not bear any labeling, even though the packages of other products described in the catalog might require labeling.

The status under the CSPA of a marketing material such as a catalog that depicts or advertises other items *in addition to* the regulated product that the catalog accompanies is a question of interpretation. Although a depiction of a regulated product in a catalog would appear to meet the plain meaning of the term ''descriptive material,'' the Commission believes that requiring labeling in such a circumstance will do little to increase the protection provided by the point-of-purchase warning on the product's label. Accordingly, the Commission has excluded such catalogs and similar marketing materials from the definition of ''descriptive material,'' unless they contain additional information, such as instructions for use of the regulated product it accompanies or a list of accessories intended to be used solely with that product.

d. Descriptive Material Intended for Use by Children

Some commenters recommended that descriptive material intended for use by children not require precautionary labeling, if the warnings are included on a separate package insert intended for adults. The commenters, citing the Senate report, reasoned that the statutory warnings are intended for adult purchasers and that young children would be unable to understand and appreciate the hazards. Consumer advocates, however, favored requiring that such material be labeled, noting that the material is often read by adults even though it is intended for children and that many children are capable of reading and understanding the warnings.

The Commission believes that the inclusion of a properly labeled insert in addition to instructions for children is adequate to satisfy the objectives of the legislation without compromising safety. The final rule exempts from the labeling requirements descriptive material intended solely for use by children, provided that the package of the product also contains a properly labeled insert intended for adults that is prominently identified as a warning for parents.

6. Definition of Package

The proposed regulation defined the term ''package'' as the immediate package in which a product subject to labeling is sold or is intended to be stored, as well as to any outer container or wrapping. Commenters expressed concern that this definition could require labeling to appear on shrink wrap or cellophane applied over an immediate package, as well as on components of toys such as doll houses, toy medical bags, etc. that are themselves used to store other components. One commenter also suggested that the labeling requirements not apply to containers used to ship packaged products to retailers because consumers generally do not see or read information on such containers.

In response to the latter comment, the Commission notes that the CSPA only applies to retail packages intended to be distributed to consumers or to containers used to display bulk unpackaged and unlabeled items at retail. The Commission also notes that, for unpackaged, unlabeled products sold in bulk, unlabeled shrink wrap film intended to keep a toy clean or plastic ''eggs'' designed to permit toys to be dispensed from vending machines is not ''packaging'' which would require labeling under the CSPA.

With respect to the other comments, the reference to the outer container or wrapper of a product in the proposed rule tracks section 2(n) of the FHSA which requires that any labeling required under that act shall appear on the outside container or wrapper of a hazardous substance, unless the labeling is easily legible through the outside container or wrapper. This provision is equally applicable to the labeling required by the CSPA. With respect to functional components of toys that are used to store other components, the CSPA only requires that packaging intended for retail inspection must bear labeling. Thus, while cardboard boxes for games may require labeling if they have a surface that functions as a principal display panel, the Commission believes that Congress did not intend labeling to be applied directly to toys or components of toys that already bear labeling on their packaging or that are not part of the retail display. However, if such items are displayed at retail without any packaging, the items themselves would have to bear a hang tag containing the required labeling. The final regulation has been revised to clarify both of these issues.

7. Definition of ''Toy or Game''

The proposed rule did not include a definition of ''toy'' or ''game.'' However, commenters requested that the Commission clarify the scope of these terms, questioning whether arts and crafts materials, such as paint sets or bead stringing kits, are subject to the labeling requirements. Representatives of the Art and Creative Materials Institute cited a decision of the United States Court of Appeals for the Second Circuit to support the proposition that art materials are not necessarily included in the definition of a toy. This decision, however, addressed the issue of whether a flammable children's article was an educational material that was exempt from the banning requirements of the FHSA.

Past Commission actions have generally addressed the hazards associated with articles intended for use by children, including toys and games. The agency, therefore, has not previously undertaken to define either term. In the absence of a regulatory definition, however, the Commission generally looks to common dictionary definitions of terms for guidance. For example, a toy is ''an object for children to play with; especially something made for the amusement of a child or for his use in play.'' A game is ''an article for use in a physical or mental competition conducted according to rules in which the participants play in direct opposition to each other.* * *'' (In the Commission's view, the latter definition also includes games in which children compete with an item itself rather than other children.) The Commission has elected not to include definitions of the terms ''toy'' and ''game'' in the final rule, but will continue to draw upon on common dictionary definitions of these terms for guidance in administering the CSPA.

