UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

DATE: August 21, 2019

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Mary T. Boyle, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Mary A. House, Attorney, OGC

SUBJECT: Petition CP 18-1: Petition for Inflatable Head Protective Devices

BALLOT VOTE DUE Tuesday, August 27, 2019

CPSC staff is forwarding a briefing package to the Commission regarding a petition submitted by Hövding Sweden AB. The petition requests that the U.S. Consumer Product Safety Commission (CPSC) exempt "inflatable head protective devices for bicyclists," from the testing requirements of the Safety Standard for Bicycle Helmets, 16 C.F.R. part 1203 (part 1203), if such product complies with, and is certified to, requirements in a standard developed by SP Technical Research Institute of Sweden, SP-method 4439, *Inflatable head protective devices with electronic triggering system for pedal cyclists* (SP Method). In the attached briefing package, CPSC staff recommends that the Commission deny the petition.

Please indicate your vote on the following options:

I. Grant the petition and direct staff to begin developing a notice of proposed rulemaking or an advance notice of proposed rulemaking.

______________________________ ____________________
(Signature) (Date)

II. Defer the petition.

______________________________ ____________________
(Signature) (Date)

III. Deny the petition and direct staff to draft a letter of denial to the petitioner.

______________________________ ____________________
(Signature) (Date)

IV. Take other action specified below.

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(Signature) (Date)

Attachment: Staff Briefing Package for Petition CP 18-1: Petition for Inflatable Head Protective Devices

Briefing Package on the Petition for Inflatable Head Protective Devices

Petition CP 18-1
Requesting an Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

August 21, 2019

Brian M. Baker, Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences
Office of Hazard Identification and Reduction

U.S. Consumer Product Safety Commission
5 Research Place
Rockville, MD 20850

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Executive Summary

On December 15, 2017, Hövding Sweden AB (Hövding, or petitioner) filed a petition with the U.S. Consumer Product Safety Commission (CPSC), requesting that the Commission exempt inflatable head protective devices for bicyclists (such as the Hövding product) from the requirements of the mandatory bicycle helmet standard under 16 CFR part 1203 – Safety Standard for Bicycle Helmets (part 1203. or federal regulation). The petitioner sought the exemption for devices that meet, and are certified to, the requirements of a test method developed specifically for the Hövding product, SP-method 4439 (SP Method). The petitioner markets the product as an airbag for urban cyclists that is worn around the neck like a collar. Petitioner states that the product monitors the user's movements, and when a predetermined algorithm detects an accident scenario, the airbag deploys from the collar, and around the user's head, to provide protection. Hövding asserts, based on multiple studies, including the use of the SP Method, that the Hövding product provides a greater level of safety than traditional hard-shell helmets. In addition, Hövding states that the SP Method, specifically created to evaluate the Hövding product, is more stringent than the requirements in part 1203.

This briefing package considers all information provided with the petition, supplemental information the petitioner submitted (up to August 19, 2019), public comments, and all other readily available related information. Currently, no product similar to the Hövding product is offered for sale in the North American market. Therefore, because the petitioner did not submit samples of the product with the petition, staff could not examine or test the Hövding or a comparable product. Additionally, because the product is not sold in the United States, no U.S. injury data involving the product exist, and the petitioner did not provide incident data involving the product's use in other countries. These facts limit staff's ability to assess the level of protection that the Hövding product provides compared to a traditional helmet.

Staff evaluated the proposed SP Method in order to determine whether a product meeting the SP Method would provide a similar level of safety as a helmet that meets part 1203. Based on staff's comparative analysis of part 1203 and the SP Method, plus evaluation of the information submitted on the Hövding product, evaluation of the provided studies, and public comments, staff concludes that:

(1) the SP Method is not equivalent to part 1203, and overall, is less stringent than part 1203; and

(2) staff does not have sufficient information to evaluate the protective benefits of the product based on the submitted studies and non-comparative testing.

Although many benefits may be derived from the emerging technology and method described by the petitioner, staff concludes that the safety requirements in the SP Method is not equivalent to or better than requirements in part 1203. Staff believes that serious concerns arise regarding the validity and repeatability of the SP Method. Additionally, staff is uncertain about the level of protection the Hövding product would provide in several likely scenarios in an urban environment (or similar road settings). These scenarios primarily involve direct contact from pointed or other objects to the cyclist's head, where the Hövding product might not deploy by design (prior to falling), and obstructions encountered en route to the ground during a fall (prior to the product's inflation). Staff does not intend to limit developing technology, but recommends denying the petition because the petition and its associated studies failed to provide adequate data demonstrating a safety equivalency among the four physical performance tests of part 1203 and the SP Method. Specifically:

- The SP Method includes testing procedures for the most important safety test, impact attenuation. However, the testing criteria used in this evaluation – environmental pre-conditioning, impact speed, number of impacts per sample, types of impact surfaces, and impact location per sample, are significantly less stringent than part 1203.
- The SP Method excludes testing methods for the remaining three of the four critical safety requirements of part 1203, specifically the peripheral vision test, positional stability test (roll-off resistance), and dynamic strength of retention test, without substantial justification for their absence.
- In some cases, the SP Method uses significantly lower impact energy, as much as 47%, in comparison to the current regulation, by using lower speeds and shortened drop heights to conduct attenuation testing. This reduction in impact energy could be the difference between a moderate injury (*e.g.* contusion) and a severe injury (*e.g.,* skull fracture).
- The two studies attached to the petition did not employ any nationally recognized or consensus-based testing methodology to evaluate the Hövding product, such as EN 1078 or ASTM 1203; nor did the studies provide sufficient rationale for not testing the product using the test methods in part 1203.

Additionally, staff is concerned that the SP Method is not a consensus-based standard, and lacks the input of multiple stakeholders. Rather, the SP Method was developed specifically for the Hövding product, and due to the SP Method's required modification of samples, it requires the use of test samples provided by the manufacturer. This means that samples cannot be tested independently off the shelf and may not be representative of products available to consumers.

Staff recommends that the Commission deny this petition because the available information is not sufficient to determine that the Hövding product, when tested to the SP Method, would provide a similar level of protection as helmets that are tested to, and pass, part 1203 testing. Neither part 1203, nor the SP Method, provides a test method that would subject the Hövding product, or similar airbag-type head protective devices, to tests that simulate real-world use through reliable and repeatable evaluation. Staff suggests that Hövding work with voluntary standards organizations to develop an appropriate test method for its product.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: August 21, 2019

TO	:	The Commission Alberta Mills, Secretary
THROUGH	:	Patricia M. Hanz, General Counsel Mary T. Boyle, Executive Director DeWane Ray, Deputy Executive Director for Safety Operations
FROM	:	Duane Boniface, Acting Assistant Executive Director, Office of Hazard Identification and Reduction Brian M. Baker, Mechanical Engineer, Project Manager Division of Mechanical Engineering, Directorate for Laboratory Sciences
SUBJECT	:	Analysis of Petition CP18-1, Requesting Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

I. Background

On December 15, 2017, Hövding Sweden AB (Hövding, or petitioner) filed a petition with the U.S. Consumer Product Safety Commission (CPSC), requesting that the Commission exempt inflatable head protective devices for bicyclists (the Hövding product) (Figure 1) from the requirements of the mandatory standard for bicycle helmets, codified at 16 CFR part1203 – Safety Standard for Bicycle Helmets (part 1203 or federal regulation), if those devices meet the requirements of SP-method 4439 (SP Method) and are so certified.

A. The Product

Figure 1: Hövding - inflatable head protection device.

According to the petitioner, Hövding began as a student project in 2005, and as of the filing of the petition, the petitioner had sold more than 130,000 units across 16 markets in Europe and Japan. Hövding markets its product as "the world's safest bicycle helmet and an airbag for urban cyclists." The petitioner states that the Hövding product is intended to be a safety device for users age 15 and over, which is worn around the neck like a collar. The Hövding product is powered by a lithium-ion battery, and must be turned on by the user to function as intended. Product marketing indicates that, when the Hövding product detects an accident scenario, the product deploys an airbag around the head. The petition states that the product uses a proprietary, pre-programmed algorithm developed by Hövding that can distinguish normal cycling from accident scenarios, using an on-board computer system. The petition states that Hövding developed the algorithm using 2,500 patterns for accident recognition, which continues to evolve, based on data from the units involved in incidents. Currently, the Hövding product is not available in the U.S. market, and the petitioner did not submit samples of the product with the petition.

B. The Petition

The petitioner requests that the Commission: (1) exempt the Hövding product from the mandatory federal regulation, part 1203, and (2) adopt an alternate test method, the SP Method, for evaluating the Hövding product. The petitioner states that part 1203 only anticipated hard-shell helmets, but because their airbag design is different, the product cannot meet part 1203 and therefore should not be subject to its requirements. Hövding asserts that its product, if it meets the requirements of the SP Method, is superior to hard shell/clam shell helmets in reducing injuries. The petitioner states that the Hövding product will entice more bicyclists to wear head protective devices because the product design which specifies that the product be worn around the neck instead of on the head, would be more appealing to consumers. The petitioner also asserts that the SP Method is more stringent than part 1203.

