levels of injury listed in order of increasing severity: (I) head injury, (2) brain injury, and (3) severe brain injury.

Due to the small number of helmeted case subjects that suffered brain injury and severe brain injury, Harborview researchers could not estimate the protective effect of helmets against these injuries for the under 6-year-old age group. Accordingly, the Commission has not relied on this study in its consideration of whether special requirements are needed for children's helmets. However, one of Harborview's overall conclusions was that helmets are effective for all bicyclists, regardless of age, and that there is no evidence that children younger than 6 years need a different type of helmet.

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,[12] Dr. Myers explains that such modifications of the standard should be considered only if it can be shown to improve the protective qualities of helmets. 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.

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[12]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).

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 transfer of energy to the head, thereby reducing the risk of injury.

The degree to which the liner resists being crushed also 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.

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 ("less stiff") liner to further lessen the impact transmitted to the head.

A simple way to examine the effect of changing headform mass and the peak-g criterion is to model the helmet as a spring and apply the one-dimensional spring-mass impact formulas shown below. This approach is discussed by both Dr. Myers and by Mr. Jim Sundahl, Senior Engineer with Bell Sports, in his response to the proposed rule [12].

$$a_{peak} = V_o\sqrt{\frac{k}{m}} \qquad (1)$$

$$x_{peak} = V_o\sqrt{\frac{m}{k}} \qquad (2)$$

where:

a_{peak} = peak acceleration (peak-g)

V_o = impact velocity

k = liner stiffness

m = headform mass

x_{peak} = required stopping distance (liner thickness)

If the value for headform mass m is reduced in Equation (1), the value for liner stiffness k must be reduced to achieve the same peak-g at the same impact velocity. This means that if a helmet that meets the standard's criteria with a 5-kg headform did not meet the peak-g requirement using a lighter headform, the helmet liner would need to be made softer so more crushing of the liner could occur.

If the value for peak acceleration a_{peak} is reduced in Equation (1), and the other variables are held constant, the value for liner stiffness k again must be reduced. Thus, a helmet that could not comply with a reduced peak-g criterion also would need a softer liner to allow more crushing. Equation (2) shows that, with a decreased liner stiffness, a greater percentage of the 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 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 people will use.

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 suffering head injuries with minimal or no deformation of current helmet liners?

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

Unfortunately, currently available information 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.[13] 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 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

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[13] 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).

effective in reducing the risk of head and brain injuries, it would be imprudent 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 focusing on the age range of under 5 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 or (2) the protection that might be lost at the severe impact conditions that completely crush the liner.

For the reasons discussed above, the Commission did not include special provisions in the final standard for headform mass and peak-g criteria for young children's helmets. There are insufficient data to justify the changes, and these changes could provide less protection in the most serious impacts. 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.

8. Impact attenuation **test** *rig.*

a. *Type of test rig.* The originally proposed CPSC standard and the current interim mandatory standards allowed the use of either a wire- or rail-guided impact test rig. In

the revised proposal, the Commission specified only the monorail test rig, to avoid the possibility that different results would be obtained with the two types of test rigs.

Some helmet manufacturers [5, 29, 30], and the Snell Memorial Foundation [28], disagreed with the specification of the monorail type of impact test rig. Commenters stated that guidewire rigs were more widely used in the industry. Some commenters 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 require 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 testing reliability and capability. Most commenters suggested that the Commission allow both monorail and guidewire rigs.

To respond to this issue, the CPSC's 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.

Seven laboratories participated in the test program, including the CPSC lab. Five of the laboratories tested on both monorail and guidewire rigs. Two laboratories only tested on monorail rigs. Three different helmet models were used. Each helmet was impacted twice, once at the rear of the helmet and once near the crown. Tests were conducted using flat and curbstone anvils, and all testing was performed with ambient-conditioned helmets. This experiment allowed the analysis of the effect of the following variables: rig type, anvil type, helmet model, laboratory, anvil impact sequence, and impact location.

The statistical analysis of the interlaboratory results showed that for the majority of 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 readings summed across laboratories having both types of test rigs. For reasons completely unrelated to these test results, a curbstone impact in combination with another impact on any single test helmet is no longer permitted in the final standard. Since the interlaboratory data (summed across the laboratories that used both types of test rigs) show no significant differences between guidewire and

monorail rigs under test conditions within those allowed in the final standard, the standard allows either type of **rig** to be used for impact attenuation 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 independent test laboratories and in manufacturers' 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 Commission has no evidence 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 Commission concludes that both types of rigs are suitable for impact attenuation testing. Therefore, the final CPSC standard specifies that either a monorail or a guidewire test rig may be used.

b. *Accuracy check.* After evaluating the results of the multi-lab testing, the Commission concluded that the instrument system check procedure should include a procedure for calibrating the accuracy of a test rig. Therefore, the final rule includes a precision and accuracy procedure, so that laboratories can verify that their test equipment is recording accurately. The procedure requires that an aluminum sphere (spherical impactor) of a specified

dimension be dropped with a certain impact velocity onto a Modular Elastomer Programmer (MEP). A MEP is a cylindrical pad of polyurethane rubber that is used as a consistent impact medium for the systems check procedure. Pre-test and post-test impacts on an MEP to verify system recording is a standard practice of bicycle helmet test labs. All recorded impacts must 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 must not be greater than 20 g.

The range of 380 g to 425 g represents an allowable tolerance of about 10%. The interlaboratory testing showed this tolerance to be attainable between laboratories. However, test experience shows that even greater precision can be obtained for the systems check procedure within a given laboratory. The test data from the interlaboratory study show that a target range of 380 g to 425 g and a precision range of 20 g can be achieved.

c. *Test headform characteristics.* SwRI [#2] suggested that a more appropriate value for the lower limit on the resonant frequency of the headform material should be 2000 hz instead of 3000 hz.