With respect to the specific applicability of the term ''toy'' to arts and crafts sets intended for children three to five, these products are primarily intended for use in play and for the amusement of such children. The Commission therefore considers them to be ''toys.'' Such items would require labeling under the CSPA, even though a child, in the course of play, might produce a ''functional'' item for display or use. However, items such as pens and pencils for general use which might incidentally be used in play would not be considered toys.

The Commission has also received inquiries concerning the status of ''hybrid'' items, such as children's toiletries which include toys or other items subject to the CSPA. If any part of

such an item is an article subject to the CSPA, the package of the item requires labeling.

8. Educational Materials and Mail Order Sales

a. Sales to Educational Institutions

One commenter questioned whether packages of toys or games sold exclusively to schools through catalogs require labeling. The primary purpose of the CSPA is to provide a point-of-purchase warning of the hazards that products intended for older children present to children under three. Inasmuch as children under three are not typically present in a traditional school setting, requiring labeling on toys and games sold by mail *solely* to educational institutions such as kindergartens and elementary schools for use *exclusively* in those institutions would not accomplish the purposes of the CSPA. Accordingly, such items are excluded from the scope of the regulation, as long as the items are intended for children five and up. This age limitation is specified because products intended for three and four year old children may be sent to pre-schools or institutions such as day care centers where children under three may be present.

b. Mail Order Sales

A few commenters questioned whether the CSPA applies to products distributed to consumers through the mail, and, if so, whether it is sufficient to label just the mailing wrapper or whether both the product package and outer wrapper require labeling. Products exclusively distributed by mail are subject to the CSPA. Since the CSPA contemplates point-of-purchase inspection, firms can comply with the law by conspicuously labeling either the immediate product package or the outer wrapper. Such labeling need not be lithographed or printed on the wrapper. The use of a stamped label will suffice. The Commission notes that, if a product sold by mail is also sold in retail outlets, the retail package itself must be labeled.

9. Practices Under the Small Parts Regulation

The Commission's regulations addressing the choking hazards associated with toys and articles intended for children under three that contain small parts establish tests to determine whether such products will emit small parts under reasonably foreseeable conditions of use or abuse. They also exempt from the banning provisions specific items including writing materials (such as crayons, chalk, pencils and pens), books and other articles made of paper, modeling clay, and finger paints, watercolors, and other paint sets. Commenters questioned whether these policies apply to items regulated under the CSPA.

a. Use and Abuse Testing

The proposed rule did not include a requirement for ''use and abuse'' testing of toys and games. The rule noted that the Commission lacked sufficient information to establish the need to apply use and abuse tests to toys and games intended for children between three and six years of age, or on the costs associated with imposing such requirements. In addition, the decision not to require use and abuse testing was based on the language of the CSPA which referred to toys or games that ''include'' a small part.

Commenters split on the issue of applying use and abuse tests to toys and games. Consumer advocates favored requiring such tests, arguing that the failure to do so might mislead parents into believing a product without labeling is safe, even though small parts might detach from the product during play. Industry commenters, arguing against the requirement, contended that hazard and injury data do not support the need to impose such testing.

Given the absence of data relating to the costs of imposing such requirements and any potential benefits, the final rule retains the position expressed in the proposed rule and does not require use and abuse testing. Moreover, the Commission continues to believe that a reasonable reading of the phrase ''includes a small part'' provides a basis for concluding that Congress did not intend to require use and abuse testing.

The Commission notes that commenters exhibited confusion about the applicability of use and abuse tests to solid items that are intended to be removed or separated from toys or games during play or use, such as accessories for action figures and battery covers that are not screwed shut, or to items such as strip magnets that are designed to be divided into individual components. Under the Commission's existing policies, such items are evaluated by detaching them without applying use and abuse testing and placing them in the test cylinder. Similarly, if, as is discussed *infra.*, the Commission decides that products that are currently exempt from the small parts regulation require labeling, items such as modeling clay and play dough, which separate into multiple pieces of varying sizes during use, will be evaluated without compression in the form and shape in which they are sold at retail.

b. Exempt Products

The proposed rule was silent on the applicability of the CSPA to products that are exempt from the small parts regulation under 16 CFR 1501.3. Furthermore, there is no express reference in the CSPA or its legislative history to the status of products that are exempt from the small parts requirements. Commenters argued that the inclusion of balloons, which are expressly exempt from the small parts regulation, in the CSPA could be construed as an indication that Congress knew how to include exempt products within the scope of the statute when it wanted to. Since Congress only singled out balloons for coverage, other exempt products would not require labeling. Others contended that requiring products exempt from small parts testing to be labeled would also create an apparent inconsistency. For example, a felt tip marker intended for children between three and six years of age with a cap that is a small part would require labeling (assuming, of course, that the item is a toy), but the same item would require neither labeling nor compliance with the small parts regulation if it were intended for children under three.