C. CPSC Bicycle Helmet Regulation (16 CFR Part 1203)

CPSC issued its bicycle helmet regulation (Part 1203) in 1994, in response to Congress's direction in the Children's Bicycle Helmet Standard Act. In drafting its regulation, the CPSC considered standards developed by the American National Standards Institute (ANSI), the Snell Memorial Foundation, and ASTM. Part 1203 defines a "bicycle helmet" as "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." The standard requires labeling and instructions. Other key provisions include:

Peripheral Vision (1203.14)

- A visual test to ensure helmet does not obstruct bicyclist's sight lines, which could lead to unforeseen collisions or falls.
- This visual examination requires helmets to allow a field of vision of 105 degrees on the left and right sides of center.

Positional Stability (1203.15)

- A performance test that ensures the retention system's (*e.g*. chin strap or otherwise) effectiveness against allowing the helmet to "roll off" the head. The test ensures that the helmet stays aligned in the direction intended by the manufacturer. Misalignment could allow for unexpected weaknesses to be exploited during an accident scenario.
- This test involves applying a dynamic impact load to the front and rear edges of the helmet positioned on a head form according to the manufacturer's instructions.

Dynamic Strength of Retention System (1203.16 & 1203.8)

- A performance test that ensures the retention system (*e.g*., chin strap or otherwise) is strong enough to prevent breakage or excessive elongation that could allow a helmet to come off during an accident. The test ensures that during an accident, the helmet remains on a rider's head with the chin strap secured.
- This test involves applying a "shock load" (*i.e.*, a sudden application of force) to the retention system. The retention system must remain intact and not elongate more than 30 mm. This test is applied to four helmets, each conditioned in one of the following environments: ambient, hot, cold, or wet.

Impact Attenuation (1203.17 & 1203.8)

- A performance test to ensure that helmets can provide adequate impact protection in a collision while riding a bicycle.
- This test involves securing the helmet on an appropriately sized headform and dropping the helmet to achieve specified impact speeds onto three types of fixed steel anvils (flat, hemispherical, and curbstone), which represent shapes of surfaces that may be encountered in actual riding conditions. The peak headform acceleration of any impact sustained during the test shall not exceed 300 g for any helmet (values over 300 g have been shown to be associated with injuries like concussions, and skull fractures).

II. Discussion

A. Engineering Analysis of Petition CP-18-1

The petitioner did not provide samples of the product for staff to evaluate. Engineering staff focused on comparing the SP Method to part 1203, and evaluated the studies that petitioner submitted. The memorandum at Tab A provides an in-depth explanation of CPSC staff's review involving the technical analysis of petition CP-18-1.

1. Review of the SP Method 4439

The SP Technical Research Institute of Sweden specifically developed the SP Method to test the Hövding product. Development of the SP Method was not part of a consensus standard development process. The SP Method was designed to emulate the European standard for bicycle helmets regarding the impact attenuation provision, but the SP Method is not directly equivalent to that standard. The SP Method has a test for impact attenuation (as discussed below, it does not include all of the impact tests required in part 1203) and the SP Method has several performance tests specific to the Hövding product (*e.g.*, tests for the inflator, battery, sound, and durability of the product).

Staff has multiple concerns regarding the SP Method, especially regarding physical testing, which evaluates impacts at lower speeds and kinetic energies than part 1203, omits testing against more dangerous surfaces, and lacks reproducibility. These concerns are:

a. The SP Method is significantly less stringent than current CPSC bicycle helmet regulation.
b. The SP Method's procedures are not repeatable and accept a large amount of variance and variability.
c. The SP Method lacks several tests that are important for part 1203 and could apply to the Hövding product with some modification.

d. The SP Method requires that the majority of the samples tested be modified by the manufacturer, thereby eliminating "off the shelf testing."
e. The SP Method does not test the product as an entire unit, requiring multiple sub-system tests.

We discuss each of these points below and provide further details in Tab A.

a. Less Stringent Methods

Staff has determined that certain portions of the SP Method are significantly less stringent than part 1203. As an example, part 1203 specifies an impact-attenuation speed on the flat anvil surface of 6.2 m/s (13.8 mph), whereas the corresponding section of the SP Method within the same specified zones use a speed of 4.53 m/s (10.1 mph). By reducing the impact speed, the SP method reduces the test's kinetic energy by 47 percent, in comparison to the current CPSC bicycle helmet regulation. This means that, in certain test scenarios, the SP method is only impacting the sample half as hard as the current CPSC bicycle helmet regulation, which could be the difference between moderate to severe injuries. In no corresponding section of the SP Method do the impact speeds match or exceed the speeds of part 1203. The petitioner suggests that, although the SP Method uses a slower impact speed, the threshold for failure (deceleration limit measured in g) is much tighter: less than 250 g to pass the SP Method, versus less than 300 g in part 1203. This is not an equivalent comparison; when using lower speeds the energy used to strike the helmet will also be significantly lower – meaning that a sample would be more likely to pass the g-criteria at a slower speed. The petitioner has not provided any information or data to support why this method would provide an equivalent or more stringent level of testing. The changes to this deceleration limit may have a negative effect on future airbag-style safety devices. Accordingly, reliance on this approach would require additional justification.

In addition to using less stringent impact speeds, the SP Method does not conduct impact testing using all three of the anvils used in part 1203. Part 1203 tests using three types of fixed steel anvils (flat, hemispherical, and curbstone). The SP Method tests against the flat and curbstone anvils, but does not test using a hemispherical anvil. Use of the hemispherical anvil reflects a more stringent test method because the hemispherical anvil has often been associated with worst-case impact scenarios. This half domed anvil simulates a pressure point load on the helmet, and typically produces the highest g- rating during impact testing.[1]

Finally, the SP Method is not as stringent as part 1203 because it limits the number of impacts allowed per sample to one impact or a maximum of two, with the manufacturer's consent,[2] while part 1203 requires up to four impacts per sample within the same zone. Staff recognizes that the product is designed as a one-time impact product. However, traditional bicycle helmets are also intended to be replaced after an impact but, like the petitioners helmet, may receive multiple impacts in a single incident. Moreover, single-event impacts with obstructions or intrusions within an urban environment, in addition to the ground surface itself, are not uncommon[3] – and should be evaluated.

[1] Gravitational force equivalent is the amount of deceleration indexed by the acceleration due to gravity. For example, 250 g is equivalent to 250 times gravity.
[2] (SP Technical Research Institute of Sweden, 2014, p. 11).
[3] (Goldsmith, 2019, Table 3).

Taken together, staff concludes that these three deficiencies −impact attenuation speeds, the type of anvils used, and the limited number of impacts−renders the SP Method significantly less stringent than the current CPSC helmet regulation.

b. Non Repeatable and Large Variance/Variability

Technical staff is concerned that the SP Method's procedures are not repeatable and accept large variance and variability. Section 5.9: *Evaluation of the function of the triggering system* allows test labs to use a human subject to complete the required testing. Section 5.9.1.2 of the SP Method indicates the criteria for human subject limitations, stating:

> *The test persons shall have a height, weight, head circumference, and any other limitations in accordance with the manufacturers' instructions for use.*

This provision in the SP Method allows the results of these test methods to depend completely on the subject chosen for the test.

Size, weight, and anthropometry of the human subject could determine how far the subject is thrown or how hard a fall the subject experiences. Additionally, a subject's cycling experience could lead to better or worse instinctive responses to falling, skewing the reproducibility of the test from subject to subject. The reaction speed of the subject bracing themselves to fall could produce variability that cannot be reproduced from one test lab to another. All of these variables associated with a human subject play a role in testing the product, and could possibly yield different results, based on the human subject, rather than the product. Such variability is unacceptable because it prevents validation of test results among test laboratories.

c. Insufficient Testing

The petitioner claims that several tests in part 1203 are not applicable to the Hövding product:

> *The peripheral vision test (1203.14), the positional stability test (1203.15), the retention system test (1203.16) and the impact attenuation test (1203.17) cannot be applied to the Hövding because the airbag is not inflated until it is deployed in an accident. Indeed, by its very nature, the Hövding ensures no obstruction to the cyclist's peripheral vision during use. The positional stability and the retention system tests are not necessary because the non-deployed Hövding is worn around the neck, not on the head. Similarly, the impact attenuation test cannot be performed on an un-deployed Hövding*.[4]

Petitioner's statement requires additional justification supported by test data to explain why these tests should not apply to the Hövding product, but none were provided. Staff believes that these tests are critical to the evaluation of any helmet.