The important conditions for the test headforms are the material specification and the dimensions defined by the draft ISO/DIS 6220-1983 standard. This goal is accomplished by stating that the headforms shall be rigid and be constructed of K-1A magnesium alloy. Test experience shows

that headforms meeting this description will not exhibit resonant frequencies that will interfere with proper data collection. Therefore, § 1203.9 has been changed to delete reference to any lower limit on resonance frequencies. The proposal also stated that another "functionally equivalent" metal could be used as the headform material. This alternative has been eliminated in the final rule to specify the headform apparatus as precisely as possible and ensure against the use of materials that may influence the test results.

Dr. Richard Snyder, President of the George Snively Research Foundation [19], referenced two studies that related helmet fit to head size and shape. The first study was conducted by Dr. Bruce Bradtmiller of the Anthropometry Research Project, Inc. Dr. Bradtmiller also responded to the proposed rule [20]. He concluded that, for proper child-helmet sizing, head breadth and length variables were more accurate guides than using age or head circumference. Dr. Bradtmiller urges caution in basing the CPSC's rules for children's helmets on the draft IS0 DIS 6220-1983 standard for test headforms. The study shows variation in the ratio of head length to head breadth. This ratio was found to be the prime determinant for helmet fit. The IS0 standard, however, maintains a constant head breadth/length ratio. A second study also concluded that head circumference was not always a good indicator for helmet fit.

IS0 headforms are the established norm for headgear testing in the U.S., Canada, Europe, and Australia. No other system of headforms is currently available that can be shown to prevent more injuries. Therefore, the Commission is retaining the IS0 headform specification in the final CPSC standard. However, the Commission's staff will stay current on developments of test procedures and equipment that could lead to improvements in general helmet fit and in improvements that make it easier to fit and adjust helmets, especially for children.

d. *Alignment of* anvils. The Commission amended § 1203.17(a) to specify that the center of the anvil must be aligned with the center vertical axis of the accelerometer. This describes the already standard operating procedure for bicycle helmet testing and is meant to prevent impacting helmets on the "corners" of anvils.

e. *Definition of "spherical impactor."* SwRI [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.

The Commission has adopted this suggestion. The more precise specifications for a spherical impactor for use as a system check device are now in § 1203.17(b)(1), under the systems check procedure.

9. *Impact attenuation test procedure.*

a. *Anvil test schedule and use of curbstone anvil.* Six respondents [5, **12**, **27**, 29, **30**, and 31] submitted comments requesting changes to the test schedule in § **1203.13** regarding the use of the curbstone anvil. All of the respondents expressed concern over using two curbstone impacts on a single helmet. As proposed, § 1203.3(d) and Table 1203.13 did not define the conditions of the fourth impact on a helmet. The fourth impact in the proposed standard is was left to the discretion of test personnel, and thus could have been a second curbstone impact. One of the commenters was also concerned 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 without overlap may be possible on a small helmet.

The Commission 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. The Commission disagrees, however, with those commenters 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, revised § 1203.13 and Table 1203.13 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.

The Commission's 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 impact 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 this test.

The Commission acknowledges 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.

b. *Definition of 'comfort padding."* The proposed definition of comfort padding included the statement: "This padding has no significant effect on impact attenuation." SwRI [2] commented that fit padding may have some influence on impact characteristics.

The Commission agrees with this commenter and deleted this statement from the definition.

c. *Testing on more than one headform.* In the revised proposal, the standard would have tested a helmet on all sizes of headform on which it fit. "Fit" was obtained if it was not difficult to put the helmet on the headform and the helmet's comfort or fit padding was partially compressed.

PHMA [29] recommended that the situation where more than one headform will "fit" a helmet should be addressed by specifying the use of the largest headform that will accommodate the helmet, with comfort padding adjusted to optimize the fit.

The Commission concludes 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 commenter,

the Commission believes that it is more appropriate to test on the smallest headform that is appropriate for the test sample. The Commission 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.

Therefore, a helmet shall be tested on the smallest of the headforms appropriate for the helmet sample. This size headform is the smallest headform on which 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.

Bell Sports [12] remarked that, where a helmet will "fit" more than one headform size, choosing the conditioning environment for testing on the larger headform(s) that produced the highest g-value in the test on the smallest headform that the helmet fits does not necessarily provide the worst case. The commenter recommended that there be four impacts in any conditioning environment chosen by the test technician. As explained above, the Commission is not going to test a given size helmet on more than one headform size. Accordingly, this comment is no longer applicable.

d. *Number of helmets required for testing.* 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 proposed standard requires too many production helmet samples to be tested. One respondent [12] offered suggested amending § 1203.7(b) to include the statement that "Helmets can be tested with any combination of accessories."

Section 1203.7(a) of the proposed standard requires helmets to be "tested in the condition in which they are offered for sale." Additionally, they are required to pass all tests both with and without any attachments that may be offered. To adopt the suggested wording would not maintain the requirement that helmets would meet the standard with all combinations of accessories. However, the Commission agrees with these commenters that it may be impractical and unnecessary to specify an additional set of eight test helmets for each added attachment and each combination of attachments in order to test for compliance with the standard.

To address this issue, the Commission decided to specify that attachments need be tested only when they can affect the test results, and that even then only a "worst case" combination of attachments need be tested. See the changes to § 1203.7(b) and § 1203.12(d)(1). For example, in the case of a removable visor that has no influence on the retention system strength test, it would be unnecessary to test four helmets (one for each conditioning environment) to

that test with the visor attached and an additional four helmets without the visor. However, it may be possible for attachments such as visors or faceshields to influence tests such as impact attenuation or peripheral vision.

10. *Helmet conditioning.*

a. *Low-temperature environment: temperature range.* SwRI [#2] commented that the allowable temperature range in the low-temperature environment should parallel the allowable temperature ranges in the other environments.

The Commission believes it is more important for the low-temperature environment range to be consistent with the current interim standards than for the range to parallel the tolerance allowed in the other environments. Thus, this comment was not adopted. However, the proposed temperature range contained a typographical error. The range should have been (-17 to -13° C). This range is consistent with ANSI, ASTM, Snell 95 and CSA standards. This typographical error has been corrected.