Other commenters noted that the purpose of the exemptions to the small parts regulation was to avoid banning functional products which could not be produced in compliance with the small parts requirements. These commenters argued that labeling provides a reasonable alternative to alert parents purchasing toys and games for older children to the potential hazards such products may present to younger children. Furthermore, unlike the small parts performance requirements, labeling such items would not affect their ability to be produced and sold.

In its vote on the final rule, the Commission divided on the issue of whether toys and games that are exempt from the small parts regulation, if they are intended for children under three, require labeling under the CSPA, if they are intended for children three through five years of age. Accordingly, that issue will remain unresolved until such time as a majority of the Commission concurs on its resolution. Pending that resolution, toys and games that are exempted from the requirements of the small parts regulation by 16 CFR 1501.3 are not required to bear labeling under the act. However, even if the Commission elects to require labeling for exempt products, paper punch-out toys and games will still be exempt from the labeling requirements, since there is

no data to indicate that such items present a risk to children under three.

10. Bulk Sales

The CSPA requires that labeling appear not only on retail packages, but also on bins from which unpackaged and unlabeled regulated products are sold in bulk, containers for the retail display of such items, and vending machines from which they are dispensed. The labels must appear conspicuously. Administering labeling requirements of this nature is a matter of first impression for the Commission, since the FHSA and its regulations require an unpackaged hazardous substance to bear a label on the item itself or on a hang tag attached to the item.

a. Obligation to Apply Labels

One commenter questioned whether retailers are required to label store displays of items subject to the CSPA which are sold in bulk and without packaging. The CSPA requires labeling on bins, containers for retail display, and vending machines from which unpackaged items subject to the act are sold or dispensed. A retailer who fails to comply with these requirements may be subject to penalties for violating section 4(c) of the FHSA. To assist retailers in complying with the CSPA, the Commission suggests that manufacturers include, in the shipping containers for bulk products, labels for the retailer to post. For example, an 7″ × 5″ card containing the required labeling in the type size specified by 16 CFR 1500.121 would generally suffice to assure that large bins are conspicuously labeled. Smaller cards, e.g. 3″ × 5″, 2″ × 4″ would generally be adequate for smaller containers for bulk display. To provide an incentive for displaying the cards, such cards could include an area for displaying the price of the item. As an alternative to providing such labels, the invoice that accompanies bulk products or the shipping container of such products could contain a clear statement of the requirements of the law.

b. Definition of Bin or Container for Retail Display

The applicability of the CSPA to traditional dump display bins, gold fish bowls, and similar containers that contain loose merchandise to be inspected and selected by purchasers themselves is clear. However, many commenters questioned whether the law applies to a showcase or counter at which items are displayed for inspection by purchasers but are selected by a clerk or sales person at the direction of the purchasers. Examples include arcades in which premiums are redeemed for coupons, carnival booths, and fast food outlets.

In the absence of any clear indication in the legislation or its history that Congress intended to cover display cases and similar counters, the Commission interprets the CSPA as requiring labeling only for those bins and containers from which consumers select items displayed in bulk. The final rule reflects this determination.

11. Small Balls and Marbles

a. Implied Upper Age Limit—Small Balls and Marbles

The CSPA requires that packages of small balls and marbles intended for children three years of age or older, and of toys and games containing such balls and marbles, bear precautionary labeling. The proposed rule tracked the statutory language. Several commenters requested that the Commission establish an upper age limit for the purposes of labeling such products. Some suggested that an upper age limit of eight years (96 months) would be consistent with the provisions of 16 CFR 1500.53 which establishes use-and-abuse testing requirements for toys intended for children in this age group. Another comment recommended twelve or fourteen years as the upper limit, based on the age at which children reach puberty.

Individual small balls or marbles are generally used in play by children of all ages—that is, they are as likely to be used by five to seven year olds as they are by nine to eleven year olds. Because there is no distinction between the ages of the children who will use them, all such products require labeling under the CSPA.