- 16 CFR § 1203.14 (peripheral vision test) ensures that helmets do not obstruct the user's field of vision. For traditional helmets, the peripheral vision test would only apply to the helmet before an accident. Proper fit and the additional tests included in part 1203 require a bike helmet to stay in place and maintain an acceptable field of vision. Although the Hövding product is worn on the neck, peripheral vision after the product deploys may still be vital for the safety of the user. The SP Method does not address the

[4] (Petition of Hövding Sweden AB, 2017, p. 5).

possibility of the product obstructing the user's vision in the case of an unexpected deployment or an accident that leaves the user in the way of oncoming traffic.

- 16 CFR § 1203.15 (positional stability test) addresses the roll-off resistance of a helmet when worn by a user. The positional stability test ensures that throughout an accident scenario, the helmet remains on the user's head when subjected to a glancing strike about the periphery of the headform, from front to rear. Although the Hövding product is worn around the neck, once deployed, the product's airbag could be moved or flexed out of the way during certain foreseeable incident scenarios, such as those involving two head strikes which carry a high potential for injury, based on the findings from Health Sciences.
- 16 CFR § 1203.17 (impact test) assesses the impact attenuation of a helmet in multiple crash scenarios, using three different anvils (flat, curbstone, and hemispheric). The impact test is the single-most effective way for technical staff to measure the impact attenuation of a helmet in multiple situations – impacting the helmet on multiple surfaces, in different positions, after conditioning the helmet in various ways (high heat, cold, wet, and ambient). Although very specific in its methodology on how to appropriately test the Hövding product, the SP Method does not test the product with the same stringency as part 1203 tests bicycle helmets because the SP Method does not test impacts on the hemispheric anvil, and does not test on the flat or curbstone anvils with equivalent energy. Petitioner stated that the Hövding product cannot be evaluated to the impact attenuation portion of part 1203. However, both the Stanford and the Folksam studies submitted by the petitioner subjected the Hövding product to impact tests. In these studies, the helmet was pre-inflated, attached to a modified headform, and then subjected to multiple impact-attenuation tests. The SP Method also uses pre-inflated samples within its own test methods. Use of pre-inflated airbags demonstrates that the Hövding product can be evaluated to the impact-attenuation tests in part 1203, with minor modifications, and thus, be subjected to the same testing conditions as traditional helmets.

d. Sample Modification

The SP Method requires modifying samples for specific impact tests, which introduces additional questions about whether these samples represent off-the shelf or as-ordered products. Under the SP Method, 18 of the 22 samples needed for testing must be modified before they are tested. These modifications are significant, such as removing the gas generator, installing an inert inflator, installing a manual trigger, and providing a means to measure the pressure safely. Staff notes that, without significant training by the firm, laboratories may not be able to complete the product modifications without damaging the product, altering the product's performance, or risking employee health and safety. Therefore, test labs may need to request modified samples directly from the manufacturer. Modified samples, if available only directly from the manufacturer, may introduce bias into the sampling, and can limit the availability to test specific manufacturing lots. In contrast, part 1203 requires samples in the same condition as those offered for sale to consumers, which allows for unbiased sample collection, representative of what consumers are using.

e. No Test of the Entire Product

Lastly, the SP Method does not test the entire product as a complete unit. The SP Method does not test the dynamic performance of the sensors, electronics, algorithm, inflator, and the airbag as a complete system. The testing described in the SP Method evaluates each component of the product independently. All of the product's sub-systems must be tested in parallel to be representative of how consumers will experience the product during an accident scenario. Failure of one or more subsystems to interact properly with another could result in the airbag either not deploying, unevenly deploying, misfiring, failing to activate, deploying too slowly, or otherwise failing to protect in the manner that would be inferred from only testing each system independently. Without a full-system test, staff cannot compare the product's performance in the SP Method, with the protection afforded by a helmet that meets part 1203 in terms of real-world scenarios.[5]

2. *Analysis of Technical Documents*

Petitioner submitted two technical documents to support the claim that the Hövding product is safer than a traditional clam shell helmet in an urban environment:

a. a Stanford University Study, titled, *Modeling and optimization of airbag helmets for preventing head injuries* (Stanford Study); and
b. a study funded by the Swedish insurance company Folksam, titled, *Bicycle Helmet Test 2015* (Folksam Study).

a. Stanford Study

The Stanford Study focuses on optimizing the performance of an airbag helmet when dropped on a flat surface, ultimately to produce a theoretical mathematical model that identifies the key constraints in promoting safety for airbag products.[6] The petitioner references this study as evidence that the Hövding product provides a greater level of head protection than helmets that comply with part 1203. Although CPSC staff is encouraged by the theoretical safety improvements identified in the Stanford Study, the results of the mathematical modelling were not validated by physical testing. The Stanford Study states that it is a first attempt to optimize the design of expandable helmets and may not be representative of real-world performance.[7] The Study focuses primarily on flat impacts to limited portions of the head, specifically the crown (top or vertex) and side (parietal areas - between the ear and temple), and does not explore other impact regions. Additionally, the Stanford Study notes that airbag helmets may not perform well under environmentally adverse conditions. Environmental exposure prior to testing, including heat, cold, and water submersion, affect the measurable safety metrics found during the testing of helmets. The research calls into question the performance of the product against sharper impact anvils. Part 1203 includes two important tests that impact the helmet against hemispherical and curbstone anvils (Figure 2) to evaluate a helmet's impact attenuation against points or edges (*e.g.*, fire hydrant or concrete curbs), which are foreseeable impact scenarios for consumers. These type of impacts could potentially puncture the airbag or strike through the inflated pocket of protection offered by the inflated device, reducing the effectiveness of an airbag helmet.

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[5] CPSC staff notes that the SP Method, the Stanford Study, and the Folksam Study, all appear to test with a pre-inflated airbag.

[6] The Stanford Study refers to the Hövding product as an airbag helmet.
[7] (Mehmet Kurt, 2017, p. 7).

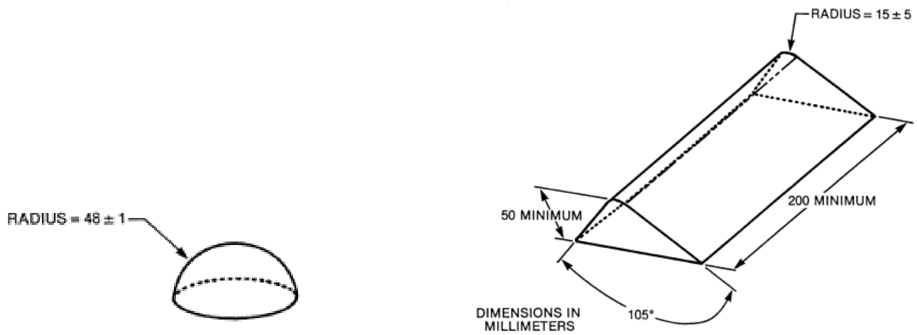

Figure 2: Hemispherical Anvil (Left); Curbstone Anvil (right)

The Stanford University research provides some information about the potential future of the airbag technology; however, petitioner did not make a direct comparison with part 1203, through either their methodology or their conditioning methods, to support a conclusion that the technology offers an improvement on, or equivalent level of safety to, part 1203. Furthermore, the results of the Stanford Study were not verified through validation testing of the actual product. Specifically, the Study does not address several important elements, including environmental exposure, hemispherical and curbstone anvil impacts, and empirical testing, to validate the mathematical modeling. As a result, staff does not believe that the Hövding product's performance within this study is representative of the entire range of all conditions, specifically those relating to impact, seen in the real world.

b. Folksam Study

The Folksam Study (TAB A), in conjunction with the Royal Institute of Technology (KTH), tested various helmets under four distinct impact conditions: a flat anvil impact to the crown of the head, and three additional impacts−rolling forward, rolling rearward, and rolling to the side−against an inclined flat surface anvil designed to produce rotation about each axis of the head and helmet.

Staff reviewed the Folksam Study and concluded that the study represents a subset of potential real-world crashes. Folksam conducted tests only on flat surfaces, and at significantly lower speeds than what is required in part 1203. Like the Stanford Study, the Folksam Study did not include the hemispherical or curbstone anvils, which, as shown by CPSC historical data, can result in the most severe impacts and that were developed to represent real-world impacts. The Folksam Study implies that if the Hövding product were tested on a hemispherical anvil, the product would need a hard outer shell to distribute the force across a larger area to provide similar levels of protection to a traditional helmet.

Staff remains optimistic about potential advancements that may build upon the research that has been conducted and is encouraged by the translational and rotational performance of the product. However, the lack of testing with specific anvil surfaces (hemispherical and curbstone) and testing pre-inflated samples at lower speeds than required for testing in part 1203, leads staff to conclude that the results of the Folksam Study cannot be considered representative of the product's expected real-world performance and does not provide evidence to the staff that the Folksam test methodology is as stringent as part 1203.

B. Health Sciences Analysis - Injury Assessment & Mitigation Potential

Health Sciences staff reviewed the types of crash scenarios and injuries that the Hövding product would and would not address and discussed how the product compared to traditional bicycle helmets that meet part 1203. The memo at Tab B provides more detail about staff's review involving injury assessment and mitigation potential of the Hövding product.