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

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, the immersion method of wet-conditioning is retained.

c. *Reconditioning time.* The revised proposed standard provided that a helmet that was removed from its conditioning environment for more than 3 minutes before testing would be reconditioned for 5 minutes for each minute beyond the allotted 3 minutes before testing could be resumed. SwRI [2] noted that there would be potentially no upper limit to the exposure time to recondition a helmet once it is removed from the conditioning environment for more than 3 minutes.

The Commission agrees with this comment and has added a 4-hour limit to the reconditioning time in § 1203.13(c).

11. *Labels.*

a. *Label format and content.* 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."

The Commission agrees that more emphasis should be placed on the warning labels. Accordingly, the signal word "WARNING" is used with the warnings required by § 1203.6(a)(2)-(5). See § 1203.6(a)(6). The Commission concludes that the signal word will be more effective than a

symbol , and the limited size of the inside of a helmet, and the amount of information already required on the labels, prevents the use of both a signal word and a symbol.

The limited space also prevents using the additional suggested language 'failure to follow the warnings may result in serious injury or death.,, In addition, this language could possibly mislead some to conclude that proper use of a helmet will always prevent serious injury or death. Accordingly, the Commission is not requiring a warning symbol or the suggested language that "failure to follow the warnings may result in serious injury or death.,,

b. Use *label.* The proposed standard required a label stating "Not for Motor Vehicle Use.' Some comments addressed this choice of language. [Comments **11, 13, 22,** 26.]

Two commenters stated that "Not for Motor Vehicle Use,, wrongly suggested the helmet was appropriate for any use other than motor vehicles. Another commenter 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 fourth commenter argued that "For Bicycle Use Only,, was a positive statement to which users are more likely to respond.

On reconsideration, the Commission concludes that neither the "Not for Motor Vehicle Use,, label nor the "For Bicycle Use Only,, label adequately conveys the circumstances under which helmets that meet the CPSC standard are

appropriate. It is reasonable to assume that helmets that are certified to the CPSC standard will also provide head protection for roller skaters, in-line skaters, and, perhaps, some other recreational activities. In-line skaters should not be discouraged from wearing a helmet by a label stating "For Bicycle Use Only.,,

The Commission also believes that consumers understand both the differences between bicycle helmets and motorcycle/motorsport helmets and that bicycle helmets would not provide adequate protection for motorsport activities. Therefore, the "Not for Motor Vehicle use,, label is not a critical safety message that should be mandated in the CPSC standard. Therefore, the final CPSC standard does 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 standard for bicycle helmets.

c. *Labeling for cleaning products.* The second proposal required a label warning the user that the helmet can be damaged by contact with common substances (such as certain solvents, cleaners, etc.) and that this damage may not be visible to the user. This label is also required to 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.

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 instruction manual for the list of cleaning materials.

This label is not intended to list every possible cleaning agent that can 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. The language of § 1203.6(a)(5) has been changed to make this intent clear.

d. *Warning to replace after impact.* [Commenters 22, 23, 26.] Some respondents agreed with the proposed standard's provision that the label on the helmet should advise consumers to destroy the helmet or return it to the manufacturer if it is involved in an impact. Others disagreed and requested more guidance on whether the helmet is impaired before a consumer has to return the helmet.

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 that it is inappropriate to address them in a label. It *is* to the consumer's overall safety benefit to return the helmet to the manufacturer or destroy and replace it. Accordingly, the proposed replacement warning is not changed.

e. Durability of labels. SwRI [2] remarked that a requirement for labels to be likely to remain legible throughout the life of the helmet cannot be tested and could lead to differences between laboratories. The **PHMA** [29] also expressed concern about this requirement, stating that it was unaware of any technology that will ensure that a sticker will stand up under 5 years of the type of exposure that a helmet receives.

The Commission shares these commenters, 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 are not quantified in current standards. The Commission is not aware of any existing performance test method that can be applied in this circumstance. Since a requirement for legibility for the life of the helmet is vague and possibly unattainable, the Commission has changed the requirement to require "durable" labels.

f. *Labels on both helmets and boxes.* The American Society of Safety Engineers ("ASSE")[11] and the NSKC [22] suggested that "proper fit,, information should be on both the helmet and the outside of the box.

The Commission does not believe it is necessary to have the actual fitting instructions on the box, because there is no information indicating 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. 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. Therefore, the final standard applies § 1203.6(a) (3) to the helmet's packaging, as well as to the helmet.

12. *Instructions for fitting children's helmets.* The NSKC [22] recommended that the proposed fitting instructions to accompany children's helmets be in age-specific language.

The Commission believes that age-specific instructions are unnecessary. The proposed standard requires both a graphic representation of proper positioning and written positioning and fitting directions. The graphics will reach more children than would age-specific instructions, because they allow children of all ages to compare the way their helmet looks with the pictures. In addition, graphics convey the critical information to non-English-reading individuals and illiterates. Children and adults are likely to be better able to understand and appreciate pictures than age-specific instructions. This is more likely to effectively deliver the message, allowing both parents and children to become aware of the proper fit.

13. *Retention system strength test.* SwRI [2] asked whether both the peak: and residual displacements in the test of the dynamic strength of the retention system should be

measured in order to better describe the dynamics of the system.

Only the peak deflection reading is needed to determine failure of the retention system. This is consistent with existing U.S. bicycle helmet standards. Therefore, no change to the proposed rule was made in response to this comment.

USC-HPRL [8] suggested that the retention system test (§ 1203.13(d)) be done after impact testing. The commenter 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.

After considering this comment, the Commission decided to make no changes to the sequence for retention system testing. Testing the retention system prior to impact testing is consistent with the ASTM and Snell standards. The Commission has no evidence that the test sequence in the ASTM and Snell standards allows helmets that do not have adequate retention systems.

The commenter also recommends that the "zero" position for measuring elongation be established without the proposed step of pre-tensioning the straps with a 4-kg mass.

