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United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

VOTE SHEET

Date: DEC 2 4 1997

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey S. Bromme, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh P. Ewell, Attorney, GCRA (Ext. 2217) HE

SUBJECT : Options On Final Safety Standard For Bicycle Helmets

A staff briefing package concerning options for a final safety standard for bicycle helmets is attached. A draft Federal Register notice that would issue the final rule recommended by the staff is attached at Tab L of the briefing package for the Commission's consideration. Please indicate your vote on the following options.

I. ISSUE THE FINAL RULE ON BICYCLE HELMETS AS DRAFTED.

_____ _____
(Signature) (Date)

II. ISSUE THE DRAFT FINAL RULE FOR BICYCLE HELMETS WITH CHANGES (please specify).

_____ _____
(Signature) (Date)

III. OTHER (please specify).

_____ _____
(Signature) (Date)

Comments/Instructions:

NOTE: This document has not been reviewed or accepted by the Commission.
Initial ____ Date 12/24/97

CPSA 6 (b)(1) Cleared 12/24/97
No Mfrs/PrvtLblrs or Products Identified
Excepted by _____
Notified

BRIEFING PACKAGE

SAFETY STANDARD FOR BICYCLE HELMETS

For Further Information Contact:

Scott Heh
I?roject Manager
Directorate for Engineering Sciences
(301) 504-0494, ext 1308

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Executive Summary

The Children's Bicycle Helmet Safety Act of 1994 directs the Commission to establish a final mandatory safety standard for bicycle helmets based on the provisions of U.S. voluntary bicycle helmet standards. The Act further directs the Commission to include in the final mandatory standard a provision to protect against the risk of helmets coming off the heads of bicycle riders and provisions to address the risk of injury to children. The Act also requires that bicycle helmets manufactured after March 15, 1995, must comply with one of several existing voluntary standards that shall serve as interim mandatory standards until the final Commission standard becomes effective.

On August 15, 1994, the Commission published a notice of proposed rulemaking (NPR) that proposed a mandatory safety standard for bicycle helmets. After the staff evaluated public comments on the August 1994 proposed standard and conducted additional research, the Commission revised the proposed safety standard for bicycle helmets. The Commission published the revised proposal for public comment on December 6, 1995.

The staff has drafted a revised bicycle helmet standard for the Commission's consideration as a final rule. The recommended revisions are based on technical evaluations of comments received in response to the December 6, 1995 NPR. The most significant revisions deal with special provisions for helmets for children under age five, the specification for the impact test rig, and the use of the curbstone anvil for impact testing. The proposed final rule establishes requirements for impact attenuation, retention system strength, positional stability, labeling, instructions, certification, and recordkeeping.

The Directorate for Economic Analysis reports that any one-time costs associated with redesign of helmets are expected to be small on a per-unit basis Therefore, the Commission could conclude that the bicycle helmet standard is not expected to result in a significant economic impact on a substantial number of small entities. In addition, the standard is not expected to result in significant adverse effects on the environment.

The staff recommends that the Commission issue a final bicycle helmet standard as prepared by the Office of General Counsel. The staff also recommends that the final standard be added as an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date.

United States
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Washington, D.C. 20207

MEMORANDUM

DATE : DEC 2 4 1997

TO : The Commission
Sadye E. Dunn, Secretary

THROUGH : Jeffrey S. Bromme, General Counsel
Pamela Gilbert, Executive Director

FROM : Ronald L. Medford, Assistant Executive Director, RLM
Office of Hazard Identification and Reduction
Scott R. Heh, Project Manager,
Directorate for Engineering Sciences,
(504-0494 ext. 1308)

SUBJECT : Safety Standard for Bicycle Helmets

I. ISSUE

This briefing package presents a revision of the previously proposed bicycle helmet standard for the Commission% consideration as a final rule. The previously proposed standard was published in a notice of proposed rulemaking (NPR) on December 6, 1995. After evaluating the comments received in response to the December 1995 NPR, the staff is recommending some revisions for the final rule. The staff is recommending significant revisions to the special requirements for young children's helmets and to the anvil impact schedule in the impact testing procedures. These and other revisions suggested by the staff are presented in this briefing package.

II. BACKGROUND

On June 16, 1994, The Children% Bicycle Helmet Safety Act of 1994 (the "Act") became law. The Act directed the Commission to begin a proceeding under 5 U.S.C. 553 to: (1) review the requirements of voluntary bicycle helmet standards and establish a final standard based on such requirements; (2) include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders; (3) include in the final standard provisions that address the risk of injury to children; and (4) include additional provisions as appropriate.

The Act also required that bicycle helmets manufactured nine months or more after the enactment of the Act shall conform to at

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Initial Date 12/24/97

least one of the following interim standards: (1) the American National Standards Institute (ANSI) standard designated as Z90.4-1984; **(2)** the Snell Memorial Foundation standard designated as B-90; (3) the ASTM standard designated as F 1447-1993; or (4) any other standard that the Commission determines is appropriate. The Act provides that failure to conform to an interim standard shall be considered a violation of a consumer product safety standard promulgated under the Consumer Product Safety Act (CPSA).

On August 15, 1994, the Commission published a NPR in the Federal Register that proposed a mandatory safety standard for bicycle helmets, along with certification and recordkeeping requirements. The Commission received 37 comments from 30 individuals and organizations responding to the proposed rules.

On March 23, 1995, the Commission published a Federal, Register notice announcing the issuance of the interim mandatory standards. In addition to the standards identified in the Act, the Commission determined that the following standards are also appropriate as interim mandatory standards: Snell standards B-90(S), N-94, and B-95, ASTM F 1447-1994, **and** the Canadian voluntary bicycle helmet standard CAN/CSA-D113.2-M89. Bicycle helmets manufactured after March 15, 1995, must comply with one of the interim standards. The interim standards apply until the final Commission standard **takes effect.**

After the staff evaluated public comments on the August 1994 proposed standard and conducted additional research, the Commission revised the proposed safety standard for bicycle helmets. The Commission published the revised proposal for public comment on December 6, 1995. Thirty-one comments responding to the proposed rule were submitted to the Office of the Secretary. An index of the comments is at Tab A.

The following discussion provides an update on bicycle-related hazard data, an overview of the provisions in the proposed CPSC bicycle helmet standard, a summary of the significant issues raised in the public comments, the staff's responses to those issues, and recommended changes to the December 1995 NPR. It also includes a summary of the standard% economic and environmental considerations, options available to the Commission, and the staff's recommendation to issue a final bicycle helmet standard.

III. DISCUSSION

A. Epidemiological Information

The Directorate for Epidemiology and Health Sciences, Division of Hazard Analysis (EHHA), reviewed information on bicycle-related injuries and deaths (Tab B).

1. Deaths

Data from the National Center for Health Statistics (NCHS) indicated that in 1993, there were 907 pedalcyclist (primarily bicycle-related) deaths in the United States. Of these, 17 (about two percent) were to children under the age of five years. Research has shown that approximately 60 percent of all bicycle-related deaths involved head injury. For children under age five, about 64 percent of these deaths involved head injury. About 90 percent of the pedalcyclist deaths, including those of children under age five, involved collisions with motor vehicles.

2. Injuries

In 1996, there were an estimated 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms, based on data from CPSC's National Electronic Injury Surveillance System (NEISS). Of these, approximately 30 percent involved the head and face. Young children incurred a higher proportion of both head and facial injuries than older victims.

A 1993 EHHA study of bicycle hazards also indicated that children were at particular risk of head injury. This may have been partly because children younger than 15 years were significantly less likely to have been wearing a helmet than older victims (5 percent of victims younger than 15 were wearing a helmet, compared to **30** percent of those 15 and older). However, detailed information relating the type of helmet, age of user, and other aspects off the hazard scenario to head injury severity was not available from that study.

B. The Revised Standard

The Directorate for Engineering Sciences, Division of Mechanical Engineering (ESME), has drafted a revised bicycle helmet standard (Tab C). Public comments received in response to the December 1995 NPR, and staff responses to comments, are discussed at Tab C under the section of the rule to which they apply. The response to comments incorporates analyses and recommendations by: the Directorate for Engineering Sciences, Division of Mechanical Engineering (Tabs C and D), the Directorate for Laboratory Sciences, Division of Engineering (Tab E), the Directorate for Epidemiology and Health Sciences, Divisions of Hazard Analysis (Tabs B and F) and Hazard and Injury Data Systems (Tab I), the Directorate for Engineering Sciences, Division of Human Factors (Tab G), and the Office of Compliance, Division of Regulatory Management (Tab J).

The major provisions of the draft final standard include requirements for labeling,, peripheral vision, positional stability, retention system strength, and impact attenuation. In addition, the standard contains testing and recordkeeping requirements to ensure that bicycle helmets comply with the standard. The following provides an overview of the requirements

for each of these items and relevant changes from the December 1995 NPR version. Subsequent sections address the significant issues raised by commenters regarding special provisions for children's helmets, test rig specifications, anvil selection, and reflectivity.

1. Labeling and Instructions

Section 1203.6 of the standard requires certain labels on the helmet that inform the user about the protective limitations of the helmet, the importance of proper fit, and proper care of the helmet.

In addition to labeling requirements, the standard specifies that the helmet shall have fitting and positioning instructions, including a graphic representation of proper positioning.

In response to some of the comments received on the December 1995 NPR, the staff is recommending some minor revisions to the labeling and instructions requirements for the final rule. Changes are recommended to clarify what information is required on the label for the helmet's cleaning instructions. In addition, the staff recommends a requirement for the signal word "WARNING" to precede the warning labels on the helmet.

Staff is also recommending deletion of the proposed requirement for a helmet label that states "Not for Motor Vehicle Use." Respondents to the proposed standard expressed different views about which label is more appropriate, a label that states "Not for Motor Vehicle Use," or a label that states "For Bicycle Use Only." Human Factors reports that neither label adequately conveys the circumstances under which helmets that meet the CPSC standard may be appropriate. Further, the "Not for Motor Vehicle Use,, label is not a critical safety message that should be mandated in the CPSC standard. Therefore, the staff recommends that the final CPSC standard not require a "use" label, but maintains the requirement for a certification label that informs the consumer that the helmet is certified to the CPSC bicycle helmet standard. Further discussion of the recommended labeling revisions is in Tab C.

2. Peripheral Vision

Section 1203.12(a) of the standard requires that a helmet shall allow a minimum field of vision of 105 degrees to the left and right of straight ahead. The staff recommends no changes to this requirement proposed in the December 1995 NPR for the final standard.

3. Positional Stability (Roll-Off Test)

Congress directed the Commission to include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders. The CPSC standard addresses this risk with a positional stability requirement

(Section 1203.12(b)). The procedure tests retention system effectiveness in preventing a helmet from "rolling off" a head, either in the forward or rearward direction.

The procedure specifies a dynamic impact load of a 4-kg (8.8 lb) weight dropped from a height of 0.6 m (2 ft) to impact a steel stop anvil. This load is applied to the edge of a helmet that is placed on a headform on a support stand (See Figure 7 of Tab C). The helmet fails the test if it comes off the headform.

The staff recommends no changes to this requirement proposed in the December 1995 NPR for the final standard.

4. Dynamic Strensth of the Retention System

The standard requires the chin strap to be strong enough to resist breakage and excessive elongation, factors that may contribute to a helmet coming off the head during an accident.

Section 1203.12(c) requires that the chin strap remain intact and not elongate more than 30 mm (1.2 inches) when subjected to a dynamic load. The dynamic load is applied by releasing a 4-kg (8.8 lb) weight to fall a distance of 0.6 m (2 ft) to impact a steel stop anvil suspended from the strap (see Figure 8 of Tab C).

The staff recommends no changes to this requirement proposed in the December 1995 NPR for the final standard.

5. Impact Attenuation

The ability of the helmet to protect the head against collision is measured by securing the helmet on a headform and dropping the helmet/headform assembly from various heights to impact on one of three fixed steel anvils (flat, hemispherical, or curbstone, as shown in Figures 11, 12 and 13 of Tab C). Instrumentation within the headform records the impact in multiples of the acceleration due to gravity (g's). Impact tests are performed on helmets that have been subjected to four types of environmental conditions. These environments are: ambient (room temperature), high temperature (117° F to 127° F), low temperature (1° F to 9° F), and immersion in room temperature water for a minimum of 4 hours.

Section 1203.12(d) of the standard specifies the impact attenuation requirements, and section 1203.17 provides the test methodology. Bike helmets are impacted on the flat anvil from a height of 2 meters and on the hemispherical and curbstone anvils from a height of 1.2 meters. The standard requires that the peak acceleration during impact remain below 300-g.

After evaluating comments received in response to the December 1995 NPR, the staff is recommending for the final standard some significant revisions to the impact attenuation

requirements. These changes concern the following three issues: (1) special provisions for helmets intended for children under age five, (2) the use of the curbstone anvil in impact testing, and (3) the specification for the impact test rig. The detailed discussion on these items follows in Section C of this memorandum, "Significant Issues and Revisions/

The staff is also recommending other changes to the impact testing provisions in the December 1995 NPR for inclusion in the final standard. One change is to require a systems accuracy check for the impact test equipment. Another revision is to clarify the procedure for selecting helmet impact test parameters such as impact sites and anvil impact order. All of the recommended revisions are discussed in detail in Tab C.

6. Certification and Recordkeeping

Section 14(a) of the Consumer Product Safety Act, 15 U.S.C. 2063 (a), requires every manufacturer (including importers) and private labeler of a product that is subject to a consumer product safety standard to issue a certificate that the product conforms to the applicable standard, and to base that certificate either on a test of each product or on a reasonable testing program. The certification and recordkeeping rules are discussed below.

a. Certification Rule

The certification rule at Subpart B (beginning at Section 1203.30) of the draft final standard requires manufacturers of bicycle helmets to affix to the helmet a label that is the required certificate of compliance. This label shall state "Complies with CPSC Safety Standard for Bicycle Helmets for Persons Age 5 and Older" or "Complies with CPSC Safety Standard for Bicycle Helmets for Persons Age 1 and Older (Extended Head Coverage)." Certification labels shall also provide the name, address, and telephone number of the manufacturer or importer, an identification of the production lot, and the month and year the helmet was manufactured.

The draft certification rule requires manufacturers and importers to conduct a reasonable testing program to demonstrate that their bicycle helmets comply with the requirements of the standard. This testing program may be defined by the manufacturer, but it must provide reasonable assurance that their helmets are in compliance with the standard.

The staff is recommending some revisions to the certification requirements in the December 1995 NPR for the final standard. One revision is the addition of a requirement for a helmet label showing the manufacturer's telephone number. A second revision requires a helmet label showing the uncoded manufacturing date. Further discussion on these provisions is in Tab C.

b. Proposed Recordkeeping Rule

Subpart C (beginning at Section 1203.40) of the proposed rule requires every entity issuing certificates of compliance for bicycle helmets to maintain records that show that the certificates **are** based on a reasonable testing program. These records must be maintained for at least 3 years from the certification date of the last bicycle helmet in each production lot, and shall be available upon request by an employee of the Commission.

Staff is recommending for the final rule a minor revision to the recordkeeping requirements in the December 1995 NPR. This revision is to require firms to provide test records to the Commission within 48 hours of **a** request for records by a Commission employee.

C. Significant Issues and Revisions

1. Special Children's **Provisions**

a. Issue

The Children's Bicycle Helmet Safety Act of 1994 directed the Commission to include in the final standard special provisions that address the risk of head injury to children. The Directorate for Engineering Sciences discusses these issues in detail in Tab D.

The Commission first proposed a safety standard for bicycle helmets on August 15, 1994:. In that proposal, the only special provision for helmets for children under five years was an increased area of head coverage.

On December 6, 1995, however, the Commission proposed special provisions for headform **mass,** peak-g limit, and head coverage for bicycle helmets for children under five years. The special children's provisions were based on the on going work of voluntary standards organizations and proposals at that time in the technical literature. A comparison of the December 1995 NPR test parameters for helmets for children under five years and for older persons is shown below.

	Under 5	5 and older
Mass of test headform	3.9 kg	**5.0** kg
Peak-g limit	250-g	300-g
Head Coverage	more coverage at rear and sides of head	

The proposal for increased head coverage received no comments and continues to be recommended by staff. After

evaluating comments related to the headform mass and peak-g provisions, the staff further examined the issues associated with these requirements.

b. Discussion of Special Children's Provisions

A young child's skull has different mechanical properties than the skull of an older child or adult. These differences are especially evident for children under the age of five years. Their skulls have a lower degree of calcification, making them more flexible than adult skulls. During an impact to the head, the increased skull flexibility results in a greater transfer of kinetic energy from the impact site to the brain tissue. Besides the different mechanical properties, the mass of a young child's head is also different from that of a more mature person's head. Studies show that the head mass of children under the age of five years ranges from approximately 2.8 to 3.9 kg. This mass is lower than the 5-kg test headform mass specified in current U.S. bicycle helmet standards.