Based on information the petitioner submitted, staff is unclear what level of protection the product would provide if it were to encounter a pointed obstruction on any of the multitude of objects found in an urban environment or on the road. Part 1203 simulates these obstructions through impact attenuation testing, but the SP Method does not include all of the part 1203 impact test surfaces.

Health Sciences staff notes that the Hövding product is designed not to deploy in certain urban scenarios. Thus, the Hövding product would not protect bicyclists in those situations. The petitioner states that the airbag of the Hövding product will deploy only if the conditions match those movements upon which the algorithm was written. These patterns were accumulated through recording the movements of stunt riders, simulated crash accidents using anthropomorphic dummies, and choreographed falls, which were then compared to normal cycling. However, certain hazardous conditions exist in an urban environment, as well as on other road settings (i.e. suburban), where staff believes the device would not offer protection to the cyclist. These scenarios include direct hits from intrusive objects onto a cyclist's head.

- The owner's manual of the Hövding product states:

A head impact that occurs before Hövding has reacted and is fully inflated is called a direct hit. Examples of direct hits include an icicle falling onto a cyclist's head or a cyclist riding into a branch at head height. However, direct hits are a very unusual category of cycling accident.

- The SP Method, created specifically for the Hövding product, states:

The head protector does not offer protection in direct hit accidents and offers limited protection when the head protector has only partially reached inflated status prior to head impact. Also, the head protector offers limited protection against pointed objects.

The petitioner asserts that direct strikes are very unusual, and supported this assertion by submitting supplemental confidential materials regarding direct strikes. Upon review, staff finds that the submitted information focuses on too small of a subset of the larger injury spectrum caused by direct strikes, and does not appropriately depict the frequency of these events. Staff has shown that these events−direct strikes while on the bicycle, as well as direct strikes occurring between the time of a rider falling and striking the ground−are far more frequent than the petitioner states (TAB B, Table(s) 2 & 3). Staff notes that many objects in an urban environment may cause a direct hit to the head: bus, truck, SUV mirrors, and open doors; bridge abutments; telephone, light, and other poles; trees and tree limbs; structures, such as mail boxes, sculptures, and bus stop shelters; pedestrians and bicyclists themselves; vendor carts; and traffic control, parking, and advertising signs, are just a few of the many common hazards that could be considered "direct hits."

Impact with objects, and object intrusion while cycling, are the modes by which many severe injuries can occur, including, but not limited to: skull fractures; severe brain injuries, intracranial injuries, or hemorrhaging from cerebral lacerations and contusions; subarachnoid, subdural and extradural hemorrhages; and lastly fatalities.

Health Sciences staff reviewed the NEISS bicycle-related head injuries, reported between 2013 and 2017, for incidents in urban environments and on the road, involving both direct hits and head impacts subsequent to falls onto objects above street/ground level. There were 617 NEISS incidents in this time frame, where a cyclist struck an object causing a direct hit with their head. Table 3 in Tab B describes the objects that the bicyclists hit in descending order of frequency. Staff believes that, in all of these situations, if the Hövding product were in use, the product may not have deployed in time to offer full protection from the impact or intrusion, and consequently, the incidents could have resulted in skull fractures and/or severe brain injuries.

An additional 161 NEISS incidents did provide detail about the object that the head struck after the consumer began falling from their bicycle. The objects that were impacted (in order of descending order of frequency): curb (45), handlebars of bicycle (22), vehicle (15), pole/post (15), wall (13), barrier/guardrail (8), stairs/steps/porch (8), mailbox/metal box/transformer (6), fence (4), railing (4), trash can/dumpster (3), table/chair (3), tree (3), pipe/faucet (2), planter (2); bicycle (1), bike rack (1), edge of pool (1), fire hydrant (1), lawn mower (1), park bench (1), ramp (1), and sewer drain (1). Staff believes that, due to the relative height of these objects, and the visual evidence and other supplemental information regarding the Hövding product's deployment latency, it is possible that the product would not deploy the airbag fast enough to prevent injury in these scenarios–which could result in skull fractures/or severe brain injuries with the Hövding product in use.

The petitioner states that it is unaware of any serious, lasting head injuries resulting from approximately 1600 incidents where the Hövding product's airbag deployed. Staff does not know what "serious, lasting head injuries" means. The petitioner did not provide any injury information from locations where the product is being used. Additionally, the petition does not mention any fatalities with the product. Staff cannot be sure that no fatalities have occurred with the product. Possibly, first responders and/or family members may not be aware of the Hövding product, or be able to recognize it, particularly if the product failed to deploy, was removed by first responders, or otherwise, was not recovered after the accident.

After evaluating the limitations of the Hövding product, and based on the information submitted by the petitioner, staff has determined from an injury-mitigation standpoint, that the Hövding product is unlikely to afford head protection from many foreseeable scenarios, including many bicycling injury scenarios found in NEISS, when worn in an urban environment. Accordingly, staff concludes that the product cannot be considered a suitable alternative to a helmet that meets part 1203.

C. Human Factors Analysis

Human Factors staff considered issues related to the use of the Hövding product, such as the fit of the product, its potential use by children, differences between cycling in the United States and Europe, and the product's lights and audio signals. The memo at Tab C provides an in-depth review of CPSC staff's human factors analysis.

1. Potential Use by Children

The petitioner states that the product is intended only for ages 15 and older; however, consumers may not make this same assumption. Moreover, this information is not communicated to the consumer on the Hövding home page, nor on the "shop" page of the product website. The Hövding product accommodates three different neck sizes: Small (<36 cm), Medium (34-42 cm), and Large (38-45 cm). Human Factors staff determined the lower bound for the small size as 28 cm, using the upper bound as 36cm, and based on the ranges of the other sizes (± 3.5 cm). An anthropometric study (Snyder 1977) of U.S. children ages 2–19 years found that children as early as age 7.5 -8.5 years (95th percentile) have neck circumferences larger than the 28 cm assessed by staff. The subject's average neck circumference consistently exceeded 28 cm from ages 10.5 to 11.5 years, and at ages above 13.5 years – 95 percent or more of the neck circumferences measured in the study were greater than 28 cm. Additionally, statistics from the National Institute of Diabetes and Digestive and Kidney Diseases shows a significant increase in obesity rates among the U.S. population since the 1960s for both adults and children. Studies conducted by the North American Journal of Medical Sciences found that neck circumference displays a strong positive correlation with Body Mass Index (BMI) and other indicators of obesity. Given the increases in obesity rates and average body weight in both children and adults in the United States, along with the correlation between neck circumference and other indicators of obesity, staff believes that children of today are more likely to reach neck circumferences of 28 cm or greater at ages younger than defined by the 1977 Snyder study.

The anthropometric data, in conjunction with multiple obesity studies, shows that U.S. children as young as 7.5 – 8.5 years could meet petitioner's minimum neck circumference requirements to wear the device.

The petitioner claims on their website and in their user manual that Hövding selected the age range because the deployment algorithm was designed based on the movement patterns of adults, noting that children moved differently than adults, both when cycling and on foot. This raises additional concerns that the petitioner does not address in its submissions. The age group of children from 7.5 (or potentially younger) to age 15 may not be suitably protected by the device, but they have the same anthropometric values to wear the Hövding product. The product is activated by a zipper and snapping a magnetic button. Although gross and fine motor control develops throughout childhood, and at the ages described, the actions required to activate the product can be performed by children in this age range. As an example, school-age children often use zippers and snapping buttons on items such as jackets or pants.

2. Cycling Environments

Cycling environments between the United States and the environment Hövding in which the product was developed, hold significant differences. Copenhagenize Design Company releases a biennial index of the 20 most bicycle-friendly cities in the world, based on factors such as bicycle culture, bicycle infrastructure, perception of safety, social acceptance, urban planning, and political climate. For 2017, 18 of the cities listed on the index were in European countries, while no U.S. cities were included.[8] Since the list's inception in 2011, only four U.S. cities have made the rankings; New York City, San Francisco,

[8] The Copenhagenize Bicycle-Friendly Cities Index 2017. (n.d.). Retrieved from http://copenhagenizeindex.eu/

and Portland in 2011; Minneapolis in 2015, with no city ever making the rankings more than once. From this staff concludes that the United States possesses, on a global scale, less friendly and less forgiving scenarios for bicyclists, based on the same factors. Staff is concerned that U.S. bicyclists may exhibit riding behaviors different from European bicyclists, and this could affect how the Hövding algorithm would function when used by U.S. consumers.