There is no evidence that establishing the "zero" position after pretensioning the retention system, as proposed, would allow helmets that do not have adequate retention systems to pass the test. Therefore, the

Commission made no changes to the procedure for establishing the pre-test "zero" position.

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

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. Therefore, the Commission made no change to this section.

NSKC [22] also recommends that the Commission examine the potential influence that fitting pads may have on the helmet's ability to comply with the retention system requirements.

When testing for positional stability, the standard instructs testers 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. A similar procedure is followed to fit a bicycle helmet to the user. Although fitting a helmet to a metal headform will not account for all of the human elements involved when

consumers fit helmets to their heads, the proposed procedure is the most practical approach at this time and should help keep the helmet secure during an accident. Therefore, no change to the proposed standard was made in response to this comment.

15. *Vertical vision.* One commenter on the original proposal suggested that the Commission adopt requirements for a vertical field of vision. The Commission declined to do this because it had no information to indicate that bicycle helmets are posing a risk of injury due to inadequate upward or downward visual clearance.

In response to the second proposal, SwRI [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. However, a brow clearance requirement might, in some cases, reduce the amount of head coverage in the brow area. Further, CPSC has no information to indicate that bicycle helmets meeting existing standards are posing a risk of injury due to inadequate "upward" visual clearance. Therefore, the Commission did not add a "brow" visual clearance requirement to the final standard.

16. *Reflectivity.* Some comments on the original proposal related to possible requirements for helmets to improve a bicyclist's conspicuity in nighttime conditions. Data do 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. 16 CFR part 1512. The Commission stated that it would decide whether to propose reflectivity requirements for bicycle helmets under the authority of the Bicycle Helmet Safety Act after that work is completed

Several commenters on the revised proposal [1,7,11,13,16,17,22,23,24,26] urged that the Commission not postpone implementing bicycle helmet reflectivity requirements.

Since the revised proposal, 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 were tested using bicycle riders with reflective helmets and the other half were tested using riders wearing 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. 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 (Schroeder, 1997). Accordingly, the Commission lacks data to support a requirement for bicycle helmet reflective performance.

17. *Hard-shell requirements.* In recommendations to the Commission, Duke University researcher Barry Myers M.D., Ph.D., suggested that a test for penetration resistance be considered for the final standard. He reasons that such a test would require helmets to have hard outer shells. Dr. Myers contends that a hard shell will reduce the risk of penetration-type traumas. He further contends that a hard shell will lessen friction between the helmet and the impact surface and that this has two benefits. First, it would reduce the total change in velocity (ΔV) of the head during impact. Second, by reducing the forces on the head caused by friction between the helmet and the impact surface, it would reduce the risk of neck injury.

In support of hard-shell helmets, Dr. Myers references the latest Harborview[14] study, which reported a "consistent suggestion that hard-shell helmets are more protective against head and brain injuries than non-hard-shell helmets.,, Dr. Myers acknowledges that the differences measured were not statistically significant. However, he believes that a larger study, containing a sufficient number of severe brain injuries, might show this correlation with statistical significance.

"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.

In discussing protection against neck injury, Dr. Myers notes that automotive accidents cause serious neck injuries in about 15 to 25% of the persons who have serious head injuries, suggesting that neck injury is common among the most severely brain injured. However, since there were so few cases with severe brain injuries in Harborview's analysis of bicycling incidents, the significance of neck injury, and its mitigation by hard-shell helmets, among the severely brain injured cannot be determined from the Harborview study.

Although Dr. Myers suggests a penetration test in order to require that bike helmets have a hard shell, he states that a detailed study of the **most** severe injuries is warranted. He also recommends that, before a requirement that **all** helmets have a hard shell is adopted, there should be an evaluation of whether this would reduce the number of riders who would wear bicycle helmets.

Currently available information does not show a need to address the hazard of penetration-type head impacts to bicyclists. One study[15] suggests that the majority of helmets involved in bicycle accidents suffer impacts on flat, hard surfaces (asphalt, cement, etc.) and that penetration-type impacts are rare.

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

Regarding the contention that requiring a hard shell may reduce neck injuries, bicycle-related injury data show a low incidence of serious neck injuries. In 1996, there were 566,400 bicycle-related injuries treated in U.S. hospital emergency rooms, based on CPSC data from NEISS. Of these, about 6,630 (1%) involved the neck. Of the neck injuries, about 4,520 (68%) involved strains or sprains, 1,155 (17%) involved contusions or abrasions, 275 (4%) involved lacerations, 240 (4%) involved fractures, and 440 (7%) involved other diagnoses. These numbers show that neck fractures accounted for about 0.04% of the total number of emergency-room-treated bicycle-related injuries in 1996. Detailed information was not available to analyze whether the use of a helmet or type of helmet had an effect on the risk of neck injury.

The Harborview study also reported a low incidence of neck injury. Their report showed that 2.7% of the cases (including both helmeted and non-helmeted cases) suffered neck injury, ranging from sprain to nerve-cord injuries. There was no correlation between neck injury and helmet use or helmet type.

Dr. Myers cites that automotive accidents cause serious neck injuries **in about** 15 to 25% of the persons who have serious head injuries. However, this statistic may not be relevant to the issue of friction between the shell and the impact surface, since the neck injuries in automotive

accidents are not necessarily caused by friction between the head and an impacting surface.

Dr. Myers' advocacy of hard-shell helmets to reduce friction would seem to argue for a test to evaluate friction resistance of a helmet against typical impact surfaces, rather than for a penetration-resistance test.

One study on this issue was done by Voigt Hodgson, Ph.D., at Wayne State University? In this study, test helmets were secured to a modified Hybrid III dummy, and skid-type impacts were done on concrete at various angles from 30 to 60 degrees. Hodgson found that both hard-shell and micro-shell (or thin-shell) helmets tended to slide rather than "hang-up" on impact with concrete. (Thin-shell helmets are the type most commonly sold in the current market). No-shell helmets showed a larger tendency to hang-up on impacts with concrete. One of the conclusions of the study was that any helmet similar to those tested in the study (hard-, thin-, or no-shell) will protect the brain and neck much better than wearing no helmet.