Proponents of special provisions for young children's helmets believe that these helmets should be tested under different test parameters than helmets intended for older persons. The current test parameters are based primarily on adult head injury tolerance and on a headform mass that is approximately that of an adult head. Supporters of special provisions contend that these adult test parameters result in a helmet with a liner that is too stiff to optimally protect a young child's head. By using a headform weight that better represents a young child's head (e.g., 3.9 kg), and reducing the allowable peak-g, helmets would need to be designed with a lower density ("softer") liner to further lessen the impact transmitted to the head.

The comments received by the Commission in response to the proposed standard illustrate the complexity of the issues concerning special provisions for children's helmets. A few respondents to the proposed rule supported the lower mass and lower peak-g provisions, believing that they will lead to an improvement in head protection for small children. One respondent favored a reduced headform mass provision, but did not recommend a reduced peak-g provision, stating that it could result in a helmet with a lower margin of safety.

Several respondents questioned whether there is sufficient evidence to show that a reduced-mass headform and a lower limit for peak acceleration will result in improved head protection for children. Some respondents suggested that special children's provisions should not be adopted since epidemiological studies show that children's helmets as they exist today are protective.

The Commission requested technical views on this issue from Barry Myers, M.D., Ph.D., Associate Professor, Department of

Biomedical Engineering, Duke University. In his report', Dr. Myers explains that modification to the standard should be considered only if it can be shown to improve performance. Improvements may be shown by epidemiological or biomechanical evidence. However, considering the degree of head injury protection provided by current helmets, incremental improvement would be difficult to detect, even with a large epidemiological study.

From a biomechanical perspective, it is important to assess how changes in test headform mass and peak-g criteria would affect helmet design and protective capability. This can be done by examining how a helmet functions to protect the head in an impact.

The helmet has a crushable liner typically made of expanded polystyrene foam. If the liner is crushed as the head presses against the inside of the helmet during impact, the liner allows the head to stop over a longer distance and time than would otherwise be the case. This reduces the impact energy that is transmitted to the head, thereby reducing the risk of injury.

The degree to which the liner resists being crushed affects the helmet's protective qualities. For a given impact, a helmet liner that is too soft will "bottom out," thereby losing its protective ability to allow relative movement between the head and the object being impacted. Conversely, a liner that is too hard will not allow sufficient crushing to adequately protect the head.

Effect of changing mass and peak-g on helmet design

A detailed discussion on the effect on changing the headform mass and peak-g criterion is at Tab D. In summary, keeping other variables constant, a decrease in headform mass requires a decrease in liner stiffness. Similarly, with other variables kept constant, a reduction in the peak-g criterion requires a decrease in liner stiffness. When liner stiffness is decreased, a greater percentage of the helmet's available crush distance will be used during impact.

The biomechanical analysis shows that, for impact conditions that do not result in complete compression of the helmet's liner, it is possible to lessen the impact energy transmitted to the head (and reduce the risk of injury) by reducing the stiffness of the liner. However, as the impact energy increases, a helmet with a softer liner will bottom out (crush beyond its protective capacity) under less severe conditions than a helmet with a more

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'Myers, Barry, M.D., Ph.D. "An Evaluation of A Helmet Standard for Children." Report to the U.S. Consumer Product Safety Commission (July 1997).

rigid liner of the same thickness. To compensate, the softer helmet would have to be made thicker to prevent bottoming out. However, there is a limit to how thick a helmet can be before it is no longer practical or appealing to the user. Therefore, the goal of helmet design is to optimize liner density and thickness to protect against the widest range of impact conditions and still have a product that people will use.

Effect on Protective Performance

The biomechanical analysis suggests that reducing the liner stiffness could have both a positive and a negative influence on the protection provided by helmets under existing criteria. Therefore, it is necessary to also examine available epidemiological data that relate to this issue. Decreasing the liner stiffness would benefit those who experience injuries with minimal or no liner deformation of current helmets. However, a decrease in liner stiffness could increase the number of head injuries that occur during more severe impacts that cause the helmet liner to bottom out.

To learn the effect on the level of protection offered by softer helmet liners for children under 5, two questions would need to be answered:

1. Are children under age 5 suffering head injuries with minimal or no liner deformation of current helmets?

2. Are children under age 5 suffering head injuries with a bottomed-out liner?

Unfortunately, currently available information is limited and does not answer either of these questions. Therefore, it is uncertain whether young children would benefit from special provisions for headform mass and peak-g.

The only known study to examine the relationship between helmet damage and head injury was completed in 1996 by the Snell Memorial Foundation and the Harborview Injury Prevention and Research Center.[2] Of those bicycle helmets collected from individuals (of various ages) who went to a hospital, 40% of the helmets had no deformation, 14% had significant damage in which the helmet was approaching a bottomed-out condition, and 7% of the helmets had catastrophic damage. The data were not presented specifically for the under-5 age group or any other specific age

[2] Rivara, Frederick P., MD, MPH, Thompson, Diane C., MS, Thompson, Robert S., MD "Circumstances and Severity of Bicycle Injuries." Snell Memorial Foundation/Harborview Injury Prevention and Research Center (1996).

group. The study showed that there was a risk of head and brain injury even with no or minimal helmet damage. The risk of injury increased moderately as the severity of helmet damage increased, until catastrophic damage was reached. As expected, the risk of head and brain injury jumped dramatically when a helmet was damaged catastrophically. This study suggests that if helmets for all ages were designed with softer liners, there is a potential to both improve the protection for lower-severity impacts and increase the risk of injury at the higher-severity impacts.

Since the risk of injury rises dramatically with catastrophic helmet damage, and current helmets are effective in reducing the risk of head and brain injuries, the staff does not support a change to require softer helmet liners for bicyclists of all ages. The available data are insufficient to determine that such a change would increase overall protection. When focussing on the age range of under five years, currently available information is even more sparse. Therefore, if helmets for children under age 5 were made with softer liners, there are insufficient data to estimate either (1) the level of protection that might be gained at the lower-severity impacts, and (2) the protection that might be lost at the severe impact conditions that completely crush the liner.

c. Recommendation for Children% Helmets Requirements

Based on the items discussed above, the CPSC staff recommends that there be no special provisions in the final standard for headform mass and peak-g criteria for young children's helmets. The staff recommends this approach because of insufficient data to justify the changes and the consideration that these changes could provide less protection during the more severe impacts which could result in more serious head injuries to children. However, should future studies provide evidence that young children, or bicyclists of any age, could benefit from decreased liner stiffness, the Commission could consider revisions to the bicycle helmet standard at that time.

2. Use of the Curbstone Anvil for Impact Tests

Six respondents to the proposed rule expressed concern over using two curbstone impacts on a single helmet. As proposed, Section 1203.3(d) and Table 1203.13 do not define the conditions of the fourth impact on a helmet. The fourth impact in the proposed standard is left to the discretion of test personnel, and thus could be a second curbstone impact. Two commenters on this issue wrote that the footprint of the curbstone impact can overlap other impact sites and violate the "single impact" principle of testing. The length of the curbstone anvil restricts the location of impact sites that can be used without overlap. The use of a second curbstone anvil, and the damage caused by curbstone impacts, can restrict the selection of test sites further to the point where only three impacts may be

possible on a small helmet without overlap. Another of the commenters expressed concern about impacting the helmet with the curbstone anvil after the helmet was conditioned in a wet environment.

After evaluating the comments on this issue, the staff recommends revisions to the test schedule at Section **1203.13** and Table **1203.13**. The staff agrees that the previously proposed test schedule should be revised to prevent the possibility of striking a test helmet with more than one curbstone impact. The potential for overlapping "footprints" of curbstone impacts combined with other impacts on a single test helmet goes beyond the intended principle of a single impact for a given area. Staff disagrees, however, with the commenter who recommended that only ambient-conditioned helmets be subjected to a curbstone impact. To ensure adequate protection against impact against curbstone-type shapes, tests for that anvil, as well as the other test anvils, should be carried out in all of the environmental conditions prescribed by the standard. Accordingly, section 1203.13 and Table 1203.13 of the draft final standard contain a revised test schedule to incorporate a single curbstone impact on each of four "clean" helmet samples, one from each of the conditioning environments. Four additional helmets (one for each environment) are struck four times each, twice with the flat anvil and twice with the hemispherical anvil.

3. Specification for the Impact Test Rig

The CPSC specified the monorail-type of test rig for bicycle helmet impact testing in the December 6, 1995 proposed standard. Currently, U.S. voluntary bicycle helmet standards allow the use of either monorail or guidewire types of test rigs. The CPSC specified the monorail type to avoid the possibility that different results would be obtained with the two types of test rigs.

In their comments responding to the proposed rule, several helmet manufacturers and the Snell Memorial Foundation disagreed with the specification of the monorail test rig in the proposed CPSC standard. The respondents stated that guidewire type rigs are more commonly used in the industry. Most respondents suggested that the CPSC standard specify that either guidewire or monorail rigs may be used to test for the impact requirements.

To respond to this issue, CPSC staff initiated a seven-laboratory comparison test program. The main purpose of the study was to determine if there are statistically significant mean differences in test results when using monorail and guidewire test rigs under standardized testing conditions. The statistical analysis of the test results is at Tab F of the briefing package. The staff discussion and recommendations are at Tab C - Attachment 3.

The statistical analysis of the interlaboratory results showed that in almost all examinations of test variable combinations, the choice of test rig did not have an appreciable effect on test results. However, on the Model I helmets, and only when the second impact was on the curbstone anvil, the monorail showed a significantly higher mean logarithm for peak-g summed across laboratories having both types of test rigs. For reasons completely unrelated to these test results (see above discussion on use of the curbstone anvil), a curbstone impact in combination with another impact on a single test helmet is no longer in the final standard being recommended by the staff. Since the interlaboratory data (summed across labs using both types of rigs) show no significant differences between guidewire and monorail rigs under test conditions within those defined in the draft final standard, the standard should allow either type of rig to be used for impact testing.

Over the last 15-20 years, voluntary standards in the U.S. have allowed both monorail and guidewire types of test rigs. Both types of test rigs have been used extensively in both independent test laboratories and manufacturer's in-house test facilities. The Snell Memorial Foundation, one of the established helmet test organizations in the U.S., uses guidewire rigs to test conformance to their standards. The staff has no evidence to conclude that the allowance of both types of test rigs in voluntary standards has resulted in a compromise of safety for bicycle helmet users.

For the reasons discussed above, the technical staff recommends that both types of rigs are suitable for impact attenuation testing, and that the CPSC standard specify that either a monorail or a guidewire test rig may be used.

4. Reflectivity

Some comments on the original proposal (August 1994) related to possible requirements for helmets to improve a bicyclist's conspicuity in nighttime conditions. Data show an increased risk of injury while bicycling during non-daylight hours. The Commission indicated that it would study this issue further in conjunction with planned work on evaluating the bicycle reflector requirements of CPSC's mandatory requirements for bicycles. The Commission stated that it would decide whether to propose reflectivity requirements for bicycle helmets under the authority of the Children% Bicycle Helmet Safety Act of 1994 after that work is completed.

Several commenters on the revised proposal (December 1995) urged that the Commission not postpone implementing bicycle helmet reflectivity requirements.

Since the revised proposal, the Commission staff conducted field testing on bicycle reflectors and examined the issue of

reflectivity on bicycle helmets. In the field testing, half (24/48) of the subjects were tested using bicycle riders wearing a reflective helmet and the other half were tested using riders wearing a non-reflective helmet. The reflective tape used on the helmets met a proposed Standard on Use of Retroreflective Materials on Bicycle Helmets that was balloted by the ASTM Headgear Subcommittee. The study failed to show that the particular helmet reflective strip used in the study would increase the distance at which a bicycle can be detected or recognized (Tab I). Accordingly, the staff does not have sufficient information to recommend for the final rule a requirement for bicycle helmet reflective performance.

E. Economic and Environmental Considerations

The Commission's Directorate for Economics (EC) prepared an economic assessment on small business and an assessment of environmental considerations related to the bicycle helmet safety standard (Tab K) .

Economic Considerations

The vast majority of helmets now sold conform to one (or more) of three existing voluntary standards. Many of these helmets probably already comply with the impact attenuation requirements of the new rule. On a per-unit basis, costs associated with redesign and testing thus are expected to be small.

The standard's labeling requirements are unlikely to have a significant impact on firms, since virtually all bicycle helmets now bear a permanent label on their inside surface. Industry sources report that, given sufficient lead time to modify these labels, any increased cost of labeling would be insignificant.

The vast majority of manufacturers now use third-party testing and monitoring for product liability reasons, and are likely to continue to do so in the future. The standard allows for self-certification and self-monitoring, however, which is substantially less costly than third-party testing and monitoring.

The Commission received two comments on the 1995 proposal that related to the economic effects of the revision. These involved the cost associated with the specification of a monorail test device, and the effect of the curbstone testing procedure.

A comment from Trek Bicycle Corporation approved specifying a single test apparatus, but was concerned that the Commission chose a monorail-guided test rig over a wire-guided unit. Trek said that the majority of members in the Protective Headgear Manufacturers Association (PHMA) test on wire-guided equipment and that some firms may be forced to purchase monorail units to

eliminate product liability concerns. The firm stated, "the burden of this unnecessary expense may provide need for additional analysis of the financial impact to small business, as required by the Regulatory Flexibility Act."

Based on contacts with industry and testing facilities, it appears that, of those manufacturers that have in-house test labs, an estimated 5 to **10** have only a wire-guided rig. Most commercial, independent, and academic bicycle helmet test labs have a monorail test rig, and many of those labs also have one or more wire-guided rigs. The estimated cost to purchase a monorail-guided rig is about $20,000.

An interlaboratory study comparing the results of monorail and guidewire rigs showed no significant differences between the two types of rigs in test conditions that are within the parameters of the draft final standard. Therefore, the staff has recommended that the final standard be revised to specify that either a monorail or a guidewire rig may be used to test for the impact requirements. Consequently, the potential cost considerations to laboratories using guidewire rigs should no longer apply.

Another commenter, Bell Sports, noted that the proposal included impact testing requirements that allowed two impacts with a device simulating helmet contact with a curb. Bell estimated that "the addition of the curbstone anvil . . . and with the option of using it twice on any helmet might well increase the retail price of bicycle helmets by $2.00 to $10.00."

The standard is intended to address helmet safety from a single impact on a given area. For this reason, the impact testing requirement has been changed to require only a single curbstone impact simulation test per helmet test sample. Consequently, the potential changes in helmet design that could have been needed to comply with two curbstone impact tests no longer apply.

Small Business Effects

Of the **30** current manufacturers of bicycle helmets, all but two would be considered small businesses under Small Business Administration employment criteria (less than 100 employees). As the Commission found previously, the one-time costs of redesign are expected to be small on a per-unit basis.

Since the per-unit costs of modifying production molds will be relatively low, EC reports that the Commission could conclude that the rule will not have a significant impact on a substantial number of small entities.

Environmental Considerations

The requirements of the standard are not expected to have a

significant effect on the materials used in production or packaging, or on the amount of materials discarded due to the regulation. Therefore, no significant environmental effects are expected from this rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

IV. DRAFT FEDERAL REGISTER NOTICE - FINAL RULE

The Office of General Counsel (OGC) prepared a draft Federal Register notice that issues a CPSC Safety Standard for Bicycle Helmets (Tab L). In addition, the draft Federal Register notice issues the final standard as an interim standard, so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date. The draft notice incorporates the staff recommended revisions to the standard and includes a supplementary information section that summarizes staff responses to comments on the December 1995 NPR.

V. OPTIONS

The following options are available to the Commission:

1. Issue a final bicycle helmet standard in the Federal Register as drafted.

2. Issue a final bicycle helmet standard in the Federal Register with changes directed by the **Commission.**

VI. RECOMMENDATION

The staff recommends that the Commission issue a final bicycle helmet standard as drafted.

The Act provides that the final standard shall take effect one year from the date it is issued and shall be considered a consumer product safety standard promulgated under the Consumer Product Safety Act. These requirements will establish a single mandatory performance standard that will include provisions not currently addressed by U.S. voluntary bicycle helmet standards. They will also provide the consumer a means to identify bicycle helmet compliance with a Federal safety standard.