3. Visible and Audible Signals

The Hövding product uses both visual and audible signals to indicate its status. The lights, located on the collar below the head, may not be easy to check while riding. Thus, users must rely instead on the audible signals only. For audible signals to be effective, the user must be able to distinguish the various signals. According to the user manual, the Hövding product uses distinct signals for the following alerts:

- Power on: ascending tone in three steps;
- Power off: descending tone in three steps;
- Low battery: two short beeps, recurring every 5 minutes until critical battery level is reached;
- Critical battery: low battery signal 10 consecutive times, followed by power-off signal to indicate that product is off.
- Product fault: loud, long signal that Petitioner states is hard to mistake for other sounds; followed by power-off signal to indicate that product is off.

The petitioner did not provide a sample to staff, and therefore, staff was unable to verify the distinct nature of each tone. However, since the product is intended for urban cycling, these signals must be loud enough to hear over the noise associated with urban environments. Results of a study of street noise levels in New York City showed that the sound pressure levels ranged from 55.8 dBA (noise level of conversational speaking) to 95.0 dBA (noise level of Boeing 737 aircraft at one nautical mile) with an average noise level of 73.4 dBA (noise level of typical consumer-grade vacuum).[9] This study also showed a strong correlation between noise levels and density of vehicular traffic. The petitioner provided no information on the volume of the Hövding product's audio signals; nor has staff found any readily available information or any performance requirement in the SP Method. Staff is concerned that users may not be able to detect these audio signals reliably, especially in urban areas with high vehicular traffic density, which could create potentially hazardous scenarios. If the product powers off and the rider does not hear the signal, the rider would not know to stop cycling, and would be cycling without any head protection.

4. Other Concerns

Given the concerns discussed, Human Factors staff does not believe that Hövding has provided sufficient information in its petition request for CPSC staff to assess the safety and efficacy of the Hövding product, compared to traditional bicycle helmets. Staff notes that the Hövding product will likely appeal to some consumers as a more fashionable, convenient, or comfortable alternative to traditional helmets. However, staff does not have data to determine to what degree, this would lead to more riders wearing the airbag helmets, compared to traditional helmets. Staff has the following additional concerns, which are discussed in the memo at TAB C: recharging options, as a USB wall adapter is not included with the device; whether the product can be activated without zipping the collar; will extreme hairstyles impede inflation of the airbag due to the bulk, volume, or stiffness of the hairstyle (*e.g.* locked hair, Mohawks);

[9] Mcalexander, T. P., Gershon, R. R., & Neitzel, R. L. (2015). Street-level noise in an urban setting: Assessment and contribution to personal exposure. *Environmental Health*, *14*(1). doi:10.1186/s12940-015-0006-y

how to use the product in conjunction with cargo bikes, baskets, and others means of transporting items; users deactivating the product; and falling objects.

D. Incident Data

Using CPSC databases, Division of Hazard Analysis staff reviewed bicycle incidents involving head injuries to understand the severity and magnitude of the hazard. The memo at Tab E provides a more in-depth discussion of CPSC staff's review.

Because the Hövding product (or similar airbag helmets) is not available to the U.S. market, CPSC does not have associated data for this specific product in any of CPSC's epidemiological databases, the Consumer Product Safety Risk Management System (CPSRMS), and the National Emergency Injury Surveillance System (NEISS); moreover, the petitioner did not provide any data from other countries. As such, CPSC staff cannot assess the Hövding product's potential for injury prevention or injury reduction, based on incident data. Staff would be able to discern whether a trend exists in reported injuries or fatalities. Staff did not find such a trend.

1. Annual Injury Estimates

CPSC staff conducted an annual assessment of injuries, with a range starting from the last major revision of part 1203, to the date Hövding submitted the petition. From 2013 through 2017, CPSC staff estimates a total of 380,500 emergency department-treated head injuries associated with bicycles with a 95 percent confidence interval (C.I.) ranging from 275,000 to 485,900 (Tab E: Table 1). Staff also estimates that the bulk of the injuries (67%) are in the age group of 15 years and older (Tab E: Table 2).

From these yearly estimates, for head injuries associated with bicycles, staff found no statistically significant, increasing or decreasing linear trend.

2. Reported Deaths

CPSC staff is aware of 925 fatalities involving bicycle head injuries that were reported to have occurred from 2013 through 2017.[10] The majority of victims were in the age group 15 years and older. *See* Tab E: Table 3.

E. Market Information and Other Economic Issues

Economic Analysis staff reviewed market information about the Hövding product, the U.S. helmet market, and societal costs of bicycle-related head injuries and deaths in the United States. The memo at Tab D provides a more in-depth review of CPSC staff's review of these economic issues.

The petitioner asserts that their product is sold in 16 European markets and Japan, identified as: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Great Britain, Ireland, Japan, Netherlands, Norway, Slovakia, Spain, Sweden, Switzerland, and Turkey. The petition states that the company sold more than 60,000 units since its inception in 2005, but the company's website currently states that, since its inception in 2005, the company has sold more than 130,000 units. If accurate, this suggests that more

[10] Staff's summary of information on these fatalities is based on anecdotal data (CPSRMS) collected from reports of incidents received by the CPSC from various sources. Staff's summary does not represent a complete set of all incidents that may have occurred; nor do the data constitute a statistical sample representing all fatalities with head injuries for bicyclists. Staff's summary represents a minimum count for the number of deaths from bicycle-related head injuries.

than half of Hövding's sales were in 2018, indicating a significant uptick in sales over the last year. The submitted petition did not provide a market assessment or market research; however, staff would find the comparison of sales between the Hövding product and traditional clam-shell style helmets very useful in its assessment.

The Hövding product retails for 299 EUR on the company's website, which is the equivalent of $340 USD.[11] However, some retailers were offering lower prices for the Hövding product, such as 219 EUR, or approximately 250 USD.[12,13] If the Hövding product inflates or deploys, whether due to the bicyclist being involved in a crash or in error (there are instances of the helmet inflating when a user puts on a jacket or makes other quick movements), the product must be replaced. In most European countries, Hövding offers a Crash Replacement Program that provides a discount for a new Hövding product. The replacement cost is quoted as being 99 EUR on some websites, or approximately 110 USD.[14,15]

1. *U.S. Helmet Market*

Staff's analysis found that the average retail price of standard bicycle helmets in the United States is $116, significantly lower than the cost of the Hövding product ($340)[11], based on a search of the 24 most popular helmet brands in the U.S. market. This value likely could be lower if we knew the number of units sold, by model, or brand, because it is plausible that a greater number of lower-cost helmets are sold in the U.S. market. The lowest-cost helmet found was $25, and the highest was $400. The majority of helmets identified in this analysis were under $200. Thus, the Hövding product would be more expensive than most helmets in the U.S. market, but may provide some unique features that might appeal to some consumers who are willing to pay the higher price.

2. *Societal Costs of Bicycle-Related Head Injuries and Deaths*

As discussed in Tab E, the societal costs of bicycle-related head injuries are high, approximately $20.8 billion a year. However, staff is unable to determine whether or how allowing an exemption for the Hövding product would affect these costs. If the Hövding product is effective in mitigating the severity of some head injuries for some bicycle riders who reject or resist wearing the standard bicycle helmets, but would wear the Hövding product, then an exemption could reduce the societal costs associated with bicycle head injuries. Alternatively, if the Hövding product is not as effective as the standard helmets, and some bicyclists who are now wearing the standard helmets switch to using the Hövding product, there is potential for a rise in societal costs. The impact on societal costs would be uncertain if the Hövding product is found to be more effective in some scenarios and less effective in others. Additional information on the effectiveness of the Hövding product at mitigating head injuries, relative to the effectiveness of helmets that meet the bicycle helmet standard, coupled with the likelihood that people would choose to use the Hövding product, is needed before staff can make any conclusions regarding the potential impact on societal costs.

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[11] Prices, exchange rate and website were accessed on February 4, 2019.
[12] http://www.cloud9cycles.com/hovding/
[13] https://voltbikes.co.uk/electric-bike-helmet.php
[14] http://www.cloud9cycles.com/hovding/
[15] https://www.theguardian.com/technology/2015/jun/15/hovding-inflatable-bicycle-helmet,

F. Public Comments

The memo at Tab F provides an in-depth review of CPSC staff's response to comments on the petition.

CPSC published a request for comments on the petition in the *Federal Register* on March 9, 2018, with a comment period ending on May 8, 2018. The Commission received forty-eight (48) comments. Many of the consumer commenters expressed support for the petition, with some substantive comments from experienced users and self-proclaimed avid cyclists. These commenters generally expressed the belief that the Hövding product provides better protection from falls and impacts than a traditional helmet. Many of these commenters mistakenly believe that the Hövding product is tested to the European standard. Comments from industry experts, such as the Bicycle Helmet Safety Institute (BHSI), and the Bicycle Product Suppliers Association (BPSA), did not support the petition, stating that granting the requested exemption would potentially lower safety standards through the alternative test method, and that any alternative test method should follow the typical guidelines of public standard development (*i.e*. round-robin evaluation, evaluation from standards committees). Industry commenters state that the SP Method does not give the same level of protection and is not equivalent in its severity as part 1203. One commenter substantiated the claim made by Hövding that they would prefer to use the Hövding product rather than a traditional helmet because they would be more likely to wear it due to its freedom; staff however, is unable to substantiate this claim because the product is not sold in North America. In addition, one commenter discusses how the Hövding product could be tested to the existing federal regulation with only slight modifications. This same commenter also presented information from partial testing conducted by a French consumer advocacy publication, *Que Choisir*, and published by the Swedish Association of Consumers magazine, *Råd & Rön*, stating that when the Hövding product was tested to international standards, the Hövding product did not pass, and the results were considerably worse than traditional bicycle helmets (Råd & Rön, 2014).