Harborview reports that there was a consistent trend indicating that hard-shell helmets provided better protection against head and brain injury than non-hard-shell helmets. However, in order for the results to be

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[16]Voigt R. Hodgson, Ph.D., "Skid Tests on a Select Group of Bicycle Helmets to Determine Their Head-Neck Protective Characteristics,,, Department of Neurosurgery, Wayne State University, Detroit, MI (March 8, 1991).

statistically significant, the number of people in the study would have had to be 11 times greater.

The Commission concludes that the following considerations are relevant to any possible requirement for hard-shell bicycle helmets:

1. Studies of bicycle helmets damaged in accidents suggest that penetration-type helmet impacts are rare occurrences. In addition, bicycle-related injury data suggest a low incidence of serious neck injuries. For the small portion of incidents that involve serious neck injury or penetration-type hazards, available information is insufficient to estimate the degree of improved protective performance that hard-shell helmets may offer over non-hard-shell helmets.

2. Non-hard-shell bicycle helmets are effective in preventing serious head and brain injuries. There are no known studies that report a statistically significant finding that hard-shell helmets offer better protection than non-hard-shell helmets.

3. A standard applying to all bicycle helmets has to balance the protective benefit that might be provided by a hard shell against the additional cost, weight, bulk, and discomfort caused by such a requirement. Such undesirable qualities may discourage some users from wearing helmets, which could more than cancel the effects of any additional protective qualities. This is an especially important

consideration, given the popularity of non-hard-shell bicycle helmets.

After considering these factors, the Commission concludes that the available information does not support including a penetration test, or any other test that would require all bike helmets to have a hard shell, in the final rule.

D. Certification Testing and Labeling

1. *General.* Section 14(a) of the CPSA, 15 U.S.C. *2063* (a), requires that every manufacturer (including importers) and private labeler of a product that is subject to a consumer product safety standard 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.,, Regulations implementing these certification requirements are codified in Subpart B of the Safety Standard for Bicycle Helmets.

2. The certification rule. The proposed certification rule would require manufacturers of bicycle helmets that are manufactured after the final standard becomes effective to affix permanent labels to the helmets stating that the helmet complies with the applicable CPSC standard. These labels would be the "certificates of compliance,,, as that term is used in § 14(a) of the CPSA.

In some instances, 'the label on the bicycle helmet may not be immediately visible to the ultimate purchaser of the

helmet prior to purchase because of packaging or other marketing practices. In those cases, the final rule requires an identical second label on the helmet's package or, if the package is not visible-as when the item is sold from a catalog, for example--on the promotional material used in connection with the sale of the bicycle helmet.

The certification label also contains the name, address, and telephone number of the manufacturer or importer, and identifies the production lot and the month and year the product was manufactured. Some of the required information may be in code.

The certification rule requires each manufacturer or importer to conduct a reasonable testing program to demonstrate that its bicycle helmets comply with the standard. This reasonable testing program may be defined by the manufacturer or importer, but must include either the tests prescribed in the standard or any other reasonable test procedures that assure compliance with the standard.

The certification rule provides that the required testing program will test bicycle helmets sampled from each production lot so that there is a reasonable assurance that, if the bicycle helmets selected for testing meet the standard, all bicycle helmets in the lot will meet the standard.

The rule provides that bicycle helmet importers may rely in good faith on the foreign manufacturer's certificate

of compliance, provided that a reasonable testing program has been performed by or for the foreign manufacturer and the importer is a U.S. resident or has a resident agent in the U.S.

3. *Reasonable testing program.* Proposed § 1203.33(b)(4) stated that 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 helmets in the lot have been identified and destroyed or altered . . . to make them conform to the standard.,, Trek USA [5] commented 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 commenter suggested a change in the wording of § 1203.33(b)(4) from "a bicycle helmet,, to "any bicycle helmet,, that fails to conform to the testing criteria. The commenter asserts that this change would provide more flexibility, as it would remove the possibility of an anomaly in the testing causing a lack of certification of an entire lot.

The Commission did not make the requested change in the wording of § 1203.33(b)(4). First, it does not appear that the requested language would change the meaning of this requirement. Second, the purpose of the testing program is

to detect possible failures of bicycle helmets in a production lot and to reasonably ensure that the helmets that are certified comply with the standard. The Commission intends that failure of one helmet would trigger an investigation to determine whether the failure extends 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 wording of § 1203.33(b)(4) has been changed to make this intent clear.

a. *Changes in materials or vendors.* The proposed standard provides that when there are changes in parts, suppliers, or production methods, a new production lot should be established for the purposes of certification testing. The PHMA [29] wants clarification of when there are material or vendor changes. PHMA requests that the Commission use the Safety Equipment Institute ("SEI") guidance to help firms understand the terms material changes, design changes, and vendor changes.

The Commission does not think that establishing definitions as stated in the SEI "Definition of Term,, would add any significant clarification for the industry as a whole. Each firm can institute its own testing program, 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 its 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 Commission made no revision to the proposed rule in response to this comment. However, manufacturers and importers should keep records describing the testing program and explaining why the program is sufficient to reasonably determine that all of the firm's bicycle helmets comply with the standard. Similarly, when the testing program detects noncomplying helmets, the firm should record the actions taken and why those actions are sufficient to reasonably ensure that no noncomplying helmets remain in the production lot. See Subpart C of Part 1203.

b. *Pre-market clearance and market surveillance.* The Snell Memorial Foundation [28] and Paul H. Appel [25] propose the adoption of the pre-market clearance and 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 to keep inadequate helmets off the market.

All firms must ensure that bicycle helmets sold in the United States are certified to the mandatory bicycle helmet standard, and that the certifications are based 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 or 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 1 year, or both.