TAB A

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: March 7, 1996

TO : ESME/Scott Heh

Through: Sadye E. Dunn, Secretary

FROM : Martha Kosh
Records and Reference Assistant

SUBJECT: Safety Standard for Bicycle Helmets 16 CFR Part 1512, FR, Vol. 60, No. 236, December 6, 1995

ATTACHED ARE COMMENT!; ON THE CC96-1

COMMENT	DATE	SIGNED BY	AFFILIATION
CC96-1-1	12/14/95	R. C. Wasserman MD, MPh	Department of Pediatrics University of Vermont One South Prospect Burlington, VT 05401
CC96-1-2	1/11/96	Daniel Pomerening Sr. Research Engr.	Southwest Research Institute 6220 Culebra Road P.O. Drawer 28510 San Antonio, TX 78228
CC96-1-3	1/17/96	F. K. Winston, MD Asst. Professor of Pediatrics	The Children's Hospital Philadelphia 34th St. & Civic Blvd. Philadelphia, PA 19104
CC96-1-4	1/17/96	Susan Baker Professor	Johns Hopkins University School of Hygiene and Public Health Department of Health Policy & Management 624 North Broadway Baltimore, MD 21205
CC96-1-5	1/17/96	Mark Stevens Sr. Helmet Engr.	Trek Bicycle Corporation 801 W. Madison St. P.O. Box 183 Waterloo, WI 53594

Safety Standard for Bicycle Helmets 16 CFR Part 1512, FR. Vo. 60, No. 236, December 6, 1995

CC96-1-6	1/18/96	Frederick Rivara, M.D.,Director	Harborview Injury Prevention & Research Center 325 Ninth Ave., ZX-10 Seattle, WA 98104
CC96-1-7	1/19/96	Jane McCormack, RN Trauma Nurse Coordinator	University Medical Center at Stony Brook, NY
CC96-1-8	1/23/96	Hugh Hurt, Jr. Professor David Thorn Director	University of Southern California Head Protection Research Laboratory 927 West 35th Pl., Rm 114 Los Angeles, CA 90089
CC96-1-9	1/27/96	Diane Thompson Epidemiologist	Harborview Injury Prevention & Research Center 325 Ninth Ave, ZX-10 Seattle, WA 98104
CC96-1-10 rec'd 2/13	2/1/96	T. Gennarelli, MD L. Thibault, Sc.D	Medical College of Pennsylvania & Hahnemann University Broad & Vine Mail Stop 455 Philadelphia, PA 19102
CC96-1-11 rec'd 2/13	2/6/96	L. Oldendorf, P.E., GSP, President	American Society of Safety Engineers 1800 East Oakton St. Des Plaines, IL 60018
CC96-1-12	2/6/96	Jim Sundahl Senior Engineer	Bell Sports 10601 N. Hayden Rd. Suite I-100 Scottsdale, AZ 85260
CC96-1-13	2/7/96	Philip Graitcer, D.M.D., M.P.H. Associate Professor and Director, World Health Organization Helmet Initiative	The Rollins School of Public Health of Emory University 1518 Clifton Rd, NE Alanta, GA 30322

Safety Standard for Bicycle Helmets 16 CFR Part 1512, FR, Vol. 60, No. 236, December 6, 3.995

CC96-1-14 2/8/96	Frank Sabantano President	London Bridge BMX Association 2990 Starline Drive Lake Havasu City, AZ 86403
CC96-1-15 2/13/96	Harold Fenner, M.D.	Norte Vista Medical Center 2410 North Fowler Hobbs, N-M 88240
CC96-1-16 2/14/96	Randy Swart Director	Bicycle Helmet Safety Institute 4611 Seventh St. South Arlington, VA 22204
CC96-1-17 2/16/96	Lori Kuller	3M Safety and Security Systems Division 3M Center St. Paul, Mn 55144
CC96-1-18 2/19/96	Richard Snyder President	BioDynamics International Scientific Research and Consultation 3720 N. Silver Drive Tucson, AZ 85749
CC96-1-19 2/19/96	Richard Snyder President	George Snively Research Foundation 1821 Brazos Hobbs, NM 88240
CC96-1-20 2/19/96	Bruce Bradtmiller President	Anthropology Research Project, Inc. P.O. Box 307 503 Xeania Ave. Yellow Springs, OH 45387
CC96-1-21 2/20/96	Maurice Keenan President	American Academy of Pediatrics The Homer Building 601 Thirteenth St., NW Suite 400 North Washington, DC 20005
CC96-1-22 2/20/96	Heather Paul Executive Director	National Safe Kids Campaign 111 Michigan Ave, NW Washington, DC 20010‘

Safety Standard for Bicycle Helmets 16 CFR Part 1512, FR. Vol. 60, No. 236, December 6, 1995.

CC96-1-23 2/20/96	Mary E. Fise General Counsel	Consumer Federation of America 1424 16th St., NW Suite 604 Washington, DC 20036
CC96-1-24 2/20/96	Bill Hauda Executive Director	Bicycle Federation of Wisconsin
CC96-1-25 2/20/96	Paul Appel Atty at Law	Paul Appel 168 Duane Street New York, NY 10013
CC96-1-26 2/18/96	Paula Romeo	2159 S. Fish Hatchery Rd Oregon, WI 53575
CC96-1-27 2/26/96	Michael Grim Director of R&D	Giro Sport Design 380 Encinal Street Santa Cruz, CA 95060
CC96-1-28 2/20/96	Edward Becker Executive Director	Snell Memorial Foundation West Coast Test Facility 6731-A 32nd Street North Highlands, CA 95660
CC96-1-29 2/01/96	Thorn Parks President	Protective Headgear Manufacturers' Assoc. 1333 30th Street San Diego, CA 92154
CC96-1-30 2/19/96	Dennis Piper Director, Corporate Affairs	Troxel Cycling and Fitness 1333 30th Street San Diego, CA 92154
CC96-1-31 3/8/96	John Sabelli, P.E. Staff Engineer Performance Div.	Inchcape Testing Services ETL Testing Laboratories 3933 U.S. Rt. 11 Cortland, NY 15045

Harold A. Fenner, M.D. (5/30/96)
Snell Memorial Foundation
1318 North Del Paso
Hobba, NM 88240

TAB B

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: OCT 20 [illegible]

TO : Scott Heh, ESME

Through: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Epidemiology and Health Sciences
Susan Ahmed, Ph.D., Director, Hazard Analysis Division (EHHA)

FROM : Deborah K. Tinsworth, EHHA DKT

SUBJECT: Injury Data Related to Proposed Requirements for Children's Bicycle Helmets

This memorandum provides available data on fatal and non-fatal bicycle-related head injuries to children. It was prepared in support of efforts to evaluate the need for separate requirements for helmets intended for children younger than five years of age in the proposed U.S. Consumer Product Safety Commission (CPSC) standard for bicycle helmets. Specifically, the proposed testing requirements for children's helmets include a reduced headform mass, a lower allowable peak acceleration, and increased head coverage.

DEATHS

Data from the National Center for Health Statistics (NCHS) indicated that in 1993, there were 907 pedalcyclist (primarily bicycle-related) deaths in the United States.[1] Of these, 17 (about two percent) were children under the age of five years. Research has shown that approximately 60 percent of all bicycle-related deaths involved head injury. For children under age five, about 64 percent involved head injury (1)(2). Information on the impact forces involved in these fatal incidents was not available, although almost 90 percent of the pedalcyclist deaths, including those of children under age five, involved collisions with motor vehicles.

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[1]NCHS collects information on all deaths that occur in the United States each year. Data on deaths involving bicycles were obtained from NCHS mortality data tapes for 1993. Using international classifications published by the World Health Organization, bicycle-related deaths were selected from External Cause of Death Codes E800 through E807, with fourth digit .3; E810 through E825, with fourth digit .6; E826.1; and E826.9.

INJURIES

In 1996, there were an estimated 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms, based on data from CPSC's National Electronic Injury Surveillance System (NEISS). Of these, approximately 30 percent involved the head and face. As shown in Table 1, young children incurred a higher proportion of both head and facial injuries than older victims.

TABLE 1

ESTIMATED BICYCLE-RELATED INJURIES:
BODY PART BY AGE OF VICTIM

		Age of Victim		
Body Part	Total	0-4	5-14	15+
Total	566,400	40,100	315,700	210,600
(Percent)	100%*	100%	100%	100%
Head/Face	31%	59%	33%	22%
Head	11%	17%	12%	9%
Face	15%	29%	16%	10%
Eye	cl%	cl%	cl%	<1%
Mouth	4%	11%	4%	2%
Ear	cl%	1%	<1%	cl%
Other	69%	41%	67%	78%

*Column detail may not add to total due to rounding

SOURCE: NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS), 1996; U.S. CONSUMER PRODUCT SAFETY COMMISSION/AHA

Because helmets may protect more against head injuries than some facial injuries,[2] head injuries were also examined separately. As shown in Table 2, the types of injuries incurred by young children were somewhat different than those incurred by older children and adults. Younger children had a smaller

[2]Recent research indicated that helmets reduced the risk of serious injury to the upper and middle face by about 65 percent, but had no significant effect on serious injury to the lower face (3).

proportion of concussions and internal injuries to the head than older victims and a larger proportion of relatively minor head injuries (i.e., lacerations, contusions, and abrasions). The extent to which these differences can be attributed to the use of helmets or other aspects of the hazard scenario, or to the physiology of young children, is not known, however. It is also possible that caregivers are more likely to bring young children to the emergency room for relatively minor injuries, since young children may not be able to evaluate their own symptoms.

TABLE 2

ESTIMATED BICYCLE-RELATED INJURIES:
TYPE OF HEAD INJURY BY AGE OF VICTIM

	Age of Victim			
	Total	0-4	5-14	15+
Total Head Injuries	64,900	6,800	39,000	19,100
(Percent)	100%	100%	100%	100%
Concuss/Internal Inj	50%	34%	53%	51%
Lacer/Contus/Abras	42%	60%	39%	40%
Fracture	3%	2%	3%	3%
Other	5%	4%	5%	6%

SOURCE: NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS), 1996; U.S. CONSUMER PRODUCT SAFETY COMMISSION/AHA

A 1993 AHA study of bicycle hazards also indicated that children were at particular risk of head injury. This may have been partly because children younger than 15 years were significantly less likely to have been wearing a helmet than older victims (5 percent of victims younger than 15 were wearing a helmet, compared to 30 percent of those 15 and older). However, detailed information relating the type of helmet, age of user, and other aspects of the hazard scenario to head injury severity was not available from that study **(4)**.

A 1996 study of about 3,400 injured bicyclists in the Seattle, Washington area, included an evaluation of the protective effectiveness of helmets in different age groups (5). When bicyclists treated in hospital emergency rooms for head injuries were compared to bicyclists who sought care for other

types of injuries at the same emergency rooms, helmet use was associated with a reduction in the risk of any head injury by 69 percent, brain injury by 65 percent, and severe brain injury by 74 percent?

By age group, the reduction in the risk of head injury ranged from 73 percent for children under 6 years to 59 percent for teens in the 13-19 year-old age group.[4] Based on the results of their study, the authors concluded that helmets were effective for all bicyclists, regardless of age, and that there was no evidence that children younger than 6 years need a different type of helmet. However, for children younger than six years, there was only one helmeted child with a brain injury (a concussion), and no helmeted children with severe brain injuries. Thus, the protective effects of helmets on brain injuries and severe brain injuries were not calculated for this age group.

---

[3]Head injury included superficial lacerations, abrasions, and bruises on the scalp, forehead, and ears, as well as skull fractures, concussions, cerebral contusions and lacerations, and all intracranial hemorrhages. Brain injury included physician-diagnosed concussion and more serious brain injuries. Severe brain injury included intracranial injury or hemorrhage, cerebral lacerations/contusions, and subarachnoid, subdural, and extradural hemorrhage.

A widely-cited 1989 (study, published by the same authors, found that riders with helmets had an 85 percent reduction in their risk of head injury, and an 88 percent reduction in their risk of brain injury, when compared to cyclists without helmets (6). These results were found when patients who sought emergency room care for bicycle-related head injuries were compared to bicyclists in the community who had crashes, regardless of injury or medical care.

[4]The estimated reduction in risk for children 6-12 years of age was 70 percent.

CONCLUSIONS

Information that relates aspects of the hazard scenarios to the nature and severity of head injury was not available in sufficient detail to conclude whether, on the basis of the available injury data alone, separate performance requirements for bicycle helmets intended for children under the age of five years would further reduce head injuries A recent study of helmet effectiveness indicated that current helmets were equally protective for all ages of bicyclists for head injuries in general. However, data were insufficient to evaluate whether this was the case for incidents resulting in brain injury or severe brain injury.

It was evident, however, that children and adults are at risk of head injury or death while bicycling, and that helmets can reduce this risk considerably. A 1991 CPSC survey of bicycle and helmet usage indicated that only about 18 percent of all bicyclists and 17 percent of bicyclists age 10 and younger wore helmets all or most of the time (7). Efforts to increase helmet use by bicyclists of all ages are clearly important to reduce the frequency and severity of injury.

REFERENCES

1. Sachs, Jeffrey, J., MPH; Holmgreen, Patricia, MS; Smith Suzanne M., MD; Sosin, Daniel M., MD. "Bicycle-Associated Head Injuries and Deaths in the United States from 1984 through 1988." Journal of the American Medical Association. 266 (December 1991): 3016-3018.

2. Sosin, Daniel M., MD, MPH; Sacks, Jeffrey J, MD, MPH; and Webb, Kevin W. "Pediatric Head Injuries and Deaths from Bicycling in the United States." Pediatrics. 98 (November 1996) : 868-870.

3. Thompson, Diane C., MS; Nunn, Martha E., DDS; Thompson, Robert S., MD; and Rivara, Frederick P., MD, MPH. "Effectiveness of Bicycle Safety Helmets in Preventing Serious Facial Injury." Journal of the American Medical Association. 276 (December 1996): 1974-1975.

4. Tinsworth, Deborah K., MS; Polen, Curtis; and Cassidy, Suzanne. "Bicycle-Related Injuries: Injury, Hazard, and Risk Patterns." International Journal for Consumer Safety. I (December 1994): 207-220.

5. Thompson, Diane C., MS; Rivara, Frederick P, MD, MPH; and Thompson, Robert S., MD. "Effectiveness of Bicycle Safety Helmets in Preventing Head Injuries." Journal of the American Medical Association. 276 (December 1996): 1968-1973.

6. Thompson, Robert S., MD; Rivara, Frederick P., MD, MPH; and Thompson, Diane C., MS. "A Case Control Study of the Effectiveness of Bicycle Safety Helmets." The New England Journal of Medicine. 320 (May 1989): 1361-1367.

7. Rogers, Gregory B. "The Characteristics and Use Patterns of Bicycle Riders in the United States." Journal of Safety Research. 25(1994): 83-96.

TAB C

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: DEC 2 2 1997

TO : File

THROUGH : Andrew G. Stadnik, Associate Executive Director for Engineering Sciences

FROM : Scott Heh, ESME, Bicycle Helmet Project Manager, 504-0494 ext. 1308

SUBJECT : Recommended Revisions to the Proposed Regulation for Bicycle Helmets and a Summary of Staff Responses to Comments

This memorandum presents a revised CPSC bicycle helmet regulation and an overview of CPSC staff assessments of comments received in response to the proposed bicycle helmet regulation published in the Federal Register on 12/6/95. Each substantive revision to the proposed rule is accompanied by a discussion that explains why staff is recommending the change.

The proposed revisions and response to comments incorporate analyses and recommendations by: The Directorate for Laboratory Sciences, Division of Engineering Laboratory (LSE), The Directorate for Engineering Sciences, Divisions of Human Factors (ESHF) and Mechanical Engineering (ESME), The Directorate for Epidemiology and Health Sciences, Divisions of Hazard Analysis (EHHA) and Hazard and Injury Data Systems (EHDS), and The Office of Compliance, Division of Regulatory Management (CRM). The analyses of each office are attached as Tabs in the briefing package that transmits a revised bicycle helmet standard for approval by the Commission as a final rule.

In the attached draft standard, new text is shown in double underline and deleted text from the previous version is shown in ~~strikeout~~. The staff's assessments of comments are shown in italic text that is double indented.

Attachments:
1. Revised Proposed Standard with Response to Comments
2. Responses to Other Comments and General Issues
3. Engineering Sciences Recommendations on the Specification of the Impact Test Rig and Other Impact Testing Procedures

ATTACHMENT 1
REVISED PROPOSED RULE FOR BICYCLE HELMETS WITH RESPONSES TO COMMENTS

Part 1203 — SAFETY STANDARD FOR BICYCLE HELMETS

Subpart A-The Standard

Subpart B-Certification

Subpart C-Recordkeeping

Subpart D-Bicycle Helmets Manufactured From March 16, 1995, Through Date That Is 1 Year After The Final Rule Is Issued

Figures for Part 1203

AUTHORITY: Secs. 201-207, Pub. L. 103-267, 108 Stat. 726-729, 15 U.S.C. 6001-6006.

Subpart A-The Standard

§ 1203.1 Scope, general requirements, and effective date.