The Commission, however, distinguishes balls and marbles contained in toys and games from those intended for general use. The former are often intended for children of a specified age based on the level of intellectual or physical development of children in that age group. Even in the absence of precautionary labeling, the Commission believes it highly unlikely that a parent would consider purchasing a toy or game containing a small ball or marble intended for a child over eight years of age for a child under three. For example, as the Commission's age grading guidelines recognize, nine to twelve year olds have developed sufficient fine motor coordination for labyrinth or maze games that require maneuvering a marble along a pathway and for games requiring careful shooting or aiming of markers. Such games, however, would have virtually no play value for children under three. The final rule therefore only requires labeling for toys and games containing a small ball or marble that are intended for children under 8 years of age. This age limit also follows the maximum age limit specified in the Commission's regulations prescribing tests to determine whether a children's article presents a hazard during reasonably foreseeable use or abuse.

b. Balls for General Use in Sports

One commenter questioned whether ping pong balls and golf balls require labeling under the CSPA, reasoning that, since children utilize such products, the products qualify as a toy or game intended for children under seven years of age. The commenter, however, did not address the issue of status of these items as small balls under the CSPA.

The Commission believes that the CSPA was not designed to cover balls generally intended for use in sports such as golf or ping pong which might incidentally be used by children over three. If, however, such a ball is labeled or marketed as being intended for children or is part of toy, game, or equipment set specifically intended for children over three years of age but less than eight years old, the labeling requirements apply.

c. Definition of Ball

The proposed rule defined a ''ball'' as a spheroid, ovoid, or elliptical object that is designed or intended to be thrown, hit, kicked, rolled, or bounced. One commenter requested that the definition of the term ''ball'' be expanded to include items that are dropped, commenting that some toys or games incorporate such a feature. The Commission believes that this comment has merit and has revised the final rule accordingly. Another commenter questioned whether tethered balls are subject to the CSPA only if they fail use and abuse testing. Unlike small parts which only present a hazard when they detach during use or abuse, small balls present a choking hazard even when tethered. Thus, tethered balls are subject to the labeling requirements, regardless of whether they pass use or abuse tests. A third commenter questioned how to determine whether a ball is permanently enclosed in a maze. As discussed previously, the rule does not require use or abuse testing to determine whether small parts are present for the purposes of CSPA labeling. However, the final rule does reflect a limited exception to this determination. The determination of whether a ball is permanently enclosed in a maze or similar container

is made by subjecting the container to the appropriate test in 16 CFR 1500.52 or 53 simulating the use and abuse of a toy or article intended for use by children under three, in the case of banned small balls, or three or over for labeling purposes.

d. Marbles

Since marbles are primarily intended for use by children, the labeling requirements generally apply to all packages, games, or toys containing marbles. Marbles that are not intended for children include collectors' marbles and marbles for ornamental or industrial use. In addition, the Commission has excepted from the labeling requirements marbles that are permanently enclosed in a game or toy. As is the case with small balls, the determination of accessibility can be made by applying the tests of 16 CFR 1500.53.

e. Template for Testing Balls

The proposed regulation bans any ball intended for children under three years of age that, under the influence of its own weight, passes, in any orientation, through a circular hole with a diameter of 1.75 inches in a rigid template. One commenter questioned whether the template must have the same dimensions as the template used to test rattles. The pacifier regulation, 16 CFR 1511 provides a better point of reference for testing than the rattle regulation, since the procedure for testing pacifiers is similar to that used to test small balls. While the final rule does not incorporate all of the external dimensions of the pacifier test fixture, to assure that the template is rigid, the rule indicates that the depth of the template for testing small balls must be at least ¼ inch (6mm.), consistent with that of the pacifier test fixture.

12. Balloons

The CSPA requires that the packaging of any latex balloon and any descriptive material which accompanies such a balloon bear specific labeling statements warning that uninflated balloons or pieces of balloons can choke or suffocate children under eight years of age. In the case of bulk sales of balloons, the bin, container for retail display, or vending machine from which the balloons are sold or dispensed must bear the required labeling statements.

a. Unpackaged Balloons Distributed Individually

One commenter expressed concern that the CSPA may require performers, such as professional magicians, who distribute individual unpackaged balloons to members of their audiences either to label the individual balloons or wear a tag or sign containing the required warnings. The law imposes neither requirement feared by the commenter.