III. Commission Options

A. Grant the Petition

If, based on the information provided by the petitioner and contained in this briefing package, the Commission concludes that the petition submitted sufficient evidence that the SP Method is likely equivalent to, or more stringent than, part 1203, and that airbag helmets tested to the SP Method can likely address the risk of injury or death associated with bicycle crashes as effectively as helmets tested to part 1203, the Commission may grant the petition and direct staff to develop an advance notice of proposed rulemaking (ANPR), or a notice of proposed rulemaking (NPR), to revise part 1203 to include an exemption for airbag helmets from part 1203, if such helmets meet the SP Method.

B. Deny the Petition

If the Commission concludes that the available information does not support a finding that the SP Method is equivalent to part 1203, and that airbag helmets tested to the SP Method are not likely to provide a similar level of protection from head injuries or death associated with bicycle crashes as effectively as helmets tested to part 1203, the Commission may deny the petition.

Even if the Commission denies the petition, the Commission can direct the staff to work with the petitioner through a voluntary consensus standard development organization to address the issues discussed in the briefing package regarding the SP Method.

C. Deferring Decision on the Petition

If the Commission concludes that there is insufficient information to make a decision on the petition and wants additional information or staff work before deciding whether to grant or deny the petition, the Commission could defer its decision and direct staff to obtain the additional information or perform the additional work. The Commission could set deadlines for staff to provide updates on the progress of its work. Ultimately, the Commission must decide whether to grant or deny the petition.

IV. Conclusion & Staff Recommendation

Staff recommends that the Commission deny Petition CP-18-1. Staff does not recommend beginning rulemaking to exempt this product from the requirements in part 1203. The petitioner did not provide evidence that the product can meet an equivalent standard capable of matching or exceeding the safety specifications set by part 1203.

The petition lacks evidence to support several of the petitioner's claims. Specifically, the petition fails to provide evidence that the SP Method is an equivalent or more rigorous standard than current regulation and that the Hövding product, and airbag products of a similar nature, intended to protect the head during cycling, can provide equivalent or more protection in the same areas as a standard helmet that meets 16 CFR part 1203. Staff finds that many of the supporting documents and studies presented by the petitioner hold promise for airbag helmets like Hövding's. However an appropriate test method for such products must address staff's concerns about the lack of documented protection from several foreseeable risks addressed by part 1203. A standard that is developed through the consensus standards process might be able to address these concerns, and staff intends to raise these concerns with ASTM to determine whether technological advances, such as airbag products, can be addressed in the appropriate voluntary standard.

References

European Committe For Standardization. (2012). *EN 1078:2012+A1:2012, Helmets for pedal cyclists and for users of skateboards and.*

Folksam. (2015). *Bicycle helmet test.*

Mehmet Kurt, K. L. (2017). Modeling and optimization of airbag helmets for. *Annals of Biomedical Engineering*, 1148-1160.

Petition of Hövding Sweden AB, CP18-1 (12 15, 2017).

Råd & Rön. (2014, 09 06). *Uppblåsbara cykelhjälmen klarar inte säkerhetsstandarden [Inflatable bicycle helmet does not meet the safety standard]*. Retrieved from Råd & Rön: Utges av Sveriges Konsumenter: https://www.radron.se/artiklar/Uppblasbara-cykelhjalmen-klarar-inte-sakerhetsstandarden/

SP Technical Research Institute of Sweden. (2014). *SP-method 4439, Inflatable head protective devices with electronic.*

TAB A: Engineering Analysis of Petition CP 18 – 1

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: July 26, 2019

TO : Brian Baker, Mechanical Engineer, Project Manager
Division of Mechanical Engineering, Directorate for Laboratory Sciences

THROUGH : Andrew G. Stadnik, Assistant Executive Director, Laboratory Sciences
Michael Nelson, Director - Division of Mechanical Engineering

FROM : Vineed Dayal, Mechanical Engineer
Division of Mechanical Engineering, Directorate for Laboratory Sciences

Ian Hall, Mechanical Engineer
Division of Mechanical Engineering, Directorate for Laboratory Sciences

SUBJECT : Engineering Analysis of Petition CP-18-1, Regarding an Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

I. SUMMARY

U.S. Consumer Product Safety Commission (CPSC) Division of Mechanical Engineering, Directorate for Laboratory Sciences staff prepared this memorandum in response to a petition submitted by Hövding Sweden AB (Hövding or petitioner). The petition requests that CPSC "exempt inflatable head protective devices for bicyclists from the requirements of 16 CFR part 1203, the bicycle helmet standard, if those devices meet the requirements of SP-method 4439 and are so certified."[16]

Upon review of the information submitted by the petitioner, staff concludes that SP-method 4439 (SP Method), is overall less stringent than the U.S. mandatory bicycle helmet regulation codified in 16 CFR part 1203 (part 1203) and that testing to the SP Method represents a lower level of safety. Specifically, staff concludes that:

- The SP Method is not equivalent to part 1203 because the SP Method:
  - does not require 3 of the 4 required performance tests in part 1203;
  - does not require impact attenuation testing on a hemispheric anvil, as required in part 1203;
  - requires lower rates of speed for impact attenuation testing than part 1203;

[16] (Petition of Hövding Sweden AB, 2017, p. 5).

- o requires the majority, potentially all, samples tested to be substantially modified, prior to testing, versus off-the-shelf testing required in part 1203; and
- o does not contain sample conditioning and other performance and labeling requirements equivalent to part 1203, as described here.

Staff is also concerned that the SP Method does not contain a full system test to ensure the airbag inflates appropriately during a crash scenario (*i.e*., inflates to an adequate level of pressure and thickness in time to provide head protection at impact). Finally, staff states that the SP Method was developed by a test institute in Sweden. It is not a consensus-based standard, so it did not benefit from stakeholder input in the manner that benefits standards created through voluntary consensus processes.

The two studies provided by the petitioner as evidence of product performance did not provide adequate data demonstrating that inflatable head protective devices for bicyclists, such as the Hövding product, afford an equivalent level of head protection as traditional bicycle helmets that meet part 1203. Furthermore, Hövding did not present sufficient evidence to demonstrate that initiating a rulemaking to exempt the Hövding product from part 1203 and allow adherence to the SP Method would not decrease safety, because the SP Method is less stringent than part 1203, and it could negatively affect consumer safety.

The Hövding product is not currently available in the U.S., and the petitioner did not provide product samples for examination and testing; nor did the Petitioner provide public information detailing how to conduct the testing described in the SP Method. Without samples to test or testing videos to evaluate, engineering staff focused on comparing the SP Method to part 1203, and reviewed the studies attached to the petition. Below we analyze and compare the SP Method to part 1203, and provide a technical analysis of the studies attached to the petition.

II. BACKGROUND

A. Hövding product - "inflatable protective headgear for bicyclists"[17]

According to the petition, the Hövding product is an airbag for cyclists, designed to protect a bicyclist's head while riding in an urban environment. The Hövding product is worn around the neck like a collar and is intended for use by cyclists of ages 15 years and older. The product detects the user's movements, and when the system determines an accident is occurring, the airbag deploys out of the collar and around the user's head. The product's airbag is deployed by a gas canister inside the collar that fills the airbag with helium gas. The Hövding product is charged via USB, and the battery provides up to 9 hours of active usage time. According to the petition, approximately 60,000 Hövding products have been sold in the European and Japanese markets, and the company is aware of approximately 1600 deployments.

The petition states that the Hövding product will entice more bicyclists to wear head protective devices due to the product design: it is worn around the neck, instead of on the head. The petition states: "[T]here are ample testing and experiential evidence that the Hövding product provides significantly superior head protection to that provided by helmets that do comply with the U.S. standard."[18] Hövding cites performance data from two studies as evidence that the Hövding product is more protective than helmets that conform to the U.S. mandatory standard. Finally, the petition states that the SP Method is more stringent than the mandatory standard for bicycle helmets, which is codified in part 1203.

[17] (Petition of Hövding Sweden AB, 2017, p. 1).
[18] (Petition of Hövding Sweden AB, 2017, p. 1)

The petition states that because the scope in part 1203 includes any headgear intended to provide protection to the head while riding a bicycle, the Hövding product cannot be sold in the United States because it is unable to meet the current bicycle helmet regulation in part 1203. The petition asserts that the Hövding product cannot be subjected to the required tests in part 1203, due to its inherent design as an inflatable product worn as a neck collar. In addition, the petition states that several local governments require cyclists to wear a helmet that meets part 1203, which is another barrier for many potential users.