(a) *Scope.* This standard describes test methods and defines minimum performance criteria for all bicycle helmets, as defined in § 1203.4(b).

(b) General requirements.

(i) Projections. All projections on bicycle helmets must meet the construction requirements of § 1203.5.

(ii) *Labeling and instructions.* All bicycle helmets must have the labeling and instructions required by § 1203.6.

(iii) *Performance tests.* All bicycle helmets must be capable of meeting the peripheral vision, positional stability, dynamic strength of retention system, and impact-attenuation tests described in §§ 1203.7-1203.17.

(iv) *Units.* The values stated in International System of Units ("SI") measurements are the standard. The inch-pound values stated in parentheses are for information only.

(c) *Effective date.* The standard shall become effective [insert date that is 1 year after publication] and shall apply to all bicycle helmets manufactured after that date. Bicycle helmets manufactured between March 16, 1995, and [insert date that is 1 year after publication], inclusive, are subject to the requirements of Subpart D, rather than this Subpart A.

§ 1203.2 Purpose and basis.

The purpose and basis of this standard is to reduce the likelihood of serious injury and death to bicyclists resulting from impacts to the head, pursuant to 15 U.S.C. 6001-6006.

§ 1203.3 Referenced documents.

The following documents are referenced in this standard.

(a) Draft ISO/DIS Standard 6220-1983 - Headforms for Use in the Testing of Protective Helmets.'

(b) Federal Motor Vehicle Safety Standard 218, Motorcycle Helmets.[2]

(c) SAE Recommended Practice SAE J211 OCT88, Instrumentation for Impact Tests.[3]

§ 1203.4 Definitions

(a) *Basic plane* means an anatomical plane that includes the auditory meatuses (the external ear openings) and the inferior orbital rims (the bottom edges of the eye sockets). The IS0 headforms are marked with a plane corresponding to this basic plane (see Figures 1 and 2 of this part).

~~(b) *Bicycle helmet* means any headgear that is either marketed as, or has a reasonably foreseeable use as, a device intended to provide protection from head injuries while riding a bicycle.~~

'Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[2]Available from the Department of Transportation, National Highway Traffic Safety Administration, Office of Vehicle Safety Standards, 400 7th St. S.W., Washington D.C!. 20590.

[3]Available from Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096.

(b) *Bicycle* helmet means anv headgear that is either marketed as, or implied throush marketing and/or promotional information to be, a device intended to provide protection from head injuries while riding a bicycle.

(c) Comfort *or fit padding* means resilient lining material used to configure the helmet for a range of different head sizes. ~~This padding ha~~-s ~~no significant effect on impact attenuation~~

(d) *Coronal plane* is an anatomical plane perpendicular to both the basic and midsagittal planes and containing the midpoint of a line connecting the right and left auditory meatuses. The IS0 headforms are marked with a transverse plane corresponding to this coronal plane (see Figures 1 and 2 of this part).

(e) *Field of vision* is the angle of peripheral vision allowed by the helmet when positioned on the reference headform.

(f) *Helmet positioning index (HPI)* is the vertical distance from the brow of the helmet to the reference plane, when placed on a reference headform. The vertical distance shall be specified by the manufacturer for ~~each size of headform the helmet fits~~ for each size and model of the manufacturer's helmets for the appropriate size of headform for each helmet as described in 81203.10

(g) Midsagittal plane is an anatomical plane perpendicular to the basic plane and containing the midpoint of the line connecting the notches of the right and left inferior orbital ridges and the midpoint of the line connecting the superior rims of the right and left auditory meatuses. The IS0 headforms are marked with a longitudinal plane corresponding to the midsagittal plane (see Figures 1 and 2 of this part).

(h) *Modular elastomer programmer* (MEP) is a cylindrical pad, typically consisting of a polyurethane rubber, used as a consistent impact medium for the systems check procedure.

(i) *Preload ballast* is a "bean bag" filled with lead shot that is placed on the helmet to secure its position on the headform. The mass of the preload ballast is 5 kg (11 lb).

(j) Projection is any part of the helmet, internal or external, that extends beyond the faired surface.

(k) *Reference headform* is a headform used as a measuring device and contoured in the same configuration as one of the test headforms A, E, J, M, and 0 defined in draft IS0 DIS 6220-1983. The reference headform shall include surface markings corresponding to the basic, coronal, midsagittal, and reference planes (see Figures 1 and 2 of this part).

(1) *Reference plane* is a plane marked on the IS0 headforms at a specified distance above and parallel to the basic plane (see Figure 3 to this part).

(m) *Retention system* is the complete assembly that secures the helmet in a stable position on the wearer's head.

(n) *Shield* means optional equipment for helmets that is used in place of goggles to protect the eyes.

(o) *Spherical imwactor* is a 146 mm (5.75 in) diameter aluminum sphere that is specifically machined for mounting onto the ball-arm connector of the drop-test assembly. The impactor is used to check the electronic equipment (see § 1203.17).

(p) *Test headform is* a solid model in the shape of a human head of sizes A, E, J, M, and 0 as defined in draft ISO/DIS 6220-1983. Headforms used for the impact attenuation test shall be constructed of K-1A magnesium alloy ~~or functionally equivalent metal~~. The test headforms shall include surface markings corresponding to the basic, coronal, midsagittal, and reference planes (see Figure 2 of this part).

(q) *Test region* is the area of the helmet, on and above a specified test line, that is subject to impact testing.

~~(r) *Visor (peak)* is optional helmet equipment for protection against sun or glare, and is sometimes used as a rock . . dirt deflector.~~

Discussion

The staff recommends deletion of the term "visor" since it is not referenced anywhere in the standard.

Comment:(b) bicycle helmet - Bell Sports [12] suggested that the phrase "or has a reasonably foreseeable use as a device intended to provide protection from head injuries while riding a bicycle" is too broad a definition. Bell maintains there are many helmets that have a foreseeable use by bike *riders that should not have to be certified to a bike helmet standard (e.g., baseball and roller hockey helmets).*

Response: HF responds at Tab G. The respondent suggested that "football helmets, baseball battinghelmets, and motorcycle helmets" will also be "easily foreseeable" uses as bicycle helmets; Human Factors staff disagrees. The design of these helmets and the activities for which they are intended (except motorcycle riding) are not similar to and are not typically associated with bicycle riding. Therefore, the helmets for these activities are not likely to be used as bicycle helmets. As for motorcycle helmets, the size and construction of these helmets will likely deter bicyclists from using them while bike riding, In fact, one of the most frequently reported reasons stated for not wearing a bicycle helmet is because they are too hot; another is that they are too bulky. Current bicycle helmets are smaller and lighter than motorcycle helmets, so it is unlikely consumers will use the larger motorcycle helmet for bicycle riding.

Human Factors judges that the examples given by the respondent would not likely be considered 'reasonably foreseeable use..." as stated in the proposed definition of bicycle helmet. However, in order to provide more guidance through the definition, Human Factors recommends the definition read: Bicycle helmet means any headgear that either is specifically marketed as, or implied through marketing and/or promotional information to be, a device intended to provide protection from head injuries while riding a bicycle.

The staff also recommends that the following language appear as a footnote to the bicycle helmet definition in order to add further clarification: "Helmets specifically marketed for exclusive use in a designated activity, such as skateboarding, rollerblading, baseball, roller hockey, etc., would be excluded from this definition because the specific focus of their marketing makes it unlikely that such helmets would be purchased for other than their stated use. However, a multi-purpose helmet---one marketed or represented as providing protection either during general use or in a variety of specific activities other than bicycling-would fall within the definition of bicycle helmet if a reasonable consumer could conclude, based on the helmet's marketing or representations, that bicycling is among the activities in which the helmet is intended to be used. In making this determination, the Commission will consider the types of specific activities, if any, for which the helmet is marketed, the similarity of the appearance, design, and construction of the helmet to other helmets marketed or recognized as bicycle helmets, and the presence, prominence, and clarity of any warnings, on the helmet or its packaging or promotional materials, against the use of the helmet as a bicycle helmet. A multi-purpose helmet marketed without specific reference to the activities in which the helmet is to be used will be presumed to be a bicycle helmet. The presence of warnings or disclaimers

advising against the use of a multi-purpose helmet during bicycling is a relevant, but not necessarily controlling, factor in the determination of whether a multi-purpose helmet is a bicycle helmet.

Comment: (c) comfort padding - Southwest Research Institute (SRI) [2] commented that fit padding may have some influence on impact characteristics.

Response: ESME agrees with this respondent and recommends deleting the sentence stating that: fit padding has no influence on impact characteristics.

Comment: (o) spherical impactor - SRI [2] suggested that it is more important to specify a 5-kg combined drop mass for the spherical impactor and the drop assembly than to specify a 4-kg mass for the impactor itself.

Response: ESME recommends that the definition for spherical impactor be revised as shown above. The more precise specifications for a spherical impactor for use as a system check device are located in § 1203.17 under the systems check procedure.

§ *1203.5.* Construction **Requirements - Projections**

Any unfaired projection extending more than 7 mm (0.28 in.) from the helmet's outer surface shall break away or collapse when impacted with forces equivalent to those produced by the applicable impact-attenuation tests in § 1203.17 of this standard. ~~Rigid projections on the inner surface shall not exceed 2mm (0.08in) and shall not make contact with the test headform after testing in accordance with § 1203.17.~~ There shall be no fixture on the helmet's inner surface projectins more than 2 mm (0.08 in.) into the helmet interior.

Discussion:
Comment: SRI [2] remarked that the proposed standard does not state how to determine if an internal projection makes contact with the headform during testing.

Comment : The National Safe Kids Campaign (NSKC) [22] submitted two recommendations regarding projections on the helmet. First, they urged that the Commission prohibit any external projections on helmets intended for children. The NSKC believes that external projections, such as visors, are unnecessary components of helmets intended for children. Second, they suggested that instead of requiring inner surface projections to not exceed 2 mm, the inside of the helmet should contain no sharp edges or rigid internal projections.

Response: ESME recommends that the section on internal projections be revised as shown above. The purpose of this section is to prohibit potentially hazardous projections but make some allowance for common helmet construction practices. The language above is consistent with Snell helmet standards and staff is not aware of problems associated with hazardous projections on helmets meeting existing standards.

Response: In response to prohibiting external projections on children's helmets, the proposed language is consistent with existing voluntary standards. In addition, Section 1203.7 of the

standard requires that helmets must pass all tests, both with and without any attachments that may be offered by the manufacturer. It is ES opinion that this provision, combined with the requirement that external projectionsmustbreak away *or collapse, will address the potential hazard of external projections on helmets intended for riders of all ages. ES recommends no changes in response to this comment.*

Comment: NSKC [22] also urged the Commission to include safety requirements for fittingpads in the final standard. The respondent asserted that since fitting pads are often necessary to ensure a secure fit, the standard should address the integrity of the materials *used to construct them, as well as their thickness, durability, and adhesiveness.*

Response: The interim mandatory standards have no provisions that address fittingpads as suggested by the respondent. CPSC staff has no information to lead us to believe that long-term integrity of fitting pads is a problem with helmet's meeting existing standards. It is ES opinion that introducing new requirements for fitting pads is not essential at this time and recommends no change to the proposed standard in response to this comment.

Comment: NSKC recommends that the potential influence fitting pads may have on the helmet's ability to comply with the retention system requirements should be examined.

Response: When testing for positional stability, the standard instructs to position and fit the helmet on the test headform according to the manufacturer's instructions. This procedure may involve changing the size and position of the fit pads in order to achieve a secure fit in the estimation of test personnel. While fitting a helmet to a metal headform will not account for all of the human elements involved when a person fits a helmet to their own head, it is ES opinion that the current procedure is the most practical approach at this time and should help keep the helmet secure during an accident. ES recommends no change to the CPSC standard in response to this comment.

§ 1203.6 Labeling and instructions.

(a) *Labeling.* Each helmet shall be marked with durable labeling so that the following information is legible and easily visible to the user-a& ~~is likely to remain on the helmet and legible throughout the intended design life of the helmet:~~

(1) Model designation.

(2) A warning to the user that no helmet can protect against all possible impacts and that serious injury or death could occur.

(3) A warning on both the helmet and the packaging that for maximum protection the helmet must be fitted and attached properly to the wearer's head in accordance with the manufacturer's fitting instructions.

(4) A warning to the user that the helmet may, after receiving an impact, be damaged to the point that it is no longer adequate to protect the head against further impacts, and that this damage may not be visible to the user. This label shall also state that a helmet that has sustained an impact should be returned to the manufacturer for inspection, or be destroyed and replaced.

~~(5) A warning to the user that the helmet can be damaged by contact with common substances (for example, certain solvents, cleaners, etc.) , and~~

~~that this damage may not be visible to the user. This label shall also state any recommended cleaning agents and procedures, list any known common substances that damage the helmet, and warn against contacting the helmet with these substances.~~

(5) A warning to the user that the helmet can be damased bv contact with common substances (for example, certain solvents [ammonia], cleaners [bleach], etc.), and that this damage mav not be visible to the user. This label shall state in generic terms some recommended cleaning agents and procedures (for example, wipe with mild soap and water). list the most common substances that damage the helmet, warn against contacting the helmet with these substances, and refer users to the instruction manual for more specific care and cleaning information.

~~(6) The statement "Not For Motor Vehicle Use".~~

(6) *Signal* word. The helmet labels required bv paragraphs (2)-(5) shall include the signal word "WARNING" at the beginning of each statement, unless two or more of the statements appear altogether on the same label, in which case the signal word need only appear once, at the beginning. The signal word "WARNING" shall be in all capital letters, bold print, and a type size equal to or greater than the other text on the label.

(b) *Instructions.* Each helmet shall have fitting and positioning instructions, including a graphic representation of proper positioning.

Discussion

Comment: SRI [2] remarked that requiring labels to likely remain legible throughout the life of the helmet is not a requirement that can be tested and could lead to differences between labs. The PHMA [29] also expressed concern with this requirement, stating that it was unaware of any technology which will ensure that a sticker will stand up under five years of the type of exposure that a helmet receives.

Response: ES staff shares these *commenter's concerns. Current voluntary bicycle helmet standards require "durable" labeling or labeling that is "likely to remain legible for the life of the helmet." These conditions have not been quantified in current standards. ESME is not aware of any existing performance test methods that can be applied in this circumstance. Since a requirement for legibility for* the *life of the helmet is vague and possibly unattainable, ES staff recommends a change to require 'durable" labels.*

Comment: Labeling of cleaningproducts: Several respondents [2, 11, 12, 29] expressed concern that too much information about cleaning products would be needed on the label and argued that consumers should be directed to the instructions manual for the list of cleaning materials.

Response: ESHF responds (Tab G) that this label is not intended to list everypossible cleaning agent that should or should not be used on the helmet. Since the consumer may not always have the owner's manual, a label on the helmet should provide some general cleaning instructions and warnings. ESHF suggests the wording shown above for the label on cleaning instructions.

Comment: "Not for Motor 'Vehicle Use" vs "For Bicycle Use" helmet labels (Respondents 11, 13, 22, 26). Two respondents stated that "Not for Motor Vehicle Use" suggested the helmet was appropriate for other activities which may not be appropriate. Another respondent felt that "Not for Motor Vehicle Use" allows the helmet to be used for other activities similar to bicycle riding, where no alternative

helmet exists. A third respondent argued that "For Bicycle Use Only" was a positive statement to which users are more likely to respond.

Response: ESHF responds (Tab G) that neither the "Not for Motor Vehicle Use" label nor a "For Bicycle Use Only" label adequately conveys the "use" circumstances under which helmets that meet the CPSC standard are appropriate. HF concludes that it is reasonable to assume that helmets that are certified to the CPSC standard will also provide head protection for roller/in-line skaters and perhaps some other recreational activities. In-line skaters should not be discouraged from wearing a helmet by a label that states "For Bicycle Use Only." ESHF also believes that consumers understand the differences between bicycle helmets and motorcycle/motorsport helmets and that bicycle helmets would not provide adequate protection formotorsport activities. Therefore, the "Not for Motor Vehicle use" label is not a critical safety message that should be mandated in the CPSC standard. ESHF recommends that the CPSC standardnotrequire a "use" label, but maintain the requirement for a certification label that informs the consumer that the helmet is certified to the CPSC standard for helmets for bicycle use.

Comment: Two respondents [22, 23] urged the Commission to require "an appropriate symbol to appear adjacent to the statement of compliance on the label" and to add wording to warn that "failure to follow the warnings may result in serious injury or death."

Response: In Tab G, ESHF writes that the ANSI labeling format would be burdensome for labels on bicycle helmets. The limited size of the inside of a helmet and the amount of information proposed for placement on the labels restricts the use of the full ANSI labeling recommendations. ESHF does suggest that the signal word "WARNING" should be used and is more appropriate than just a symbol. ESHF recommends the changes shown in double underline above.