Packages of balloons must bear precautionary labeling. However, the bulk sale requirements of the law are designed to require labeling on containers in which multiple products are held for retail sale. The Commission does not believe that Congress intended these provisions to extend to individuals who distribute unpackaged balloons that are not held in some form of container for retail display. Thus, unpackaged individual balloons distributed as part of a professional performance are not subject to the requirement. The same is true for balloons used in commercial birthday programs which are blown up prior to arrival of the children and are used to decorate the table and party area, even though individual balloons may be given to the children as they leave.

If, however, a performer receives packages of balloons that are unlabeled and distributes the packages to the public, the performer must take steps to assure that the packages are properly labeled. A performer can comply with these requirements by purchasing packages of balloons that are properly labeled or by placing a sticker label containing the required labeling on unlabeled balloon packages prior to distributing them to the public.

b. Books and Videos

The same commenter questioned the applicability of the labeling requirements to books and videos describing balloon sculpture. Descriptive material such as a book or videotape would only require precautionary labeling when that material is packaged with a package of balloons or when the material is intended to be distributed at the same time such a package is sold or delivered to a purchaser. The fact that a consumer who receives an instructional videotape or book may subsequently purchase balloons does not bring the tape or book within the ambit of the law. If an individual or company packages or distributes to the public a package of balloons together with a videotape, instruction sheet, or book that is classified as descriptive material, that individual or company has the obligation to assure that the descriptive material is properly labeled.

13. Exports

Some commenters questioned whether the CSPA requirements apply to products manufactured in the United States exclusively for export. Products intended for export that are labeled in accordance with the specifications of the foreign purchaser and with the laws of the country to which they are to be exported do not require labeling under the CSPA, as long as the shipping container is clearly marked that the product is for export and the product is, in fact, exported. 15 U.S.C. 1264(b)(3). However, under existing Commission policy, the manufacturer or exporter of the product must comply with the export notification requirements of 15 U.S.C. 1273(d) and 16 C.F.R. 1019.

14. Products Manufactured Outside the United States

The CSPA includes an alternative to labeling descriptive materials for products manufactured outside the United States and shipped directly to consumers. Under the alternative, if the shipping container contains other accompanying material that is labeled conspicuously, the descriptive material need not be labeled. One commenter requested clarification that products packaged abroad and shipped to a U.S. affiliate for shipment to consumers be included in the scope of this exception. The commenter noted that the Senate Report contemplated this type of arrangement. The Commission accepts this suggestion and has revised the final regulation accordingly.

15. Effective Date

Several commenters requested that the Commission delay the effective date of the final rule to permit package labels to be redesigned and printed. Some suggested a delay of six months, while others requested a year. However, no commenter provided a detailed breakdown of the time frames involved.

Based on its experience with administering the prominence and conspicuousness requirements of 16 CFR 1500.121, the Commission agrees that a delayed effective date is appropriate. Accordingly, the final regulation becomes effective with respect to products manufactured in or imported into the United States six months after publication of the final rule. However, since the effective date of the law was January 1, 1995, the labeling statements required by the act must appear on the principal display panel of product packages in advance of publication of the final rule. In recognition of this fact, packages with labels lithographed or printed before the effective date of the rule may be used for a period of up to six months after the effective date if they display the specific statements prescribed in the statute on the principal display panel in a manner

that is generally conspicuous. This approach will permit packages containing labeling that may not meet some of the more technical aspects of the rule, but are in substantial compliance with the requirements of the law, to be exhausted. It will also save the unnecessary expense associated with destroying such packaging, without compromising safety.

C. Impact on Small Businesses

In accordance with section 3(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Any obligations imposed upon such entities arise under the express provisions of section 24 of the FHSA. This regulation simply clarifies the obligations imposed by that law on certain toys, games, balloons, marbles, and balls. The regulation itself, therefore, will have no significant economic impact on small businesses, either beneficial or negative, beyond that which results from the statutory provisions.

D. Environmental Considerations

The proposed rule falls within the provisions of 16 C.F.R. 1021.5(c) which designates categories of actions conducted by the Consumer Product Safety Commission that normally have little or no potential for affecting the human environment. The Commission does not believe that the rule contains any unusual aspects which may produce effects on the human environment, nor can the Commission foresee any circumstance in which the rule proposed below may produce such effects. For this reason, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 16 CFR Part 1500

Business and industry, Consumer protection, Hazardous materials, Infants and children, Labeling, Packaging and containers.