The Commission has statutory authority to inspect manufacturers, importers, distributors, and retailers of bicycle helmets. This authority includes the right to review and copy records relevant to compliance with the bicycle helmet standard. The Commission may also 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 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. 15 U.S.C. 2064(b). Failure to report could subject a firm to severe penalties.

Based on these considerations, 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. Therefore, the Commission made no revision to the proposed rule in response to this comment.

4. *Certificate of compliance.*

a. *Coding of date of manufacture.* The proposed standard required the certification label to contain the month and year of manufacture, but allowed this information to be in code. Mr. L.E. Oldendorf, P.E., from ASSE[11], the Bicycle Helmet Safety Institute ("BHSI")[16], the Bicycle Federation of Wisconsin [24], and Paula Romeo [26] opposed allowing manufacturers to code the month and year of manufacture. These commenters felt that uncoded dates would help consumers deternnine whether their helmet was subject to a recall. One commenter stated that an uncoded production date is necessary to assist consumers when they wish to replace their helmet after 5 years.

As the commenters noted, an uncoded manufacture date would make it easier for consumers to tell when their helmets are subject to a recall. This information also would help users determine when the helmet's useful life is over

and the helmet should be replaced. Snell helmet standards require that the manufacture date be uncoded, and it is already a common practice in the industry. Accordingly, the Commission has revised the standard to require an uncoded date of manufacture.

b. *Telephone number on label.* Two commenters [23 and 26] urged that the Commission require labels showing the manufacturer's telephone number. They 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.

The telephone number would be helpful for consumers during a recall or to inquire about a damaged bicycle helmet because they could determine the status of their helmets quicker than by a written inquiry. Obtaining a quicker response would enable the consumer to replace a defective helmet sooner and thus reduce the possibility of injuries caused by having an accident while wearing a defective helmet. Therefore, the Commission is requiring the telephone number of the U.S. manufacturer or importer on the helmet's labeling.

c. *Certification label on children's helmets.* PHMA [29] suggested that a label showing certification for children under 5 is needed on the packaging, but is not needed inside the helmet.

The Commission does not agree. Since helmets for small children are likely to be shared with or passed on to 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, this labeling will be required on both the box and the helmet.

d. *Minimum age on labels for children's helmets.* Section 14(a) of the CPSA requires that certifying firms issue a certificate certifying that the product conforms to all applicable consumer product safety standards. 15 U.S.C. 2063(a). Accordingly, the original proposal would have required the label statement "Complies with CPSC Safety Standard for Bicycle Helmets (16 CFR part 1203)". This was changed in the revised proposal because the Commission wanted to guard against the possibility that small adult helmets will be purchased for children. Therefore, the revised proposed standard required that helmets that do not comply with the requirements for young children's helmets would be labeled ‘Complies with CPSC Safety Standard for Bicycle Helmets for Adults and Children Age 5 and Older (16 CFR 1203)". Under that proposal, helmets intended for children 4 years of age and younger would bear a label stating "Complies with CPSC Safety Standard for Bicycle

Helmets for Children Under 5 Years (16 CFR 1203)". That proposal further provided that helmets that comply with both standards could be labeled "Complies with the CPSC Safety Standard for Bicycle Helmets for Persons of All Ages,,, or equivalent language.

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 5. This would better convey the message that infants (children under age 1) should not be passengers on a bicycle under any circumstance.

The Commission agrees with the commenter that children under 1 year of age should not be on bicycles. Children are just learning to sit unsupported at about 9 months of age. Until this age, infants have not developed sufficient bone mass and muscle 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. Because pediatricians recommend against having children under age 1 as passengers on bicycles, the Commission does not want the certification label to 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 1-4 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.

For the reasons given above, the proposed label indicating that helmets comply with the standard for helmets for children under 5 years has been amended to state that the helmets comply with the CPSC standard for "persons age 1 and older.,,

e. *Identifying the Commission.* 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 commenter believes that the acronym is likely to lead to consumer confusion, but that the use of the full name of the Commission will clearly identify the helmet as meeting a federal safety standard.

The rationale presented by the commenter for using the full name of the Commission instead of using the acronym is logical. 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. However, the Commission believes manufacturers, should have the choice of which language to use. Accordingly, the following wording has been added to §§ 1203.34(b)(1) and 1203.34(d): "this label may spell out U.S. Consumer Product Safety Commission instead of 'CPSC'."

f. *Certification label on packaging.* The proposed standard provided that the certification compliance label shall also be on the helmets, packaging or promotional material if the label is not immediately visible on the product. NSKC [22] requested that the final standard require that such package label be legible and prominent, and placed on the main display panel of the packaging so that it is easily visible to the purchaser.

The Commission agrees with the commenter and has added the following wording to § 1203.34(d): "The label shall be legible, readily visible, and placed 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.,,

E. Recordkeeping

1. *Introduction.* Section 16(b) of the CPSA requires that:

> Every person who is a manufacturer, private labeler, or distributor of a consumer product shall establish and maintain such records, make such reports, and provide such information as the Commission may reasonably require for the purposes of implementing this Act, or to determine compliance with rules or orders prescribed under this Act.

15 U.S.C. 2065(b).

The rule requires every entity issuing certificates of compliance for bicycle helmets to maintain records that show the certificates are based on a reasonable testing program. These records were proposed to be maintained for a period of at least 3 years from the date of certification of the last bicycle helmet in each production lot and to be available to any designated officer or employee of the Commission upon request in accordance with § 16 (b) of the CPSA, **15 U.S.C. 2065** (b).

2. Location of test records. The original proposal required that records be kept by the importer in the U.S. to allow inspection by CPSC staff within 48 hours of a request by an employee of the Commission. In response to a comment on the original proposal, the Commission revised the regulation to state that if the importer can provide the records to the CPSC staff within the 48-hour time period, the records will be considered kept in the **U.S.**

SwRI [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.

The Commission agrees with this comment, and the final rule provides that all firms are required to provide records for immediate inspection and copying upon request by a Commission employee. 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.