Comment: The NSKC [22] recommended that helmets designed and intended for children be accompanied by fitting instructions which are crafted in age-specific language. The ASSE [11] and the NSKC suggested that *"proper fit" information should be on both the helmet and the outside of the box.*

Response: ESHF (Tab G) judges an age-specific instruction sheet unnecessary. The proposed standard requires graphics, along with written fitting directions. The graphics are better able to reach more children than age-specific instructions because they allow children of all ages to compare the way their helmet looks with the pictures. In addition, graphics are able to convey the critical information to non-English reading individuals and illiterates. Children and adults are likely to be better able to understand and appreciate the pictures. This is more likely to effectively deliver the message, allowing both parents and children to become aware of the proper fit.

A label on the box promoting the need for "proper fit" could inform parents, before they buy the helmet, that they need to properly fit the helmet to the child. Staff does not believe it is necessary to have the actual fitting instructions on the box, because staff is not aware of any information which indicates that such a label would be effective in assuring proper fit. However, it is important that consumers be aware that helmets do come in different sizes and that

proper fit is important. Therefore, HF recommends that section 1203.6(a)(3) also apply to *the helmet packaging.*

Comment: A few respondents made remarks about the warning to replace a helmet after impact [22, 23, 26]. Some respondents agreed with the staff's position that the label on the helmet should advise consumers to return the helmet to the manufacturer or destroy it if it is involved in an impact. Others disagreed and requested more guidance on whether the helmet is impaired before a consumer has to go through the hassle of returning the helmet.

Response: ESHF responds at Tab G. The variety of factors (impact surface, impact location on helmet, impact speed, etc.) that are involved in an impact to a helmet, and the level of interaction of each factor, are so complex, it is inappropriate to address them in a label. It is to the consumer% overall safety benefit to return the helmet to the manufacturer or destroy and replace it. Human Factors recommends leaving the replacement warning as currently proposed.

§ 1203.7 Samples for testing.

(a) *General.* Helmets shall be tested in the condition in which they are offered for sale. To meet the standard, they must be able to pass all tests, both with and without any attachments that may be offered by the helmet's manufacturer, and **with all** possible combinations of such attachments.

~~(b) *Number of samples.* Five samples of each size for each model and combination of attachments offered for sale are required to test conformance to this standard. If a helmet fits more than one size of test headform, two additional samples are needed for each additional headform size for the testing described in § 1203.10 -- Selecting the test headform.~~

(b) *Number of samwles.* Eight samples of each helmet size for each model offered for sale are required to test conformance to this standard.

Comment: Four respondents commented on the number of helmets required **for** *testing when the helmet includes attachments, (e.g., removable visor, face shield) and possible combinations of attachments [5, 12, 29, and 301. They expressed concern that the standard requires an excessive/prohibitive number of helmet tests on production samples, as written. One respondent [12] offered suggested wording to amend Section 1203.7 (b) to include the statement that "Helmets can be tested with any combination of accessories."*

Response: Section 1203.7(a) of the proposed standard requires that helmets shall be tested in the condition in which they are offered **for** *sale. They must be able to pass all tests, both with and without any attachments that may be offered by the helmet's manufacturer, and with* **all** *possible combinations of such attachments. Staff continues to recommend that the standard require that bicycle helmets pass all* **tests** *both with and without any attachments that may be included. However, staff concurs with respondents that it may be impractical and unnecessary to specify an additional set of eight test samples for each attachment, and each combination of attachments, that come with the helmet.*

To address this issue, staff recommends that *the phrase "and combination of attachments" be deleted from § 1203.7 (b). Staff also recommends that attachments be included as one of the parameters in § 1203.12(d)(1) that the Commission will consider when testing a "worst case" combination of test parameters for impact attenuation.*

Discussion

ES recommends additional revisions to increase the number of test samples from five to eight and to delete the requirement for additional test samples .if the helmet fits more than one size test headform. These revisions are to reflect changesmade to § 1203.10-Selecting the test headform and § 1203.13-Test Schedule.

§ 1203.8 Conditioning environments.

Helmets shall be conditioned to one of the following environments prior to testing in accordance with the test schedule at § *1203.13.* The barometric pressure in all conditioning environments shall be *75* to 110 kPa *(22.2* to *32.6* inches of Hg). All test helmets shall be stabilized within the ambient condition for at least 4 hours prior to further conditioning and testing. Storage or shipment within this ambient range satisfies this requirement.

(a) *Ambient condition.* The ambient condition of the test laboratory shall be within 17°C to 27°C (63°F to 81°F), and 20 to 80 percent relative humidity. The ambient test helmet does not need further conditioning.

(b) *Low temperature.* The helmet shall be kept at a temperature of ~~-16°C~~ -17°C to -13°C (~~3°F~~ 1°F to 9°F) for 4 to 24 hours prior to testing.

(c) *High temperature.* The helmet shall be kept at a temperature of 47°C to 53°C (117°F to 127°F) for 4 to 24 hours prior to testing.

(d) *Water immersion.* The helmet shall be fully immersed "crown" down in potable water at a temperature of 17°C to 27°C (63°F to 81°F) to a crown depth of 305 mm ± 25 mm (12 in. ± 1 in.) for 4 to 24 hours prior to testing.

Discussion

Comment: SRI [#2] commented that the allowable temperature range in the low-temperature environment should parallel the allowable temperature ranges in the other environments.

Response: LSE staff notes that the temperature range in the NPR contained a typographical error (Tab E). The range should have been (-17 to -13° C). This tolerance range is consistent with ANSI, ASTM, Snell 95 and CSA standards. The staff do not recommend expanding the low-temperature range beyond that of current standards.

Comment: Paula Romeo [26] suggested that the *water-immersion environment was unrealistic and recommended* a *spray conditioning environment.*

Response: LSE responded to similar comments in a previous memorandum (Sushinsky to Heh, August 3, 1995). Commission testing of both immersed and water-sprayed helmets under various time durations showed no consistent trend in resulting peak acceleration levels. The immersion environment has the advantages of being easier to define and of subjecting the helmet to a uniform conditioning exposure. Since testing showed that these commenters' concerns were unfounded, staff recommended and continues to recommend retaining the immersion method of wet-conditioning.

§ 1203.9 Test headforms.

~~The headforms used for testing shall be sizes A, E, J, M, and O as defined by DRAFT ISO/DIS 6220-1983. Headforms used for impact testing shall be constructed of K-1A magnesium alloy or other functionally equivalent metal and must have no resonant frequencies below 3000 hz.~~

The headforms used for testing shall be selected from sizes A, E, J, M, and 0 as defined by draft **ISO/DIS** 6220-1983, in accordance with § **1203.10**. Headforms used for impact testing shall be rigid and be constructed of low-resonance K-1A maanesium alloy.

Discussion
Comment: SRI [#2] suggested that a more appropriate value for the lower limit on resonant frequency should be 2000 hz instead of 3000 hz.

Response: The important conditions for the test headforms are the material specification and the dimensions defined by ISO/DIS 6220-1983. ESME recommends that this section be stated, "Headforms used for impact testing shall be rigid and be constructed of low resonance K-IA magnesium alloy." Test experience shows that headforms meeting this description will not exhibit resonant frequencies that will interfere with proper data collection. The specification for K-IA magnesium alloy will ensure against the use of materials that may inf.Zuence the test results.

§ 1203.10 Selecting the test headform.

~~A helmet shall be tested on the appropriate size(s) of headform(s) on which it fits. Fit means that it is not physically difficult to put the helmet on the headform, and that the helmet's comfort or fit padding is partially compressed. A complete set of five helmets of each size and model shall be tested on the smallest size test headform on which they fit. Two additional helmets shall be tested on each of the larger headforms the helmets fit. Testing on the larger headform(s) will include at least one peripheral vision test, dynamic retention test, positional stability test, and impact attenuation test (complete set of four impacts) using the conditioning environment that produced the highest g value in the impact attenuation tests on the smallest headform the helmet fit.~~

A helmet shall be tested on the smallest headforms appropriate for the helmet sample. headform size is for a helmet if all of the helmet's sizing pads are partially compressed when the helmet is equipped with its thickest sizing pads and positioned correctly on the reference headform. A complete set of eisht helmets of each size and model shall be tested.

Discussion
Comment: SRI[2], suggested that the order of tests in the last sentence of 1203.10 be arranged to parallel the test order specified in 1203.12 of the standard.

Response: This editorial suggestion is reflected above.

Comment: PHMA [29] suggested that *the proposed definition of fit is not adequate. The respondent recommended that this section specify*

the use of the largest headform that will accommodate the helmet, with comfort padding adjusted to optimize the fit.

Response: ES staff recommends that it is appropriate to simplify the test procedure by testing on only one size headform. This is consistent with the current interim mandatory standards. However, in contrast to the respondent, ES believes it more appropriate to test on the smallest headform that is appropriate for the test sample. ES believes that the smaller headform will represent the more stringent test condition for the positional stability test. *Testing on only one size headform will lessen the number of test samples needed to test compliance to the standard. ES recommends that the standard be revised with the language shown above.*

Comment: Bell Sports [12] remarked that in choosing the conditioning environment for testing on a second headform, the highest g-value does not necessarily provide the worst case. They recommended that there be four impacts in any conditioning environment chosen by test personnel.

Response: Testing the helmet on only one size headform eliminates the need to choose a environment for testing on a second size headform.

§ 1203.11 Marking the impact test line.

Prior to testing, the impact test line shall be determined for each helmet in the following manner.

(a) Position the helmet on the appropriate headform as specified by the manufacturer's helmet positioning index (HPI), with the brow parallel to the basic plane. Place a 5-kg (11-lb) preload ballast on top of the helmet to set the comfort or fit padding.

(b) Draw the impact test line on the outer surface of the helmet coinciding with the intersection of the surface of the helmet with the impact line planes defined from the reference headform as shown in:

(1) Figure 4 of this part for helmets intended only for persons 5 years of age and older.

(2) Figure 5 of this part for helmets intended for ~~children under 5 years of age.~~ persons age 1 and older.

(c) The center of the impact sites shall be selected at any point on the helmet on or above the impact test line.

Discussion

Comment: Snell [28] discussed the practical problems in certifying helmets when only a test line is specified. Snell recommended that the standard be amended to require coverage below the test line, particularly at the front and rear of a helmet.

Response: LSE responds (Tab E) that staff recommends a singular line that is the center of impact line. This recommendation is based primarily on the fact that coverage does not imply impact protection. The only area on the helmet required to pass impact protection requirements is the area above the test line. Therefore, staff does not recommend specifying additional coverage beyond the test line.

Comment: Extent of Coverage - The manufacturers of the PHMA [29] reported that they believed the proposed CPSC standard requires coverage at *the rear of the head lower than any other standard.*

They stated that they are not aware of any studies that indicate that lower coverage at the *rear is warranted. They also stated their concern that the helmet wearing public will not purchase helmets which* are *perceived to be more "clunky" or "bulbous" as helmets with extended coverage are likely be perceived. Mr. Becker of Snell [28] stated that the CPSC proposed coverages are more extensive than all current U.S. standards except for Snell's B-95 and N-94 helmet standards. He stated that unless the CPSC coverage is changed, many contemporary helmet models that have protected their wearers from life threatening injury will disappear from the market. Snell urged that the CPSC adopt the coverage described in the ASTM F1447-94 or the Snell B-90 standards. These coverages reflect the current state of the industry and should be expected of every bicycle helmet.*

Response: The proposed CPSC test line is not lower at the rear of the helmet than all other standards. The proposed CPSC test line is somewhat lower at the rear of the helmet than the test (impact) lines in the Snell B-90 andASTMF1447 standards. However, the CPSC line is higher at the rear of the helmet than the impact lines in the following interim mandatory standards: Snell B-95 and N-94, CAN/CSA-D113.2, and ANSI Z90.4-1984. Staff is aware of two studies that show that it is not uncommon for helmets involved in accidents to suffer impacts at the rear portion of the helmet. A Bell Sports study of 1100 helmets involved in accidents [4] found that 26 percent of the impacts were at the rear of the helmet and that the majority of these rear impacts occurred within 50 mm from the bottom edge of the helmet. Another study, by Technisearch of Australia', examined the effect of lowering the test line from the Snell B-90 standard to the test lines in the Snell B-95 and N-94 standards. The Technisearch study was based on examinations of 104 bicyclist helmets whose riders sustained impacts to the head during accidents. The study concluded that the B-90 standard test line would have provided coverage for 51% of the *impacts. The test line of the B-95 standard would provide coverage for 65% of the impacts. The increase from 51% to 65% was represented by 20 additional impact sites that would fall within the area of the B-95 coverage, including 8 impact sites at the rear portion of the helmet.*

One of the directions of the Children's Bicycle Helmet Safety Act was to *include provisions from existing appropriate standards for adoption in the final CPSC standard. ES staff considers the CPSC test line to be a reasonable requirement that falls within test lines of established North American bicycle helmet standards.*

§ 1203.12 Test requirements.

(a) *Peripheral vision.* ~~The helmet~~ All bicycle helmets shall allow unobstructed vision through a minimum of 105° to the left and right sides of the midsagittal plane when measured in accordance with § 1203.14 of this standard.

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[4] Dean Fisher and Terry Stern, "Helmets Work!," Bell Sports, Inc., AAAM/IRCOBI Conference, Lyon, France (September 1994)

'Martin Williams, "Test Line Requirements and Snell B-95 and N-94 Standards, " Technisearch Engineering & Scientific Services (August 1994)

(b) *Positional stability.* ~~The helmet shall not release from the test headform~~ No bicycle helmet shall come off of the test headform when tested in accordance with § 1203.15 of this standard.

(c) *Dynamic strength of retention system.* ~~The~~ All bicycle helmets shall have a retention system ~~shall~~ that will remain intact without elongating more than 30 mm (1.2 in.) when tested in accordance with § 1203.16 of this standard.

~~(d) *Impact attenuation criteria.*~~

~~(1) *For bicycle helmets intended for adults and children 5 years and older.* The peak acceleration of any impact shall not exceed 300 g when the helmet is tested in accordance with § 1203.17 of this standard.~~

~~(2) *For bicycle helmets intended for children under 5 years.* The peak acceleration of any impact shall not exceed 250 g when the helmet is tested in accordance with § 1203.17 of this standard.~~

(d) *Impact attenuation criteria.*

(1) *General.* A helmet fails the impact attenuation performance test of this standard if a failure under paragraph (d)(2) of this section can be induced under any combination of impact site, anvil type, anvil impact order, or conditioning environment permissible under the standard, either with attachments or without attachments, or combinations of attachments, that are provided with the helmet. Thus, the Commission will test for a "worst case" combination of test parameters. What constitutes a worst case may vary, depending on the Particular helmet involved.

(2) Peak acceleration. The peak acceleration of any impact shall not exceed 300 g when the helmet is tested in accordance with § 1203.17 of this standard.

Discussion

Test conditions such as impact site, anvil type, anvil impact order, and conditioning environment may influence impact attenuation test results. Helmet attachments also may influence test results. Staff recommends the addition of § 1203.12(d) (1) to clarify that the Commission will test for a "worst case" combination of test parameters. Further discussion is in Attachment 3 , to this memorandum.

Comment: SRI[2] suggested that requirements for visual clearance at the brow be considered and that this would be especially important for racers who ride in the crouch position.

Response: ES staff is wary of proposing a brow clearance requirement that in some cases may reduce the amount of head coverage in the brow area. Further, CPSC staff has no information to indicate that bicycle helmets meeting existing standards are posing a risk of injury due to inadequate "upward" visual clearance. Therefore, ES staff does not recommend adding a "brow" visual clearance requirement at this time.

Comment: Respondents 3, 4, 6, 9, 10, 12, 13, 15, 18, 19, 27, 28, 29, 30 did not agree with the 250-g failure criteria for helmets for children under five years of age. Most cited lack of available data to support the change. A few respondents [8, 16] supported the 250-g criteria, stating that they believed it would result in better head protection for young children.

Response: CPSC staff recommends that the impact attenuation criteria for helmets for children ages 1 to 5 years be 300-g, as first proposed in the August 1994 proposed standard. There is

insufficient evidence that reducing the allowablepeak-gyoungwould result in helmets that offer improved head protection for young children. See ES memorandum at Tab D for a detailed discussion of children's helmets issues.

§ 1203.13 Test schedule.

(a) Helmet sample 1 of the set of ~~five~~ eight helmets, as designated in Table 1203.13, shall be tested for peripheral vision in accordance with § 1203.14 of this standard.