B. US Regulation Overview: 16 CFR Part 1203 – Safety Standard for Bicycle Helmets

The purpose of the U.S. mandatory standard for bicycle helmets is "[. . .] to reduce the likelihood of serious injury and death to bicyclists resulting from impacts to the head." 16 CFR § 1203.2. CPSC began rulemaking pursuant to the 1994 Children's Bicycle Helmet Safety Act (CBHSA), when Congress directed the CPSC to issue a rule that addressed hazards associated with bicycle helmets, including helmets coming off the head and risks of injury to children. The CBHSA required that bicycle helmets manufactured after March 16, 1995 conform to at least one of the following interim safety standards: (1) The American National Standards Institute (ANSI) standard designated as Z90.4– 1984, (2) the Snell Memorial Foundation standard designated as B– 90, (3) the ASTM (formerly the American Society for Testing and Materials) standard designated as F 1447, or (4) any other standard that the Commission determines is appropriate. 15 U.S.C. § 6004(a)–(b).[19]

The Act directed CPSC to begin a proceeding under the Administrative Procedure Act, 5 U.S.C. 553, to: (a) Review the requirements of the interim standards described above and establish a final standard based on such requirements; (b) Include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders; (c) Include in the final standard provisions that address the risk of injury to children; and (d) Include additional provisions as appropriate. 15 U.S.C. 6004(c). The Commission developed part 1203 by reviewing the bicycle helmet standards identified in the statute, as well as international bicycle helmet standards, and draft revisions of the ANSI, ASTM, and Snell standards that were then under consideration. The Commission went through two rounds of comments on the proposed standard, and then issued a final rule for bicycle helmets on March 10, 1998, codified at 16 CFR part 1203. 63 *Fed. Reg*. 11,712 (Mar. 10, 1998).

The CBHSA provided that the final Bike Helmet Standard "shall be considered a consumer product safety standard promulgated under the Consumer Product Safety Act." *Id.* § 6004(d). Pursuant to section 14 of the CPSA, and Subpart B of part 1203, all bicycle helmets imported or sold in the U.S. must be tested and certified to part 1203.

Section 1203.4(b) of the regulation defines a Bicycle Helmet as "[. . .] any headgear that is either marketed as, or implied through marketing promotion to be, a device intended to provide protection from head injuries while riding a bicycle." To address the risk of death and head injuries associated with riding a bicycle, part 1203 contains the following seven major requirements briefly described below. Appendices I, II, and III provide detailed information on the performance requirements for each provision of part 1203.

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[19] On March 23, 1995, the Commission published its determination that five additional voluntary safety standards for bicycle helmets are appropriate as interim mandatory standards. 60 FR 15,231. These standards are ASTM F 1447– 1994; Snell B–90S, N–94, and B–95; and the Canadian voluntary standard CAN/ CSA–D113.2–M89. In that notice, the Commission also clarified that the ASTM standard F 1447 referred to in the Act is the 1993 version of that standard.

Labels and Instructions (1203.6)

- A visual examination that requires helmets be accompanied with the necessary instructions and include certain labels on the helmet.

Construction (1203.5)

- A visual examination that ensures projections (features extending out from shell of helmet) on the helmet will not cause additional harm during a collision.
- This test requires all *exterior* projections exceeding 7 mm on the helmet to break away or collapse in a collision. It also requires any *interior* projections in the helmet to be less than 2 mm.

Peripheral Vision (1203.14)

- A visual examination that requires helmets to allow a field of vision of 105 degrees on the left and right sides of center.
- [Additional info to mimic cover memo needed]

Positional Stability (1203.15)

- A performance test that ensures the retention system's (*e.g*. chin strap or otherwise) effectiveness against allowing the helmet to "roll off" the head.
- This test involves applying a dynamic impact load to the front and rear edges of the helmet positioned on a headform according to the manufacturer's instructions.

Dynamic Strength of Retention System (1203.16 & 1203.8)

- A performance test that ensures the retention system (*e.g*. chin strap or otherwise) is strong enough to prevent breakage or excessive elongation that could allow a helmet to come off during an accident.
- This test involves applying a "shock load" (*i.e*. a sudden application of force) to the retention system. The retention system must remain intact and not elongate more than 30 mm. This test is applied to four helmets, each conditioned in one of the following environments: ambient, hot, cold, or wet.

Impact Attenuation (1203.17 & 1203.8)

- A performance test to ensure that helmets can provide adequate impact protection in a collision while riding a bicycle.
- This test involves securing the helmet on an appropriately sized headform and dropping the helmet to achieve specified impact speeds onto three types of fixed steel anvils (flat, hemispherical, and curbstone). These anvils represent shapes of surfaces that may be encountered in actual riding conditions. The helmet must provide protection at all points within a required coverage zone that is specific to the headform size. The peak headform acceleration of any impact sustained during the test shall not exceed 300 g for any helmet. Helmets are to be tested in any allowable "worst case" combination of the following parameters: impact location, anvil impact order, anvil type, and conditioning environment.

Certification & Recordkeeping (Subparts B & C, 1203.30 to 1203.41)

- The regulation requires all helmets sold in the U.S. to include certification to a "reasonable test program." This program must be equivalent or more stringent than the regulation.
- The regulation requires every entity issuing certifications of compliance for bicycle helmets to maintain records that show that certifications are based on a reasonable testing

program. All records must be maintained for at least 3 years, and must be provided to the Commission within 48 hours upon request.

In the review conducted as part of this briefing package, staff reaffirmed the value of these requirements.

C. U.S. Voluntary Standard Overview: ASTM F1447 – Standard Specification for Helmets Used in Recreational Bicycling or Roller Skating

ASTM F1447, *Standard Specification for Helmets Used in Recreational Bicycling or Roller Skating*, is a voluntary standard developed and maintained through industry and stakeholder consensus, and is very similar to the requirements of part 1203. While part 1203 has not been recently updated, ASTM F1447 has been revised as recently as June 2018. Accordingly, part 1203 sets a regulatory floor for bicycle helmet safety in the U.S.

D. EU Standard Overview: DIN EN 1078 Helmets for pedal cyclists and for users of skateboards and roller skates

DIN EN 1078, *Helmets for pedal cyclists and for users of skateboards and roller skates*, is the European Union standard for bicycle helmets. The standard is a primary method used by the E.U. to certify safety and that helmets meet the EU directive 89/686/EEC for Personal Protective Equipment.

Appendix III details the differences in testing between part 1203, EN 1078, and the SP Method. Although many of the tests in EN 1078 are similar to part 1203, EN 1078 contains a number of major differences from part 1203 requirements. Most importantly, for impact testing, EN 1078 requires lower impact speeds, and does not include hemispherical anvil impacts. The hemispherical anvil has often been associated with worst-case impact scenarios.

III. ANALYSIS OF THE SP METHOD

1. Background

The petition notes that inflatable head protective devices with electronic triggering systems are outside of the scope of the European Union's general helmet standards, EN 1078.[20] The petition explains that the SP Method was developed by the SP Technical Research Institute of Sweden (incorporated into RISE – Research Institutes of Sweden) and was intended to meet the general requirements of EU Directive 89/686/ECC applicable to all personal protective equipment sold in the E.U. Meeting the directive's requirements allows products to be sold with the "CE" mark, but it does not certify a specific product's functional safety performance, nor does it require testing to relevant European Standards.[21] [22] The SP Method is a test method; it is not a European standard.

In a phone meeting,[23] RISE indicated to CPSC staff that the SP Method was designed to meet applicable provisions of EN 1078, and that U.S. bicycle helmet test requirements were not taken into account

[20] The scope of EN 1078 covers "protective helmets" which is defined according to the standard as an "item to be worn on the head…." (European Committe For Standardization, 2012, p. 5)
[21] (Petition of Hövding Sweden AB, 2017, p. 4)
[22] (Folksam, 2015, p. 4)
[23] Insert citation to phone conference with RISE and the meeting log.

throughout the development of the SP Method. The scope of the SP Method states that it is not directly equivalent to EN 1078:

> [T]his method is applicable to performance requirements and tests for Inflatable head protectors for pedal cyclists. The standard for helmets for bicyclists, EN 1078 has been considered during the development of this test method but requirements and test methods have been developed that are not covered by EN 1078 since inflatable head protectors are outside the scope of that standard. Some requirements from EN 1078 are not applicable to an inflatable head protector, *i.e*. retention system properties and field of vision because in normal use the protector is not inflated. The head protector is not intended for use during mountain biking or competition. The head protector does not offer protection in direct hit accidents and offers limited protection when the head protector has only partially reached inflated status prior to head impact.[24]

Accordingly, the SP Method is not equivalent to EN 1078, and furthermore, as reviewed above, EN 1078 is not equivalent to the U.S. standard, part 1203. Most importantly, this shows that the SP Method does not demonstrate protections that a helmet that conforms to part 1203 will protect against from a range of foreseeable hazards including direct hit accidents and impacts when the head protector has only partially reached inflated status prior to head impact.