3. *Length of records retention.* Paula Romeo [26] raised the issue of whether certification records should be maintained for longer than 3 years, since helmets can be used for 5 years.

The purpose of records being kept for 3 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, 3 years would be sufficient to uncover any problems with the helmets. The Commission's staff would have time to obtain the records to review the firm's testing program and take any necessary enforcement action during this 3-year period. Therefore, no change was made in the rule in response to this comment.

F. Regulatory Flexibility Act Certification

Introduction. When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 5 U.S.C. 601 et *seq.*, generally requires the agency to prepare initial and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities.

The purpose of the Regulatory Flexibility Act, as stated in § 2(b) (5 U.S.C. 602 note), is to require agencies, consistent with their objectives, to fit the requirements of regulations to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulations. The Regulatory Flexibility Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605.

The Commission's previous economic findings. In the August 1994 notice of proposed rulemaking, the Commission noted that any costs associated with design changes to comply with the original proposal would be spread out over the course of production, and would be small on a per-unit basis. Costs associated with testing and monitoring were not expected to increase, since the vast majority of firms already used third parties to test for conformance to the voluntary standards. The proposal also allowed for self-certification and self-monitoring which, for some companies,

may be substantially less costly than third-party certification. The proposed labeling requirements were not expected to have a significant impact on small firms, in that virtually all helmets already bore a similar label. Based on this information, the Commission preliminarily concluded that the proposal would not have a significant impact on a substantial number of small entities. The Commission received no public comment on this conclusion.

As a result of non-economic comments of a technical nature, the Commission proposed a revised standard on December 6, 1995. In that notice, the Commission reiterated its assessment of the economic impact of the standard on small businesses. In the preamble to the 1995 proposal, the Commission again preliminarily certified that the proposed standard, if promulgated, would not have a significant economic effect on a substantial number of small entities.

Current economic: assessment and response to comments. The Commission's Directorate for Economics prepared an economic assessment of the safety standard for bicycle helmets. 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 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 blear 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 [5] approved specifying a single test apparatus, but was concerned that the Commission chose a monorail-guided test rig over a guidewire unit. Trek said that the majority of PHMA members test on wire-guided equipment and that some firms may be forced to purchase monorail units to eliminate product liability concerns. The firm stated, "[t]he 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 test rigs showed no significant differences between the two types of rigs in test conditions that are within the parameters permitted by the draft standard. Therefore, the final standard has been revised to specify that either a monorail or a guidewire apparatus may be used to test a helmet's impact attenuation performance. Consequently, the potential cost considerations for laboratories using guidewire rigs no longer apply.

Another commenter, Bell Sports [12], noted that the proposal also included impact testing requirements that allowed two impacts with a device simulating helmet contact with a curb. Bell estimated that "[t]he 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 design are expected to be small on a per-unit basis.

Spokesmen for the PHMA estimate that there are 1,000 to 1,500 bicycle-helmet molds in current use, each of which contains 4 molding cavities. Redesign may be required for one or more cavities in some molds, while other molds may not require any cavity redesign. Using a midpoint estimate of 1,250 molds, there would be some 5,000 cavities in current use in helmet molds.

The PHMA estimates that the top 4 manufacturers of bicycle helmets account for about 700 molds (or some 2,800 cavities) used in helmet production. The other 26 firms account for the remainder or, on average, 21 molds per firm (84 cavities). The PHMA estimates that 10% or less of the existing cavities would require redesign in order for the

helmets made by them to comply with the standard. Thus, smaller firms may need to redesign an average of 8.4 cavities. Each cavity costs approximately $2,500, according to the trade association. On average, the one-time cost of cavity redesign for the smaller 26 firms would be about $21,000 each.

The top 4 firms account for an estimated 75% of the 9 million helmets sold annually, according to PHMA. The remaining firms thus account for 25%, or 2.25 million helmets annually. If sales are allocated uniformly, each of the 26 firms would account for about 87,000 units. If spread over a single year's production, the average cavity redesign cost would be about 24 cents per helmet.

Further, the industry routinely replaces molds (and, thus, cavities), either because of style changes in helmet designs or because they wear out. The above estimates, however, assume that no molds would have been replaced absent the standard. Because the standard will not become effective until 1 year after the final rule is published, some of the noncomplying cavities may be replaced in that interim for reasons independent of the final standard. Consequently, the estimated one-time costs associated with the replacement of the smaller firms' mold cavities that would be attributed solely to the standard are likely to be significantly less than $21,000 each.

Regulatory flexibility certification. Because the per-unit costs of modifying production molds will be relatively low, the Commission concludes that the rule will not have a significant impact on a substantial number of small entities.

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission assessed the possible environmental effects associated with the safety standard for bicycle helmets.

The Commission's regulations, at 16 CFR 1021.5(c)(1) and (2), state that safety standards and product labeling or certification rules for consumer products normally have little or no potential for affecting the human environment. The analysis of the potential impact of this rule indicates that the rule is not expected to affect preexisting packaging or materials of construction now used by manufacturers. Existing inventories of finished products would not be rendered unusable, since § 9(g) (1) of the CPSA provides that standards apply only to products manufactured after the effective date. Changes in coverage areas for helmets may require modification or replacement of existing injection molds. Industry experts estimate that there are some 1,000 to 1,500 molds currently used by bicycle helmet producers, and that perhaps 10% are likely to be affected by

the proposed standard. Molds are constructed of aluminum, commonly weighing 40-50 pounds each. Molds are also routinely replaced due to wear or to changes in style. Helmet manufacturers send these older molds back to the firm making replacements, and the older units are melted down for use in the replacement molds. Thus, the quantity of discards resulting from the rule is likely to be small.

Especially in view of the statutory l-year effective date, it is unlikely that significant stocks of current labels will require disposal.

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.