(b) Helmet samples 1 through 4 8. as designated in Table 1203.13, shall be conditioned in the ambient, high temperature, low temperature, and water immersion environments, as follows: helmets 1 and 5 - ambient: helmets 2 and 7 - high temperature: helmets 3 and 6 - low temperature: and helmets 4 and 8 - water jmmersion. ~~respectively. Helmet 5 shall be conditioned in the ambient condition~~ .

(c) ~~Testing must begin within 2 2 from the conditioning environment. The helmet shall be returned to the conditioning environment within 3 minutes after it was removed for a minimum of 2 minutes before testing is resumed. the helmet is out of the conditioning environment for longer than 3 minutes, it shall be reconditioned for 5 minutes for each minute it is out of the conditioning environment beyond the allotted 3 minutes before testing is resumed.~~

(c) Testing must begin within 2 minutes after the helmet is removed from the conditioning environment. The helmet shall be returned to the conditioning environment within 3 minutes after it was removed, and shall remain in the conditioning environment for a minimum of 2 minutes before testing is resumed. If the helmet is out of the conditioning environment bevond 3 minutes, testing shall not resume until the helmet has been reconditioned for a period equal to at least 5 minutes for each minute the helmet was out of the conditioning environment bevond the first 3 minutes, or for 4 hours, (whichever reconditioning time is shorter) before testing is resumed.

~~(d) Helmets shall be tested for dynamic strength of the retention system prior to being tested for impact attenuation. Helmets 1 through 4 (conditioned in ambient, high temperature, low temperature, and water immersion environments) shall be tested in accordance with the dynamic retention system strength test at § 1203.16. Helmets 1 through 4 shall then be tested in accordance with the impact attenuation tests on the flat, hemispherical, and curbstone anvils in accordance with the procedure at § 1203.17. Helmet 5 (conditioned in an ambient environment) shall be tested in accordance with the positional stability tests at § 1203.15. Table 1203.13 summarizes the test schedule.~~

(d) Prior to being tested for imnact attenuation, helmets l-4 (conditioned in ambient, high temperature, low temperature. and water immersion environments) shall be tested in accordance with the dynamic retention system strength test at § 1203.16. Helmets l-4 shall then be tested in accordance with the impact attenuation tests on the flat and hemispherical anvils in accordance with the procedure at § 1203.17. Helmet 5 (ambient-conditioned) shall be-tested in accordance with the Positional stability tests at § 1203.15 prior to imnact testing. Helmets 5-8 shall then be tested in accordance with the imnact attenuation tests on the curbstone anvil in accordance with § 1203.17. Table 1203.13 summarizes the test schedule.

TABLE 1203.13 - TEST SCHEDULE

	§ 1203.14 Peripheral Vision	§ 1203.15 Positional Stability	§ 1203.16 Retention System Strength	§ 1203.17 Impact Tests	
				Anvil Type	No. of Impacts
Helmet 1 Ambient	X		X	X Flat X Hemi.	2 2
Helmet 2 High Temperature			X	X Flat X Hemi.	2 2
Helmet 3 Low Temperature			X	X Flat X Hemi.	2 2
Helmet 4 Water Immersion			X	X Flat X Hemi.	2 2
Helmet 5 Ambient		X		X Curb.	1
Helmet 6 Low Temperature				X Curb.	1
Helmet 7 High Temperature				X Curb.	1
Helmet 8 Water Immersion				X Curb.	1

Discussion

Comment: SRI [2] noted that, as written, there is potentially no upper limit to the exposure time to recondition a helmet once it is removed from the conditioning environment for more than three minutes.

Response: LSE (Tab E) agrees with the respondent and recommends the revised language shown above in 1203.13(c).

Comment: Six *respondents [5,* 12, *27, 29, 30, and 31] submitted comments requesting changes to Section 1203.13 (Test Schedule) regarding the use of the curbstone anvil. All of the respondents expressed concern over using two curbstone impacts on a single helmet. As proposed, section 1203.3(d) and Table 1203.13 do not define the conditions of* **the** *fourth impact on a helmet. The fourth impact, left to the discretion of test personnel, could be a second curbstone impact. There* **a.1** *so was concern about impacting the helmet with the curbstone anvil after the helmet was conditioned in a wet*

environment [12]. There also was concern about the curbstone footprint overlapping other impact sites and violating the "single impact" principle of testing [27 and 31]. The length of the curbstone anvil restricts the location of impact sites that can be used without overlap. The use of a second curbstone anvil, and the damage caused by curbstone impacts, can restrict the selection of test sites further to the point where only three impacts may be possible on a small helmet without overlap.

Response: The revised section 1203.13 and Table 1203.13 shown above is the ESME recommendation for a revised test schedule to incorporate a single curbstone impact on each of four "clean" helmet samples, one from each of the conditioning environments. ES and LSE staff agree that the previously proposed test schedule should be revised to prevent the possibility of striking a test helmet with more than one curbstone impact. ES staff agrees with the respondent's assertion that the potential for overlapping "footprints" of curbstone impacts combined with other impacts on a single test helmet goes beyond the intended principle of a single impact for a given area. Staff disagrees, however, with those respondents who recommended that only ambient-conditioned helmets be subjected to a curbstone impact. To ensure adequate protection against impact against curbstone-type shapes, tests for that anvil, as well as the other test anvils, should be carried out in all of the environmental conditions prescribed by the standard.

The LSE staff discovered during testing with the curbstone anvil that severe physical damage-namely splitting of the helmet from the impact point to the edge of the helmet-could occur even though the helmet did not exceed the 300 g criterion. This led to consideration of whether in such cases the curbstone anvil test should be repeated on another sample to help ensure that other helmets will not fail under this test. Staff recommends that the Commission indicate in the FR notice that, when marginal or unusual results occur in any of the standard's tests, retesting may *be appropriate, even though the 300-g criterion is not exceeded. Other conditions that may prompt the Commission to undertake verification testing include (but are not limited to) peak-g readings that are very close to the 300-g failure criterion. However, since the option of additional testing inherently exists, it is not necessary to include a provision requiring such retesting in the standard.*

§ 1203.14. Peripheral vision test.

Position the helmet on a reference headform in accordance with the HPI and place a 5-kg (11-lb) preload ballast on top of the helmet to set the comfort or fit padding. *(Note:* Peripheral vision clearance may be determined when the helmet is positioned :Eor marking the test lines.) Peripheral vision is measured horizontally from each side of the midsagittal plane around the point K (see Figure 6 of this part). Point K is located on the front surface of the reference headform at the intersection of the basic and midsagittal planes. The vision shall not be obstructed within 105 degrees from point K on each side of the midsagittal plane.

§ 1203.15 Positional stability test (roll-off resistance).

(a) *Test equipment.*

(1) Headforms. The test headforms shall comply with the dimensions of the full chin IS0 reference headforms sizes A, E, J, M, and 0.

(2) Test fixture. The headform shall be secured in a test fixture with the headform's vertical axis pointing downward and **45** degrees to the direction of gravity (see Figure 7 of this part). The test fixture shall permit rotation of the headform about its vertical axis and include means to lock the headform in the face up and face down positions.

(3) Dynamic impact apparatus. A dynamic impact apparatus shall be used to apply a shock load to a helmet secured to the test headform. The dynamic impact apparatus shall allow a 4-kg (8.8-lb) drop weight to slide in a guided free fall to impact a rigid stop anvil (see Figure 7 of this part). The entire mass of the dynamic impact assembly, including the drop weight, shall be no more than 5 kg (11 lb).

(4) *Strap or cable.* A hook and flexible strap or cable shall be used to connect the dynamic impact apparatus to the helmet. The strap or cable shall be of a material having an elongation of no more than 5 mm (0.20 in.) per 300 mm **(11.8** in.) when loaded with a 22-kg (48.5 lb) weight in a free hanging position.

(b) *Test procedure.*

(I) Orient the headform so that its face is down, and lock it in that orientation.

(2) Place the helmet on the appropriate size full chin headform in accordance with the HPI and fasten the retention system in accordance with the manufacturer's instructions. Adjust the straps to remove any slack.

(3) Suspend the dynamic impact system from the helmet by positioning the flexible strap over the helmet along the midsagittal plane and attaching the hook over the edge of the helmet as shown in Figure 7 of this part.

(4) Raise the drop weight to a height of 0.6 m (2 ft) from the stop anvil and release it, so that it impacts the stop anvil.

(5) The test shall be repeated with the headform's face pointing upwards, so that the helmet is pulled from front to rear.

Discussion

Comment: SRI [2] remarked that the ASTM Headgear Subcommittee is considering a 7-kg preload to set the helmet during testing. SRI **also** *asked whether a thin rubber pad should be specified to soften high frequency impact noise.*

Response: Testing to support the development of the positional stability test was **with** *equipment specified as proposed in the CPSC standard. Subsequent to initial ASTM discussions about possible revisions to the proposed test procedure, the ASTM F8 Headgear Subcommittee decided not to modify the pre-load and not to specify a rubber impact pad. ES therefore recommends no change to this section.*

§ 1203.16 Dynamic strength of retention system test.

(a) Test *equipment.*

(1) IS0 headforms without the lower chin portion shall be used.

(2) The retention system strength test equipment shall consist of a dynamic impact apparatus that allows a 4-kg (8.8-lb) drop weight to slide in a guided free fall to impact a rigid stop anvil (see Figure 8 of this part). Two cylindrical rollers that spin freely, with a diameter of 12.5 ± 0.5 mm **(0.49** in. ± 0.02 in.) and a center-to-center distance of 76.0 ± 1 mm (3.0 ± **0.04** in.), shall make up a stirrup that represents the bone structure of the lower jaw. The entire dynamic test apparatus hangs freely on the retention system. The entire mass of the support assembly, including the 4-kg (8.8-lb) drop weight, shall be 11 kg ± 0.5 kg (24.2 lb ± 1.1 lb).

(b) *Test procedure.*

(1) Place the helmet on the appropriate size headform on the test device according to the HPI. Fasten the strap of the retention system under the stirrup.

(2) Mark the pre-test position of the retention system, with the entire dynamic test apparatus hanging freely on the retention system.

(3) Raise the 4-kg (8.8-lb) drop weight to a height of 0.6 m (2 ft) from the stop anvil and release it, so that it impacts the stop anvil.

(4) Record the maximum elongation of the retention system during the impact. A marker system or a displacement transducer, as shown in Figure 8 of this part, are two methods of measuring the elongation.

Discussion

Comment: SRI [2] asked whether both the peak and residual displacements should be measured in order to better describe the dynamics of the system.

Response: It is ES opinion that only the peak deflection reading is needed to determine failure of the retention system. This is consistent with existing U.S. bicycle helmet standards. ES recommends no change to the proposed rule in response to this comment.

Comment: USC-HPRL [8] suggested that the retention system test (§1203.13(d)) be done after impact testing. He reasons that an accident can damage a helmet and severely compromise the retention system. The retention system must ensure that the helmet remain on the head during an accident sequence. The respondent also recommends *that the "zero" position for measuring elongation be established without pre-tensioning the straps with a 4-kg mass as called for in the standard*

Response: LSE (Tab E) staff *recommends that no changes be made to the sequence for retention system testing. The test sequence issue raised by the respondent was addressed during the prior comment period. Testing the retention system prior to impact testing is consistent with the ASTM and Snell standards. LSE staff has no evidence that the test sequence specified in the ASTM and Snell standards would allow helmets that do not have adequate retention systems. LSE staff also recommends that no changes be made to the procedure for establishing thepre-test "0" position (Tab E). There is no evidence that establishing the "0" position after pre-tensioning the retention system would allowhelmets that do not have adequate retention systems to pass the test.*

§ 1203.17 Impact attenuation test.

(a) *Impact test instruments and equipment.*

(1) *Measurement of impact attenuation.* Impact attenuation is determined by measuring the acceleration of the test headform during impact. Acceleration is measured with a uniaxial accelerometer that is capable of withstanding a shock of a least 1000 g. The helmet is secured onto the headform and dropped in a guided free fall, using a monorail or guide-wire test apparatus (see Figure 9 of this part), onto an anvil fixed to a rigid base, The center of the anvil shall be fixed in alisnment with the center vertical axis of the accelerometer. The base shall consist of a solid mass of at least 135 kg (298 lb), the upper surface of which shall consist of a steel plate at least 12 mm (0.47 in.) thick and having a surface area of at least 0.10 m^2 (1.08 ft^2).

Discussion

Text was added above to specify the alignment of the accelerometer axis with the center of the anvil. This statement reinforces already standard operatingprocedure for bicycle helmet testing and is meant to prevent impacting helmets on "corners" of anvils.

Comments: Monorail vs. Guide Wire - Some helmet manufacturers [5, 29, 30] and the Snell Memorial Foundation [28] disagreed with the specification of the monorail type of impact test rig. Respondents stated that wire-guided rigs were more widely used in the industry. Some respondents claimed that since there is no evidence that directly correlates monorail with guidewire rig results, many firms would be forced to buy monorail rigs to address liability concerns. Trek [5] stated that the burden of this expense may provide need for additional analysis of the financial impact to small business, as required by the Regulatory Flexibility Act. Snell wrote that guidewire rigs have proven reliable, efficient, and highly repeatable. They are less expensive to install than monorail devices and they are easier to maintain. Snell stated that there is no demonstrated improvement associated with the monorail rig in testingreliabilityand capability. Most respondents suggested that the Commission specify that either monorail or guidewire rigs may be used to test for impact attenuation"

Response: To respond to this issue, CPSC-ES initiated an interlaboratory compariso12 testprogram. Thepurpose of theprogram was to determine if there are statistically significant mean differences in test results when using monorail and twin-wire test rigs. Tab F presents the statistical analysis of this study. Attachment 3 to this ES memorandum is the ES discussion to support a recommendation to specify that either a monorail or a guide-wire type of test rig be used to test for impact attenuation.

(2) Accelerometer. A uniaxial accelerometer shall be mounted at the center of gravity of the test headform, with the sensitive axis aligned within 5 degrees of vertical when the test headform is in the impact position. The acceleration data channel and filtering shall comply with SAE Recommended Practice J211 OCT88, Instrumentation for Impact Tests, Requirements for Channel Class 1000.

(3) Headform and drop assembly-centers of gravity. The center of gravity of the test headform shall be located at the center of the mounting ball on the support assembly and within an inverted cone having its axis vertical, and forming a 10 degree included angle with the vertex at the point of impact. The location of the center of gravity of the drop assembly (combined test headform and support assembly) must meet FMVSS 218 S7.1.8. The center of gravity of the drop assembly shall lie within the rectangular volume bounded by x = -6.4 mm (-0.25 in.), x = 21.6 mm (0.85 in), y = 6.4 mm (0.25 in.), and y = -6.4 mm (-0.25 in), with the origin located at the center of gravity of the test headform. The oriain of the coordinate axes is at the center of the mounting ball on the supportassembly. The rectangular volume has no boundary along the z-axis. The positive z-axis is downward. **The** x-v-z axes are mutually perpendicular and have positive or negative desisnations as shown in Figure **10** of this part. Fisure **10** shows an overhead view of the x-y boundary of the drop assembly center of gravity.

~~The x-y-z axes are mutually perpendicular and have positive or negative designations as follows. The origin of the coordinate axes is at the center of the mounting ball on the support assembly. The x-y-z axes of the test headform assembly on monorail impact test equipment are oriented as follows:~~

~~From the origin, the x-axis is horizontal, with its positive direction going toward and passing through the vertical centerline of the monorail. The positive z-axis is downward. The y-axis also is horizontal, and its direction is decided by the z- and x-axes, using the right hand rule. See Figure 10 of this part for an overhead view of the x-y boundary of the location of the center of gravity.~~

~~(4) *Drop assembly.* The center of gravity of the headform shall be at the center of the mounting ball.~~

~~(i) *Mass of the drop assembly for testing helmets for adults and children 5 years of age and older.* The combined mass of the instrumented test headform and support assembly (excluding the test helmet) for the impact test shall be 5.0 ± 0.1 kg (11.00 ± 0.22 lb).~~

~~(ii) *Mass of the drop assembly for testing helmets for children under 5 years.* The combined mass of the instrumented test headform (ISO A or ISO E) and support assembly (excluding the test helmet) for the impact test shall be 3.9 ± 0.1 kg (8.60 ± 0.22 lb).~~

(4) *Drop assembly.* The combined mass of the drop assembly, which consists of the instrumented test headform and support assembly (excluding the test helmet), shall be 5.0 + 0.1 kg (11.00 + 0.22 lb).

(5) Impact anvils. Impact tests shall be performed against the three different solid *(i.e.,* without internal cavities) steel anvils described below-

(i) Flat *Anvil.* The flat anvil shall have a flat surface with an impact face having a minimum diameter of 125 mm (4.92 in.). It shall be at least 24 mm (0.94 in.) thick (see Figure 11 of this part).