E. Conclusion

Therefore, pursuant to the authority of the Child Safety Protection Act of 1994 (Pub. L. 103–267), sections 10(a) and 24(c) of the Federal Hazardous Substances Act, (15 U.S.C. 1269(a) and 1278(c)), and 5 U.S.C. 553, the Consumer Product Safety Commission amends Title 16 of the Code of Federal Regulations, Chapter II, Subchapter C, Part 1500 as set forth below.

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

1. The authority for Part 1500 is revised to read as follows:

Authority: 15 U.S.C. 1261–1278, 2079.

2. Section 1500.18 is amended by revising paragraph (a) introductory text and adding paragraph (a)(17) to read as follows:

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

(a) *Toys and other articles presenting mechanical hazards.* Under the authority of sections 2(f)(1)(D) and 24 of the act and pursuant to the provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

* * * * *

(17) Any ball intended for children under three years of age that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this paragraph, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

(i) For the purposes of this paragraph, the term ''ball'' includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term ''ball'' includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term ''ball'' also includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(ii) The term ''ball'' does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.52, the ball is not removed from the outer container.

(iii) In determining whether such a ball is intended for use by children under three years of age, the criteria specified in 16 CFR 1501.2(b) and the enforcement procedure established by 16 CFR 1501.5 shall apply.

* * * * *

3. A new section 1500.19 is added, to read as follows:

§ 1500.19 Misbranded toys and other articles intended for use by children.

(a) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term ''ball'' includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term ''ball'' also includes any multi-sided object formed by connecting planes into a generally, spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term ''ball'' does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children's toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children's games, generally as a playing piece or marker. The term ''marble'' does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR

1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Package* or packaging refers to the immediate package in which a product subject to labeling under section 24 of the act is sold, as well as to any outer container or wrapping for that package.

(7) *Descriptive material* means any discrete piece of written material separate from the label of the package that contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product. A catalog or other marketing material or advertisement that depicts other products in addition to the product it accompanies is not ''descriptive material'' unless it contains additional information, such as instructions for use of the product it accompanies or lists of accessories exclusively for use with that product, that are designed to focus the purchaser's attention on the product. Descriptive material ''accompanies'' a product subject to the labeling requirements when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. ''Descriptive material'' does not include statements that appear on the package of a product subject to the labeling requirements. ''Descriptive material'' does not include material intended solely for use by children if the package it accompanies contains a separate package insert prominently identified as a warning for parents that contains the required precautionary statements.

(8) *Bin* and *container for retail display* mean containers in which multiple unpackaged and unlabeled items are held for direct selection by and sale to consumers.

(b) *Misbranded toys and children's articles.* Pursuant to sections 2(p) and 24 of the FHSA, the following articles are misbranded hazardous substances if their packaging, any descriptive material that accompanies them, and, if unpackaged and unlabeled, any bin in which they are held for sale, any container in which they are held for retail display, or any vending machine from which they are dispensed, fails to bear the labeling statements required in paragraphs (b) (1) through (4) and paragraph (f)(3) of this section, or if such labeling statements fail to comply with the prominence and conspicuousness requirements of paragraph (d) of this section.

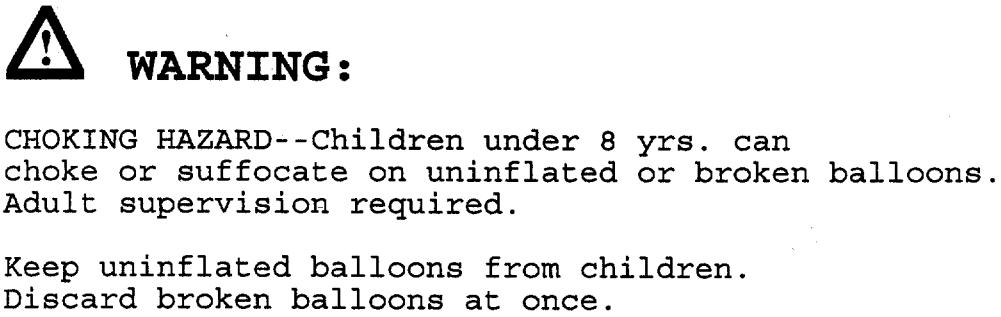
(1) With the exception of paper products such as punch-out games and similar items, any toy or game that is intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:

BILLING CODE 6355–01–P

BILLING CODE 6355–01–C

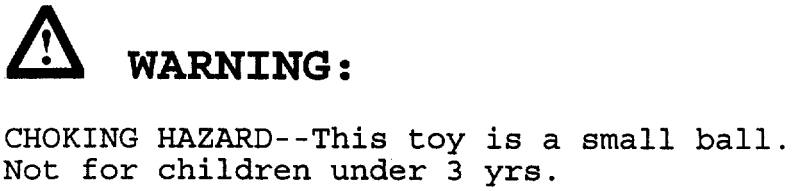
(2) Any latex balloon, or toy or game that contains a latex balloon, shall bear the following cautionary statement:

BILLING CODE 6355–01–P



(3)(I) Any small ball intended for children three years of age or older shall bear the following cautionary statement:

BILLING CODE 6355–01–P



BILLING CODE 6355–01–P

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:

BILLING CODE 6355–01–P

BILLING CODE 6355–01–C

(4)(i) Any marble intended for children three years of age or older shall bear the following cautionary statement:

BILLING CODE 6355–01–P

BILLING CODE 6355–01–C

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a marble shall bear the following cautionary statement:

BILLING CODE 6355–01–P

WARNING:

CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.

BILLING CODE 6355–01–C

(c) *Age of intended user.* In determining the ages of the children for which any toy or article subject to this section is intended, the following factors are relevant: the manufacturer's stated intent (such as the age stated on a label) if it is reasonable; the advertising, marketing, and promotion of the article; and whether the article is commonly recognized as being intended for children in this age group. In enforcing this provision, the Commission will follow the procedures set forth in 16 CFR 1501.5.

(d) *Prominence and conspicuousness of labeling statements.* The requirements of 16 CFR 1500.121 relating to the prominence and conspicuousness of precautionary labeling statements for hazardous substances shall apply to any labeling statement required under § 1500.19(b) and (f), with the following clarifications and modifications.

(1) All labeling statements required by § 1500.19(b) and (f) shall be in the English language. The statements required by paragraph (b) need not appear in the format and layout depicted in paragraph (b). The statements required by 16 CFR 1500.19(b) and (f) shall be blocked together within a square or rectangular area, with or without a border. This means that the statements must appear on at least two lines. The statements shall be separated from all other graphic material by a space no smaller than the minimum allowable height of the type size for other cautionary material (e.g., the phrase ''Not for children under 3 yrs.''). If not separated by that distance, the labeling statements must be surrounded by a border line. Label design, the use of vignettes, or the proximity of other labeling or lettering shall not obscure or render inconspicuous any labeling statement required under § 1500.19(b) and (f). This means that such statements shall appear on a solid background, which need not differ from the background color or any other color on the package label.

(2) The words ''WARNING'' or ''SAFETY WARNING'' required by section 24 of the FHSA shall be regarded as signal words.

(3) The statement ''CHOKING HAZARD'' shall be regarded as a statement of the principal hazard associated with the products subject to this section.

(4) All other remaining statements required by this section shall be regarded as ''other cautionary material'' as that term is defined in 16 CFR 1500.121(a)(2)(viii).

(5) The principal display panel for a bin, container for retail display, or vending machine shall be the side or surface designed to be most prominently displayed, shown, or presented to, or examined by, prospective purchasers. In the case of bins or containers for retail display, the cautionary material may be placed on a display card of a reasonable size in relationship to the surface area of the bin or container. The area of the display card shall constitute the area of the principal display panel. In the case of vending machines that contain a display card, the cautionary label may be placed either on the display card, on the coinage indicator decal, or on the glass or clear plastic of the machine. If there is no display card inside a vending machine, the size of the principal display panel will be calculated in accordance with 16 CFR 1500.121(c) based on the size of the front of the container from which items are dispensed, exclusive of the area of metal attachments, coin inserts, bases, etc. Any other side or surface of such a bin, container for retail sale, or vending machine that bears information, such as price or product description, for examination by purchasers shall be deemed to be a principal display panel, excluding any side or surface with information that only identifies the company that owns or operates a vending machine.

(6) All of the labeling statements required by this section, including those classified as ''other cautionary material,'' must appear on the principal display panel of the product, except as provided for by § 1500.19(f). Any signal word shall appear on the same line and in close proximity to the triangle required by section 24 of the act. Multiple messages should be provided with sufficient space between them, when feasible, to prevent them from visually blending together.

(7) All labeling statements required by this section shall comply with the following type size requirements. 16 CFR 1500.121(c)(1) explains how to compute the area of the principal display panel and letter height.