H. Paperwork Reduction Act

As noted above, U.S. manufacturers and importers of bicycle helmets will be required to conduct a reasonable testing program to ensure their products comply with the standard. They will also be required to keep records of such testing so that the Commission's staff can verify that the testing was conducted properly. This will enable the staff to obtain information indicating that a company's helmets comply with the standard, without having itself to test

helmets. U.S. manufacturers and importers of bicycle helmets will also have to label their products with specified information.

The rule thus contains "collection of information requirements" subject to the Paperwork Reduction Act of 1995, 15 U.S.C. 3501-3520, Pub. L. No. 104-13, 109 Stat. 163 (1995). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The control number may be displayed by publication in the **Federal Register**. Accordingly, the Commission submitted the proposed collection of information requirements to OMB for review under section 3507(d) of the Paperwork Reduction Act of 1995.

The Commission's staff estimates that there are about 30 manufacturers and importers subject to these collection of information requirements. There are an estimated 200 different models of bicycle helmets currently marketed in the **U.S.**

Industry sources advised the Commission's staff that the time that will be required to comply with the collection of information requirements will be from 100 to **150** hours per model per year. Therefore, the total amount of time required for compliance with these requirements will be 20,000 to 30,000 hours per year. However, these estimates are based on the amount of time that is currently expended

in complying with the similar requirements that are in the various voluntary standards. Thus, the additional burden of the final collection of information requirements is expected to be only a small fraction of the total hours given above.

The Commission solicited comments on the activities and time required to comply with these requirements and how these differ from usual and customary current industry practices, on the accuracy of the Commission's burden estimate, and on how that burden could be reduced. No comments directly addressed the Commission's burden estimate. Comments addressing the topic of reducing the number of helmets required to be tested under the standard are discussed in section C of this notice.

I. **Executive Orders**

This rule has been evaluated for federalism implications in accordance with Executive Order No. 12,612, and the rule raises no substantial federalism concerns.

Executive Order No. 12,988 requires agencies to state the preemptive effect, if any, to be given to the regulation. The preemptive effect of this rule is established by 15 U.S.C. 2075(a), which states:

> (a) Whenever a consumer product safety standard under [the CPSA] is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish

or to continue in effect any provision of a safety standard or regulation which prescribed any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

Subsection (b) of 15 U.S.C. 2075 provides that subsection (a) does not prevent the Federal Government or the government of any State or political subdivision of a State from establishing or continuing in effect a safety standard applicable to a consumer product for its own (governmental) use, and which is not identical to the consumer product safety standard applicable to the product under the CPSA, if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of injury than the consumer product safety standard.

Subsection (c) of 15 U.S.C. 2075 authorizes a State or a political subdivision of a State to request an exemption from the preemptive effect of a consumer product safety standard. The Commission may grant such a request, by rule, where the State or political subdivision standard or regulation (1) provides a significantly higher degree of

protection from such risk of injury than the consumer product safety standard and (2) does not unduly burden interstate commerce.

List of Subjects in 16 CFR Part 1203

Consumer protection, Bicycles, Incorporation by reference, Infants and children, Safety.

For the reasons given above, the Commission revises Part 1203 of Title 16 of the Code of Federal Regulations to read as follows:

Part 1203-SAFETY STANDARD FOR BICYCLE HELMETS

Subpart A-The Standard

Sec.

1203.1 Scope, general requirements, and effective date.

1203.2 Purpose.

1203.3 Referenced documents.

1203.4 Definitions.

1203.5 Construction requirements - projections.

1203.6 Labeling and instructions.

1203.7 Samples for testing.

1203.8 Conditioning environments.

1203.9 Test headforms.

1203.10 Selecting the test headform.

1203.11 Marking the impact test line.

1203.12 Test requirements.

1203.13 Test schedule.

1203.14 Peripheral vision test.

1203.15 Positional stability test (roll-off resistance).

1203.16 Dynamic strength of retention system test.

1203.17 Impact attenuation test.

Subpart B-Certification

1203.30 Purpose and scope.

1203.31 Effective date.

1203.32 Definitions.

1203.33 Certification testing.

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

Subpart C-Recordkeeping

1203.40 Effective date.

1203.41 Recordkeeping requirements.

Subpart D-Bicycle Helmets Manufactured From March 16, 1995, Through [insert date that is 1 Year after publication].

1203.51 Purpose.

1203.52 Scope and effective date.

1203.53 Interim safety standards.

Figures for Part 1203

AUTHORITY: 15 U.S.C. 2056, 2058, and 6001-6006.

Subpart B is also issued under 15 U.S.C. 2063.

Subpart C is also issued under 15 U.S.C. 2065.

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.**

(a) The following documents are incorporated by reference in this standard.

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

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

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

(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 draft ISO/DIS Standard 6220-1983 are available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036. Copies of the Federal Motor Vehicle Safety Standard 218, Motorcycle Helmets, are 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. Copies of the SAE

Recommended Practice SAE J211 **OCT88,** Instrumentation for Impact Tests, are available from Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096. 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.

§ 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 either is marketed as, or implied through marketing or promotion to be, a device intended to provide protection from head injuries while riding a bicycle?

'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

(c) Comfort or fit padding means resilient lining material used to configure the helmet for a range of different head sizes.

(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. This vertical distance shall be specified by the manufacturer for each size of each

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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.

model of the manufacturer's helmets, for the appropriate size of headform for each helmet, as described in § **1203.10**.

(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. The MEP shall be 152 mm (6 in) in diameter, and 25 mm (1 in) 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 in) thick aluminum plate. See § 1203.17(b) (1).

(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 of 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.

(0) Spherical *impactor* is an impact fixture used in the instrument system check of § 1203.17(b)(1) to test the impact-attenuation test equipment for precision and accuracy. The spherical impactor shall be a 146 mm (5.75 in) diameter aluminum sphere mounted on the ball-arm connector of the drop assembly. The total mass of the spherical-impactor drop assembly shall be 5.0 ± 0.1 kg (11.0 ± 0.22 lb).

(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 low-resonance K-1A magnesium alloy. The test headforms shall include surface markings