(ii) *Hemispherical anvil..* The hemispherical anvil shall have a hemispherical impact surface with a radius of 48 ± 1 mm (1.89 ± 0.04 in.) (see Figure 12 of this part).

(iii) *Curbstone anvil.* The curbstone anvil shall have two flat faces making an angle of 105 degrees and meeting along a striking edge having a radius of 15 mm ± 0.5 mm (0.59 ± 0.02 in.). The height of the curbstone anvil shall not be less than 50 mm (1.97 in.), and the length shall not be less than 200 mm (7.87 in.) (see Figure 13 of this part).

(b) *Test Procedure.*

(1) ~~*Instrument system check.* The impact attenuation test instrumentation shall be checked before and after each series of tests (at least at the beginning and end of each test day) by dropping an impactor with a spherical impact surface onto an elastomeric test medium (MEP). The impactor shall be dropped onto the MEP at a specified impact velocity (± 2 % of a central value) that is representative of helmet testing drop heights. Before conducting a series of drops, the center vertical axis of the accelerometer (see § 1203.17(a)(2)) shall be aligned with the geometric center of the MEP pad. Six impacts, at intervals of 75 ± 15 seconds, shall be performed at the beginning and end of the day. The first three impacts at the beginning and end of the day shall be considered warm-up drops and shall be discarded from the series. The test parameters selected at each laboratory shall produce impact accelerations shown to be repeatable within ± 2% of a central value.~~

(1) *Instrument system check (precision and accuracy).* The impact-attenuation test instrumentation shall be checked before and after each series of tests (at least at the beainnins and end of each test day) by dropping a spherical impactor onto an elastomeric test medium (MEP). The spherical impactor shall be a 146 mm (5.75 in) diameter aluminum sphere that is mounted on the ball-arm connector of the support assembly. The total mass of the spherical impactor and support assembly shall be 5.0 + 0.1 kg

(11.0 + *0.22* lb). The MEP shall be *152* mm (6 inches) in diameter and 25 mm (1 inch) thick, and shall have a durometer of 60 + 2 Shore A. The MEP shall be affixed to the top surface of a flat 6.35 mm (¼ inch) thick aluminum plate. The geometric center of the MEP shall be aligned with the center vertical axis of the accelerometer (see § 1203.17(a) (2)). The impactor shall be dropped onto the MEP at an impact velocity of 5.44 m/s + 2%. (Typically, this requires a minimum drop height of 1.50 meters (4.9 ft) plus a height adjustment to account for friction losses.) Six impacts, at intervals of 75 + 15 seconds, shall be performed at the beginning and end of the test series (at a minimum at the beginning and end of each test day). The first three of six impacts shall be considered warm-up drops, and their impact values shall be discarded from the series. The second three impacts shall be recorded. All recorded impacts shall fall within the range of 380-g to 425-g. In addition, the difference between the high and low values of the three recorded impacts shall not be greater than 20-g.

Discussion

Shown above is a revised system check procedure that includes both precision and accuracy criteria. Further discussion regarding the system check and specification for the impact test rig is provided in Attachment 3 to this ES memorandum.

Comment: Some respondents to the proposed rule favored a reduced-mass test headform for testing helmets for children ages 1 to 5. Other respondents believed the headform mass for young children's helmets should be 5 kg like most current voluntary standards.

Response: Due to insufficient evidence that a reduced-mass test headform will result in helmets that betterprotect young children, staff recommends that all helmets, including helmets for children under 5 years, be tested with a 5-kg headform assembly. The ES memorandum at Tab D has a more detailed discussion of children's helmets issues.

~~(2) *Impact sites*. Each of helmets 1 through 4 (one helmet for each conditioning environment) shall impact at four different sites, one impact on the flat anvil, one impact on the hemispherical anvil, one impact on the curbstone anvil, and one impact on an anvil chosen at the discretion of the test personnel. The center of any impact may be on or anywhere above the test line, provided it is at least 120 mm (4.72 in), measured on the surface of the helmet, from any prior impact center. Rivets and other mechanical fasteners, vents, and any other helmet feature within the test region are valid test sites.~~

(2) *Impact* sites. Eachgf helmets 1 throush 4 (one helmet for each conditioning environment) shall impact at four different sites. with two impacts on the flat anvil and two imnacts on the hemispherical anvil. The center of any impact mav be on or anvwhere above the test line. provided it is at least 120 mm (4.72 in), measured on the surface of the helmet, from anv prior impact center. Each of helmets 5 through 8 (one helmet for each conditioning environment) shall impact at one site on the curbstone. anvil. The center of the curbstone impacts may be on or anvwhere above the test line. The curbstone anvil may be placed in anv orientation as long as the center of the anvil is aligned with the axis of the accelerometer. As noted in § 1203.12 (d) (1), impact sites, the order of anvil use (flat and hemispherical) and curbstone anvil sites and orientation shall be chosen by the test personnel to provide the most severe test for the helmet. Rivets

and other mechanical fasteners, vents, and any other helmet feature within the test region are valid test sites.

Discussion

Two respondents [27 and 29] recommended a minimum distance between impacts of 150 mm or about 6 inches. One of these *respondents stated that the CPSC lowered the minimum distance from those in voluntary standards.*

Response: LSE (Tab E) and ESME staff selected 120-mm impact spacing based on recently balloted ASTM headgear standards. The Snell B-95 standard specifies a minimum impact separation of 120 mm. This distance is consistent with the Snell B-90 specification of 1/6th the maximum helmet circumference if calculated for smaller helmets. A minimum impact spacing of 150 mm limits flexibility in choosing impact sites, especially on smaller helmets. Staff recommends no change to the proposed rule in response to this comment.

(3) Impact velocity. The helmet shall be dropped onto the flat anvil ~~from a theoretical drop height of 2 meters (6.56 ft) to achieve~~ with an impact velocity of 6.2 m/s ± 3% (20.34 ft/s ± 3%). (Typically, this requires a minimum drop height of 2 meters (6.56 ft) plus a height adjustment to account for friction losses.) The helmet shall be dropped onto the hemispherical and curbstone anvils ~~from a theoretical drop height of 1.2 meters (3.94 ft) to achieve~~ with an impact velocity of 4.8 m/s ± 3% (15.75 ft/s ± 3%). (Typically, this requires a minimum drop height of 1.2 meters (3.94 ft) plus a height adjustment to account for friction losses.) The impact velocity shall be measured during the last 40 mm (1.57 in) of free-fall for each test.

Discussion

Comment: USC's Head Protection Research Lab (USC-HPRL)[8] suggested that the tolerance for the impact velocity be changed from +/- 3% to -0% to +5% to ensure that impact testing is done at no less than the specified velocity.

Response: LSE responds (Tab E) that the difference between a tolerance of ± 3% and -0%, +5% has little practical significance. LSE staff has no concerns with permitting an impact velocity of up to 3 percent lower than the target velocity. Since the commenter's suggestion wouldnotproduce a significant safetybenefit, the staff recommends no change to the proposed rule.

(4) Helmet position. Prior to each test, the helmet shall be positioned on the test headform in accordance with the HPI. The helmet shall be secured so that it does not shift position prior to impact. The helmet retention system shall be secured in a manner that does not interfere with free-fall or impact.

(5) Data. Record the maximum acceleration in g's during impact. See Subpart C, § 1203.41(b).

§ 1203.18 Reflectivity.

Comment : *Several respondents [1,7,11,13,16,17,22,23,24,26] urged that the Commission not postpone implementing bicycle helmet reflectivity requirements.*

Response: ESHF responds at Tab G that the Commission conducted field testing on bicycle reflectors and examined the issue of reflectivity

on bicycle helmets. In the field testing, half (24/48) of the subjects saw bicycle riders with reflective helmets and the other half saw non-reflective helmets. The reflective tape used on the helmets met a proposed Standard on use of Retroreflective Materials on Bicycle Helmets that was balloted by the ASTM Headgear Subcommittee. Study results failed to show that the particular helmet reflective strip used in the study would increase the distance at which a bicycle can be detected or recognized (Schroeder, 1997)(Tab I). For that reason, Human Factors still believes more research is needed to determine appropriate minimum retroreflective requirements for bicycle helmets. The staff lacks the data at this time to support a requirement for bicycle helmet reflective performance..

Subpart B-Certification

~~**§ 1203.30 Purpose and scope.**~~

~~(a) *Purpose.* Section 14(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2063(a), requires every manufacturer (including importers) and private labeler of a product which is subject to a consumer product safety standard to issue a certificate that the product conforms to the applicable standard. Section 14(a) further requires that the certificate be based either on a test of each product or on a "reasonable testing program." The purpose of this subpart is to establish requirements that manufacturers and importers of bicycle helmets subject to the Safety Standard for Bicycle Helmets (Subpart A of this Part 1203) shall issue certificates of compliance in the form specified.~~

~~(b) *Scope.* The provisions of this subpart apply to all bicycle helmets that are subject to the requirements of the Safety Standard for Bicycle Helmets.~~

§ 1203.30 Purpose, basis, and scope.

(a) *Purpose.* The purpose of this subpart is to establish reauirements that manufacturers and importers of bicvcle helmets subiect to the Safetv Standard for Bicycle Helmets (Subpart A of this Part 1203) shall issue certificates of compliance in the form specified.

(b) *Basis.* Section 14(a)(1) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2063(a) (1). requires every manufacturer (including importers) and private labeler of a product which is subiect to a consumer product safety standard to issue a certificate that the product conforms to the applicable standard. Section 14(a) (1) further reauires that the certificate be based either on a test of each product or on a "reasonable testing program." The Commission may, bv rule, designate one or more of the manufacturers and private labelers as the persons who shall issue the required certification certificate. 15 U S.C.2063(a) (2)

(c) *Scope.* The provisions of this subpart apply to all bicvcle helmets that are subject to the reauirements of the Safetv Standard for Bicycle Helmets, Subpart A of the Part 1203.

§ 1203.31 Effective date.

All bicycle helmets manufactured on or after [insert date that is 1 year plus 1 day after publication) must meet the standard and must be certified as complying with the standard in accordance with this Subpart B.

§ 1203.32 Definitions.

The following definitions shall apply to this subpart:

(a) *Foreign manufacturer* 'means an entity that manufactured a bicycle helmet outside the United States, as defined in 15 U.S.C. 2052(a)(10) and (14).

(b) *Manufacturer* means the entity that either manufactured a helmet in the United States or imported a helmet manufactured outside the United States.

(c) Private labeler means an owner of a brand or trademark that is used on a bicycle helmet subject to the standard and that is not the brand or trademark of the manufacturer of the bicycle helmet, provided the owner of the brand or trademark caused, authorized, or approved its use.

(d) *Production lot* means a quantity of bicycle helmets from which certain bicycle helmets are selected for testing prior to certifying the lot. All bicycle helmets in a lot must be essentially identical in those design, construction, and material features that relate to the ability of a bicycle helmet to comply with the standard.

(e) Reasonable testing program means any tests which are identical or equivalent to, or more stringent than, the tests defined in the standard and which are performed on one or more bicycle helmets selected from the production lot to determine whether there is reasonable assurance that all of the bicycle helmets in that lot comply with the requirements of the standard.

§ 1203.33 Certification testing.

(a) *General.* Manufacturers, as defined in § 1203.32(b), shall conduct a reasonable testing program to demonstrate that their bicycle helmets comply with the requirements of the standard.

(b) *Reasonable testing program.* This paragraph provides guidance for establishing a reasonable testing program.

(1) Within the requirements set forth below, manufacturers and importers may define their own reasonable testing programs. Reasonable testing programs may, at the option of manufacturers and importers, be conducted by an independent third party qualified to perform such testing programs. However, manufacturers, as defined in § 1203.32(b), are responsible for ensuring compliance with all requirements of this standard.

(2) As part of the reasonable testing program, the bicycle helmets shall be divided into production lots, and sample bicycle helmets from each production lot shall be tested. Whenever there is a change in parts, suppliers of parts, or production methods, and the change could affect the ability of the bicycle helmet to comply with the requirements of the standard, the manufacturer shall establish a new production lot for testing.

(3) The Commission will test for compliance with the standard by using the standard's test procedures, However, a reasonable testing program need not be identical to the tests prescribed in the standard.

(4) If the reasonable testing program shows that a bicycle helmet may not comply with one or more requirements of the standard, no bicycle helmet in the production lot can be certified as complying until ~~all noncomplying bicycle helmets in the lot have been identified and destroyed or altered by repair, redesign, or use of a different material or components to the extent necessary to make them conform to the standard.~~ sufficient actions are taken that it is reasonably likely that no noncomplying helmets remain in the production lot. All identified noncomplying bicycle helmets in the lot must be destroyed or altered by repair, redesign, or use of a different material or component, to the extent necessary to make them conform to the standard.

(5) The sale or offering for sale of a bicycle helmet that does not comply with the standard is a prohibited act and a violation of § 19(a) of the CPSA (15 U.S.C. 2068(a)), regardless of whether the bicycle helmet has been validly certified.

Discussion

Comment: Trek USA [5] believed that the proposed language describing a reasonable testing program was restrictive because it implies that if a single helmet fails any aspect of the test procedure, all of the product in the lot cannot be certified until corrective action is taken. The respondent suggested to change the wording of 1203.33(b)(4) from " . . . a bicycle helmet..." to "any bicycle helmet" that fails to meet the testing criteria. The change would provide more flexibility as it would remove the possibility of an anomaly in the testing causing a rejection of an entire lot and the resulting lack of certification.

Response: The CRM staff recommends no change in the wording in Section 1203.33(b)(4) from "a bicycle helmet" to "any bicycle helmet ." (Tab J) First, it does not appear that the requested language would change the meaning of this requirement. Secondly, the testing requirement is flexible enough for each manufacturer/producer to ensure that their helmets meet the requirements of the standard.

It is unlikely that a production lot will be rejected based on a failure of one helmet which might be an anomaly or an "outlier" when a firm has in place reasonable testingprogram. The purpose of the testing program is to detect possible failures of bicycle helmets in a production lot and to ensure that the helmets certified comply with the standard. The failure of one helmet would trigger an investigation to determine whether the failure would extend to other helmets in the production lot. That investigation should continue until it is reasonably likely that no noncomplying helmets remain in the production lot. The staff recommends that the wording of Section 1203.33(b)(4) be changed to make this intent clear.

Comment: Jane McCormack [7] requested that the Commission ensure that bike helmets meet the Snell requirements and Norte Vista Medical Center [15] requested that helmets certified to the Snell B-95 or Snell N-94 standards be considered to be in compliance with the mandatory standard.

Response: The Office of Compliance (Tab J) responds that one of the objectives of the Children's Bicycle Helmet Safety Act of 1994 is to establish a unified bicycle helmet standard that is recognized nationally by all manufacturers and consumers. Staff believes it would defeat the intent of the Congressional act to add language to the regulation stating that certified conformance to any existing voluntary standard satisfies compliance with the mandatory rule.

Comment: The PHMA [29] wants clarification of when there are material or vendor changes. PHMA requests that the staff use the Safety Equipment Institute (SEI) guidance to help firms understand the terms material changes, design changes, and vendor changes.

Response: CRM staff does not think that establishing definitions as stated in the SEI "Definition of Term" would add any significant clarification to the industry as a whole (Tab J). Each firm has the responsibility to institute its own testingprogram, as long as the testing program is reasonable.

The intent of the regulation is to ensure that all firms establish a reasonable testing program and to provide flexibility for both large and small firms. Each firm has the flexibility to define

their own terms in its quality control program, including material changes, design changes, and vendor changes, as long as the testing program is effective and reasonably able to determine whether all bicycle helmets comply with the standard.

The Compliance staff recommends no revision to the proposed rule in response to this comment.

Comment: The Snell Memorial Foundation [28] and Paul H. Appel [25] propose the adoption of the pre-market clearance and the market surveillance provisions of the Snell standard to ensure that quality bicycle helmets are produced. According to the commenters, without these two Snell provisions, government efforts will be insufficient in keeping inadequate helmets off the market.

Response: CRM replies at Tab J that all firms must ensure that bicycle helmets sold in the United States are certified to the mandatory bicycle helmet standard, that the certificationsarebased on reasonable testing programs. Firms that distribute noncomplying products are subject to various Commission enforcement actions. These actions include recall, injunctions, seizure of the product, and civil and criminal penalties. The penalties for such violations could subject a firm to penalties of up to $1.5 million and after notice of noncompliance, fines of up to $50,000 or imprisonment of individuals for not more than one year, or both.

The Commission has statutory authority to conduct inspections of manufacturers, importers, distributors, and retailers of bicycle helmets. This authority includes the review and the copying of records relevant to determine compliance with the bicycle helmet standard. The Commission also has authority to collect samples of bicycle helmets for testing to the standard.