Area sq. in	0–2	+2–5	+5–10	+10–15	+15–30	+30–100	+100–400	+400
Type Size								
Sig. Wd	3/64″	1/16″	3/32″	7/64″	1/8″	5/32″	1/4″	1/2″
St. Haz	3/64″	3/64″	1/16″	3/32″	3/32″	7/64″	5/32″	1/4″
Oth. Mat	1/32″	3/64″	1/16″	1/16″	5/64″	3/32″	7/64″	5/32″

(8) Labeling required by this section that appears on a bin, container for retail display, or vending machine shall be in reasonable proximity to any pricing or product information contained on the principal display

panel, or, if such information is not present, in close proximity to the article that is subject to the labeling requirements.

(9) Descriptive material that accompanies a product subject to the labeling requirements, including accompanying material subject to the alternative allowed by § 1500.19(f), shall comply with the requirements of 16 CFR 1500.121(c)(6) relating to literature containing instructions for use which accompanies a hazardous substance. If the descriptive material contains instructions for use, the required precautionary labeling shall be in reasonable proximity to such instructions or directions and shall be placed together within the same general area (see 16 CFR 1500.121(c)(6)).

(10) In the case of any alternative labeling statement permitted under § 1500.19(e), the requirements of 16 CFR 1500.121(b)(3) and 1500.121(c)(2)(iii) shall apply to statements or indicators on the principal display panel directing attention to the complete cautionary labeling that appears on another display panel.

(11) Any triangle required by this section shall be an equilateral triangle. The height of such a triangle shall be equal to or exceed the height of the letters of the signal word ''WARNING''. The height of the exclamation point inside the triangle shall be at least half the height of the triangle, and the exclamation point shall be centered vertically in the triangle. The triangle shall be separated from the signal word by a distance at least equal to the space occupied by the first letter of the signal word. In all other respects, triangles with exclamation points shall conform generally to the provisions of 16 CFR 1500.121 relating to signal words.

(e) *Combination of labeling statements.* The labels of products that contain more than one item subject to the requirements of this section may combine information relating to each of the respective hazards, if the resulting condensed statement contains all of the information necessary to describe the hazard presented by each article. However, in the case of a product that contains a balloon and another item subject to the labeling requirements, only the signal word and statement of hazard may be combined.

(f) *Alternative labeling statements for small packages.* Any cautionary statement required by section 1500.19(b) may be displayed on a display panel of the package of a product subject to the labeling requirement other than the principal display panel only if:

(1) The package has a principal display panel of 15 square inches or less,

(2) The full labeling statement required by paragraph (b) of this section is displayed in three or more languages on another display panel of the package of the product, and

(3)(i) In the case of a toy or game subject to § 1500.19(b)(1), a small ball subject to § 1500.19(b)(3), a marble subject to § 1500.19(b)(4), or a toy or game containing such a ball or marble, the principal display panel of the package bears the statement:

BILLING CODE 6355–01–P

SAFETY WARNING

BILLING CODE 6355–01–C

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears, or

(ii) In the case of a balloon subject to § 1500.19(b)(2) or a toy or game containing such a balloon, the principal display panel bears the statement:

BILLING CODE 6355–01–P

WARNING--CHOKING HAZARD

BILLING CODE 6355–01–C

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears.

(g) *Alternative for products manufactured outside the United States.* In the case of a product subject to the labeling requirements of § 1500.19(b) which is manufactured outside the United States and is shipped directly from the manufacturer to the consumer by United States mail or other delivery service in an immediate package that contains descriptive material, the descriptive material inside the immediate package of the product need not bear the required labeling statement only if the shipping container of the product contains other accompanying material that bears the required statements displayed in a prominent and conspicuous manner. Products shipped from abroad to a U.S. affiliate for shipment to consumers are included within the scope of this exception.

(h) *Preemption.* Section 101(e) of the Child Safety Protection Act of 1994 prohibits any state or political subdivision of a state from enacting or enforcing any requirement relating to cautionary labeling addressing small parts hazards or choking hazards associated with any toy, game, marble, small ball, or balloon intended or suitable for use by children unless the state or local requirement is identical to a requirement established by section 24 of the FHSA or by 16 CFR 1500.19. Section 101(e) allows a state or political subdivision of a state to enforce a non-identical requirement relating to cautionary labeling warning of small parts hazards or choking hazards associated with any toy subject to the provisions of section 24 of FHSA until January 1, 1995, if the non-identical requirement was in effect on October 2, 1993.

Dated: February 17, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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BILLING CODE 6355–01–P