The Commission has a vigorous enforcement program that includes joint import surveillance with U.S. Customs and compliance surveillance of domestic producers, distributors, and retailers. In addition, the staff responds to all reports of noncompliance with all interim or final mandatory standards.

From previous history with other regulations that the Commission enforces, compliance with the various CPSC standards is high. In addition, all firms have a responsibility to report noncompliance with the standard under Section 15(b) of the Consumer Product Safety Act. Failure to report would subject a firm to severe penalties.

Based on these considerations, the compliance staff believes that the agency's enforcement programs and enforcement authority will provide substantial assurance that bicycle helmets will meet the requirements for the mandatory standard. Experience in enforcing other CPSC regulations has shown that a high degree of compliance can be achieved without manufacturers using a pre-market clearance program or a third-party certifying organization.

The Compliance staff recommends no revision to the proposed rule in response to this comment.

§ 1203.34 Product certification and labeling by manufacturers (including importers).

(a) *Form of permanent label of certification.* Manufacturers, as defined in § 1203.32(a), shall issue certificates of compliance for bicycle helmets manufactured after the effective date of the standard in the form of a durable, legible, and readily visible label meeting the requirements of this section. This label is the helmet's certificate of compliance, as that term is used in § 14 of the CPSA, 15 U.S.C. 2063.

(b) *Contents of certification label.* The certification labels required by this section shall contain the following:

~~(1) The statement "Complies with CPSC Safety Standard for Bicycle Helmets for Adults and Children Age 5 and Older (16 CFR 1203)" or "Complies with CPSC Safety Standard for Bicycle Helmets for Children Under 5 Years (16 CFR 1203)", as appropriate (for a helmet that meets the criteria for both an adult helmet and a helmet for children under age 5, the label may state "Complies with the CPSC Safety Standard for Bicycle Helmets for Persons of All Ages", or equivalent language);~~

(1) The statement "Complies with CPSC Safety Standard for Bicycle Helmets for Persons Age 5 and Older" or "Complies with CPSC Safety Standard for Bicycle Helmets for Persons Age 1 and Older (Extended Head Coverage)", as appropriate. This label may spell out "U.S. Consumer Product Safety Commission" instead of "CPSC"

(2) The name of the U.S. manufacturer or importer responsible for issuing the certificate or the name of a private labeler;

(3) The address of the U.S. manufacturer or importer responsible for issuing the certificate or, if the name of a private labeler is on the label, the address of the private labeler;

(4) The name and address of the foreign manufacturer, if the helmet was manufactured outside the United States;

(5) The telephone number of the U.S. manufacturer or importer responsible for issuins the certificate or, if the name of a private labeler is on the label, the telephone number of the private labeler;

(6) An identification of the production lot; and

(7) The uncoded month and year the product was manufactured.

(c) *Coding.* (1) The information required by paragraphs (b)(4) and (b)(6), and the information referred to in paragraph (c)(2), of this section may be in code, provided:

(i) the person or firm issuing the certificate maintains a written record of the meaning of each symbol used in the code, and

(ii) the record shall be made available to the distributor, retailer, consumer, and Commission upon request.

(2) A serial number may be used in place of a production lot identification on the helmet if it can serve as a code to identify the production lot. If a bicycle helmet is manufactured for sale by a private labeler, and if the name of the private labeler is on the certification label, the name of the manufacturer or importer issuing the certificate, and the name and address of any foreign manufacturer, may also be in code.

(d) *Placement of the label(s).* The information required by paragraphs (b)(2)-(3) must be on one label, unless allowed to be in code. The other required information may be on separate labels. The label(s) required by this section must be affixed to the bicycle helmet. If the label(s) are not immediately visible to the ultimate purchaser of the bicycle helmet prior to purchase because of packaging or other marketing practices, a second label is required. That label shall state, as appropriate, ~~"Complies with CPSC Safety Standard for Bicycle Helmets for Adults and Children Age 5 and Older", or "Complies with CPSC Safety Standard for Bicycle Helmets for Children Under 5 Years". The additional label must appear on the container or, if the container is not visible before purchase, on the promotional material used with the sale of the bicycle helmet (For a helmet that meets the criteria for both an adult helmet and a helmet for children under age 5,~~

~~the label may state "Complies with the CPSC Safety Standard for Bicycle Helmets for Persons of All Ages", or equivalent language.)~~

"Complies with CPSC Safetv Standard for Bicvcle Helmets for Persons Age 5 and Older", or "Complies with CPSC Safetv Standard for Bicycle Helmets for Persons Age 1 and Older (Extended Head Coverage)" The label shall be legible, readilv visible, and&laced on the main display panel of **the** packaging or, if the packaging is not visible before purchase (e.g, catalog sales), on the promotional material used with the sale of the bicycle helmet. This label mav spell out "U.S. Consumer Product Safetv Commission" instead of "CPSC."

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Comment: Mr. L.E. Oldendorf, P.E., from the American Society of Safety Engineers (ASSE) [11], BHSI [16], the Bicycle Federation of Wisconsin [24], and Paula Romeo [26] were opposed to allowing manufacturers to code the month and year of manufacture. Respondents felt that uncoded dates would help consumers to identify if their helmet was subject to a recall. One respondent commented that an uncoded production date is necessary to assist consumers when they wish to replace their helmet after five years.

Response: ESHF and CRM (Tab G and Tab J) respond that an uncoded manufacture date would make it easier for consumers to identify their helmets. Snell helmet standards require that the manufacture date be uncoded and it is already a common practice in the industry. Staff recommends that the standardbe revised to require the uncoded date of manufacture.

Comment: Maurice Keenan, MD, from the American Academy of Pediatrics, [21] requested that a minimum age of 1 year be reflected on the label for helmets intended for children under age five. This would better convey the message that infants (children under age one) should not be passengers on a bicycle under any circumstances.

Response: ESHF agrees with the respondent that *children under one year of age should not be on bicycles (Tab G). Children are just learning to sit unsupported around 9 months of age. It is not until this age that infants have developed sufficient bone mass andmuscle tone to enable them to sit unsupported with their backs straight. Pediatricians advise against having infants sitting in a slumped or curled position for prolonged periods. This position may even be exacerbated by the added weight of a bicycle helmet on the infant's head. ESHF recommends labeling helmets for children under 5 years with a minimum age of 1 year.*

Because pediatricians recommend against having children under age 1 as passengers on bicycles, the staff recommends that the certification label not imply that children under age 1 can ride safely. Thus, the proposed language that a helmet complies with CPSC's standard "for Children Under 5 years" or "for persons of all ages" is not suitable, since these phrases include children less than 1 year old.

Further, the only difference between *the final requirements for helmets for children of ages l-4 and for helmets for older persons is that the young children's helmets cover more of the head. Therefore, children's helmets will inherently comply with the*

requirements for helmets for older persons, and the label need not indicate an upper cutoff of age 5 for meeting CPSC's requirements.

Comment: PHMA [29] suggested that a distinguishing sticker showing certification for children under 5 is needed on the packaging, but is not needed inside the helmet.

Response: ESHF responds (Tab G) that since Toddler helmets are likely to be passed/shared with multiple users, the sticker on the helmet is likely to be the only source of information available to the second or third user. Further, it is common to display helmets at retail without the box. Thus, the purchaser may not see the box until after selecting the model, if at all. Therefore ESHF recommends leaving this labeling both on the box and inside the helmet.

Comment: The NSKC [22] encouraged the Commission to modify the certification labeling to require the language "United States Consumer Product Safety Commission" rather than "CPSC" The respondent believes the acronym is likely to lead to consumer confusion, but the use of the formal name of the Commission will clearly identify the helmet as meeting a federally established safety standard.

Response: ESHF responds that the rationale presented by the respondent for using the full name of the Commission instead of using the acronym is logical (Tab G). However, the use of the Commission's full name may be impractical for some manufacturers. The amount of space available on the inside of a helmet is limited. The proposed regulation requires a number of labels and each one is supposed to be legible and easily visible to the user. Allowing the use of the acronym is a necessary compromise so that all the labels can be accommodated on the inside of the helmet. Staff believes it should be the manufacturers' choice and the following wording should be added to section 1203.34(b)(1):

" This label may spell out "U.S. Consumer Product Safety Commission" instead of "CPSC"

Comment : NSKC [22] requested that the final standard require that the certification compliance label, which is required on the packaging if the label is not immediately visible on the product, be legible and prominent:, and be placed on the main display panel of the packaging so that it is easily visible to the purchaser.

Response: The reason for requiring the label on the packaging if it is not visible on the product at time of purchase is to inform the consumer of compliance. Human Factors agrees with the respondent and suggests the following wording be added to section 1203.34(d): "The label shall be legible, readily visible and placed on the main display panel of the packaging, or if packaging is not visible before purchase, on the promotional material used with the sale of the bicycle helmet."

Comment : Two respondents [23 and 26] urged that the Commission require labels showing the manufacturer's telephone number. The respondents stated that this requirement would make it easier for the consumer to contact the manufacturer about recall information and about instructions for returning the helmet to the manufacturer after it has been damaged!.

Response: CRM responds (Tab J) that during a recall or to inquire about a damaged bicycle helmet, the telephone number would be helpful for consumers to determine the status of their helmets quicker than a written inquiry. Obtaining a quicker response could reduce the chance of a consumer wearing a defective helmet by replacing it sooner with a safer helmet. The staff recommends that the telephone number be included on the labeling of the helmets.

(e) Additional provisions for importers.

(1) General. The importer of any bicycle helmet subject to the standard in Subpart A of this Part 1203 must issue the certificate of compliance required by § 14(a) of the CPSA and this section. If a reasonable testing program meeting the requirements of this subpart has been performed by or for the foreign manufacturer of the product, the importer may rely in good faith on such tests to support the certificate of compliance, provided:

(i) the importer is a resident of the United States or has a resident agent in the United States,

(ii) there are records of such tests as required by § 1203.41 of Subpart C of this part, and

(iii) such records are available to the Commission within 48 hours of a request to the importer.

(2) Responsibility of importers. Importers that rely on tests by the foreign manufacturer to support the certificate of compliance shall-in addition to complying with paragraph (e)(1) of this section---examine the records supplied by the manufacturer to determine that they comply with § 1203.41 of Subpart C of this part.

SUBPART C-RECORDKEEPING

§ 1203.40 Effective date.

The recordkeeping requirements in this subpart are effective [insert date that is 1 year after publication of the final rule] and apply to bicycle helmets manufactured after that date.

§ 1203.41 Recordkeeping requirements.

(a) *General.* Every person issuing certificates of compliance for bicycle helmets subject to the standard in Subpart A of this part shall maintain records which show that the certificates are based on a reasonable testing program. The records shall be maintained for a period of at least 3 years from the date of certification of the last bicycle helmet in each production lot. These records shall be available, upon request, to any designated officer or employee of the Commission, in accordance with § 16(b) of the CPSA, 15 U.S.C. 2065(b)., If the records are not physically available during the inspection because they are maintained at another location, the firm must provide them to the staff within 48 hours.

(b) *Contents of records.* Complete test records shall be maintained. Records shall contain the following information.

(1) an identification of the bicycle helmets tested;

(2) an identification of the production lot;

(3) the results of the tests, including the precise nature of any failures;

(4) a description of the specific actions taken to address any failures;

(5) a detailed description of the tests; including the helmet positioning index (HPI) used to define the proper position of the helmet on the headform:

(6) the manufacturer's name and address;
(7) the model and size of each helmet tested;
(8) identifying information for each helmet tested, including the production lot for each helmet;
(9) the environmental condition under which each helmet was tested, the duration of the helmet's conditioning the temperatures in each conditioning environment, and the relative humidity and temperature of the laboratory;
(10) the peripheral vision clearance;
(11) a description of any failures to conform to any of the labeling and instruction requirements;
(12) the results of the positional stability test;
(13) the results of the dynamic strength of retention system test;
(14) performance impact results, stating the precise location of impact, type of anvil used, velocity prior to impact, and maximum acceleration measured in g's;
(15) the name and location of the test laboratory;
(16) the name of the person(s) who performed the test;
(17) the date of the test; and
(18) the system check results.
(c) Format for records. 'The records required to be maintained by this section may be in any appropriate form or format that clearly provides the required information. Certification test results may be kept on paper, microfiche, computer disk, or other retrievable media. Where records are kept on computer disk or other retrievable media, the records shall be made available to the Commission on paper copies, or via electronic mail in the same format as paper copies, upon request.

Discussion
The staff recommends that recordkeeping include the helmet positioning index (HPI) and the duration that the helmet was kept in the conditioning environment. These items are added in the list of records above.

Comment: SRI [2] commented that the 48 hour allowance to provide test records to the Commission should apply to all manufacturers or importers, whether or not the *test records are maintained within the U.S.*

Response: The Compliance staff has examined the comment and recommends that all firms be required to provide records for immediate inspection and copying upon request by a Commission employee (Tab J). If the records are not physically available during the inspection because they are maintained at another location, we recommend that the firm must provide them to the staff within a maximum of 48 hours.

Comment: SRI [2] recommended that the order of these reporting items be adjusted to coincide with the rest of the document

Response: ES made these editorial adjustments above.

Comment: Paula Romeo [26] questioned whether certification records should be maintained for longer than three years since helmets can be used for five years.

Response: CRM responds at *Tab J that the purpose for records to be kept for three years is to ensure that the helmets have time to clear the distribution channels and get into the marketplace. If*

there is a compliance problem or defect in the helmets, three years would be of sufficient time to uncover the problem. The Commission staff would have sufficient time to obtain the records to review the firm's testing program and take the necessary enforcement action during this three year period. The staff recommends no change in the record keeping retention time of three years.

Subpart D-Requirements For Bicycle Helmets Manufactured From March 17, 1995, Through [insert date that is 1 year after publication] .

§ 1203.51 Purpose and basis.

The purpose and basis of this rule is to protect bicyclists from head injuries by ensuring that bicycle helmets comply with the requirements of appropriate existing voluntary standards, as provided in 15 U.S.C. 6004(a).

§ 1203.52 Scope and effective date.

(a) Bicycle helmets manufactured after March 16, 1995, through the date that is 1 year after issuance of the final standard (Subparts A, B, and C) shall comply with the requirements of one of the standards specified in § 1203.53. This requirement shall be considered a consumer product safety standard issued under the Consumer Product Safety Act.

(b) The term "bicycle helmet" is defined at § 1203.4(b).

(c) These interim mandatory safety standards will not apply to bicycle helmets manufactured after the effective date of the final bicycle helmet standard. Those helmets are subject to the requirements of Subparts A-C of this Part 1203.

§ 1203.53 Interim safety standards.

(a) Bicycle helmets must comply with one or more of the following standards, which are incorporated herein by reference:

(1) American National Standards Institute (ANSI) standard Z90.4-1984, Protective Headgear for Bicyclists,

(2) ASTM standards F 1447-93 or F 1447-94, Standard Specification for Protective Headgear Used in Bicycling, incorporating the relevant provisions of ASTM F 1446-93 or ASTM F 1446-94, Standard Test Methods for Equipment and Procedures Used in Evaluating the Performance Characteristics of Protective Headgear, respectively,

(3) Canadian Standard Association standard, Cycling Helmets - CAN/CSA-D113.2-M89,

(4) Snell Memorial Foundation (Snell) 1990 Standard for Protective Headgear for Use in Bicycling (designation B-90),

(5) Snell 1990 Standard for Protective Headgear for Use in Bicycling, including March 9, 1994 Supplement (designation B-90S),

(6) Snell 1994 Standard for Protective Headgear for Use in Non-Motorized Sports (designation N-94), or

(7) Snell 1995 standard for Protective Headgear for Use with Bicycles B-95.

(8) Subparts A-C of this Part 1203.

Discussion

The staff recommends that the final CPSC standard be added as an interim standard so that firms will have the option of marketing helmets meeting CPSC's final standard before its effective date.

(b) This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the standards may be obtained as follows. Copies of the ANSI 290.4 standard are available from: American National Standards Institute, 11 W. 42nd Street, 13th Floor, New York, NY 10036. Copies of the ASTM standards are available from: ASTM, ~~1916 Race Street Philadelphia, PA 19103~~ 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. Copies of the Canadian Standards Association CAN/CSA-D113.2-M89 standard are available from: CSA, 178 Rexdale Boulevard, Rexdale (Toronto), Ontario, Canada, M9W 1R3. Copies of the Snell standards are available from: Snell Memorial Foundation, Inc., 6731-A 32nd Street, North Highlands,CA 95660. Copies may be inspected at the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814, or at the Office of the Federal Register, 800 N. Capitol Street NW, Room 700, Washington, DC.

Figures to Part 1203

[Insert Figures 1-13]

Dated: _____, 1997.

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Sadye E. Dunn,
Secretary, Consumer Product Safety Commission