2. Requirements of the SP Method

Appendices I, II, and III compare the performance requirements in the SP Method with those in part 1203 and EN 1078. Comparisons in Appendices I and II demonstrate that the SP Method does not contain three of the four performance tests included in part 1203 and EN 1078, including peripheral vision, positional stability, and dynamic strength of retention. The SP method and other national standards only share impact attenuation as a common feature. *See* Appendices I and II. The petition maintains that these tests are not applicable to an airbag product because the product is worn around the neck, and not on the head. CPSC staff questions whether the same, or similar, performance requirements could address the same, or similar, concerns with a product worn around the neck that inflates in a crash scenario. Without data, CPSC staff does not know whether peripheral vision, either before or after airbag deployment, could be a concern to riders in a crash scenario or in a non-crash deployment. Additionally, without data, CPSC staff does not know whether a product that is worn around the neck stays on the rider and maintains its position during riding, and upon deployment, such that the rider's head remains protected in the event of a crash. Hövding provided no information, incident data, or test data to adequately demonstrate or support the statement that these three requirements in part 1203 and EN 1078 are never applicable to an airbag product worn around the neck.

The SP Method includes a test for impact attenuation, the details of which are contained in Appendix III. Impact testing is the most significant test for helmets, because the test determines if the product absorbs enough of the impact energy to protect the head from skull fractures and death. Appendix III provides an in-depth, side-by-side analysis of the impact attenuation requirements in part 1203, the SP Method, and EN 1078. The analysis is based on the information available and CPSC staff's current interpretations of each standard's test methodology.

[24] (SP Technical Research Institute of Sweden, 2014, p. 3)

The SP Method includes additional performance requirements specific to the Hövding product that do not exist in part 1203, testing, for example, the inflator, battery, sound, and durability of the product. *See* Appendix I.

Finally, Appendices IV and V provide a visual representation of staff's interpretations of the testing schedules according to part 1203 and the SP Method, in the form of flowcharts. The flowcharts demonstrate the testing process chronologically and simplify the complexity of the numerous relations between samples, environmental conditions, modifications, and tests completed in each test methodology.

E. Comparison of Part 1203 with the SP Method

The petition states that the Hövding product cannot meet either the European Standard for bicycle helmets, EN 1078, or the U.S. bicycle helmet regulation, part 1203, which is why Hövding is seeking the exemption from part 1203. Although staff agrees with the petitioner that part 1203 does not anticipate airbag helmet designs, Hövding failed to support the statement that its product cannot be tested to the provisions of part 1203 (perhaps with some modification) and provides "significantly superior head protection to that provided by helmets that do comply with the U.S. standard."

Although CPSC staff is encouraged that SP developed new testing methods for deployable airbag head protectors, based on a review of the SP Method and the limited information available, staff cannot conclude that the tests set forth in the SP Method adequately represent the dynamic and varied crash environments seen in the real world. Additionally, the SP Method differs from part 1203 regarding sample selection, sample conditioning, and impact testing. The SP Method requires fewer impacts, on fewer anvils, and at slower speeds (and therefore lower energy). Therefore, staff concludes that the SP Method is not equivalent to part 1203, and the petition does not provide evidence that products tested to the SP Method will provide an equivalent (or higher) level of safety as bicycle helmets that meet part 1203.

Below we set forth engineering staff concerns about the SP Method, and why the SP Method is not equivalent to part 1203.

1. SP Method Impact Attenuation Requirements do not require as high a level of protection as Part 1203

Although the petition claims the SP Method provides a higher level of protection than part 1203, sections of the SP Method that correspond to the sections in the current CPSC bicycle helmet regulation may result in significantly less protection. For example regarding impact testing, the petition states "the level of protection in the Swedish standard [the SP Method] is higher than that in the CPSC standard. For example, the CPSC standard [part 1203] specifies that the peak acceleration of any impact shall not exceed 300 g's while SP-method 4439 specifies that the peak acceleration does not exceed 250 g's."[25] However, peak acceleration limit is only one variable to be considered for impact tests and does not determine the level of severity of an impact test as a whole. CPSC staff concludes that the SP Method's impact test requirements are significantly less stringent than what is required by part 1203 for the following reasons. Although the methodology and equipment are similar to part 1203, all impact speeds required by the SP Method are significantly lower than speeds required by part 1203. The SP Method specifies a nominal flat anvil impact speed of 4.53 m/s in certain orientations, compared to the 6.2 m/s specified for the corresponding test in part 1203. Impact speed is important, because a lower impact speed reduces the overall energy and severity of a particular test. In other words, by reducing the impact

[25] (Petition of Hövding Sweden AB, 2017)

speed, the SP Method reduces the test's kinetic energy by 47 percent, as compared to part 1203. This reduced kinetic energy means that in certain test scenarios, the SP method is only impacting the sample half as hard as is required by the current CPSC regulation, which could be the difference between moderate to severe injuries.

Additionally, the SP Method test protocol for impacts is limited in other ways, as compared to part 1203. In SP Method section 5.5, *shock absorbing capacity*, testing is only completed on flat and kerbstone (curbstone) impact anvils, while part 1203 requires testing on a flat anvil, a curbstone anvil, and on a hemispherical anvil. The hemispherical anvil has often been associated with worst-case impact scenarios. The SP Method also limits the number of impacts allowed per sample to one impact or a maximum of two with the manufacturer's consent,[26] while part 1203 requires up to four impacts per sample.

The petition did not provide any scientific data to justify how the significant differences between the impact tests, including those discussed above, result in an impact test that provides an equivalent or higher level of safety as part 1203. Therefore, based on the available information and historical bicycle testing experience, CPSC staff concludes that the impact test required by the SP Method is less stringent than the current federal regulation, part 1203. *See* Appendix III.

2. The SP Method Does Not Include All Tests in Part 1203

The SP Method is not equivalent to part 1203 or EN 1078 because the SP Method does not include several tests in part 1203. This is stipulated by the petition, which states:

> The peripheral vision test (1203.14), the positional stability test (1203.15), the retention system test (1203.16) and the impact attenuation test (1203.17) cannot be applied to the Hövding because the airbag is not inflated until it is deployed in an accident. Indeed, by its very nature, the Hövding ensures no obstruction to the cyclist's peripheral vision during use. The positional stability and the retention system tests are not necessary because the non-deployed Hövding is worn around the neck, not on the head. Similarly, the impact attenuation test cannot be performed on an un-deployed Hövding.[27]

Engineering staff is not convinced that all of these tests are inapplicable to the Hövding product. If the test methods in EN 1078 or part 1203 are not applicable to the Hövding product, staff would expect that the SP Method would compensate for this by including another methodology to evaluate the unaddressed hazards (*e.g.* will the product stay on during an accident, will the user have the necessary field of vision post-deployment, *etc*.). Without justification that's supported by test driven data, staff cannot concur with the petition that the peripheral vision, positional stability, and retention system tests are not applicable to the Hövding product.

3. SP Method Sample Conditioning is Less Stringent than Part 1203

The SP Method test requires 3 to 6 dedicated samples to be modified and conditioned at ambient temperatures. Impact test samples are modified by removing the original gas inflator, installing means of inflating the product manually, and installing a pressure measuring device. In contrast, part 1203 requires all samples collected to be in the condition in which they are offered for sale, then conditioned to one of four environmental conditions (*i.e*., ambient, hot, cold, and water immersion) prior to any physical testing. Additionally, 5 of the 8 samples in part 1203 are not dedicated to impact testing only. Samples are

[26] (SP Technical Research Institute of Sweden, 2014, p. 11)
[27] (Petition of Hövding Sweden AB, 2017, p. 5)

first tested to peripheral vision, dynamic strength of retention, and positional stability testing before impact attenuation testing.

Testing samples that have been substantially modified rather than samples in the condition offered for sale significantly decrease the scientific relevance of the resulting data to the real world performance of the product. Because material properties and the performance of products are subject to change based on environmental conditions, testing to environmental conditions beyond the ambient condition provides a more accurate representation of a product's performance under potentially detrimental but realistic conditions the product may be exposed to during actual use. Although dedicating specific samples to only one individual test can provide specific technical data, it does not provide the same level of rigor or realistic performance as the compounding effects of sequential testing. Samples exposed to tests sequentially carry the imposed damage and conditions caused by previous tests into the future tests, the externality of this effect means each sequential test becomes more rigorous.

4. The SP Method Does Not Conduct A Full System Test

The SP Method does not include a full system test that integrates the dynamic performance of all the components and sub-systems (*e.g*. the sensors, the electronics, the algorithm, the inflator, the airbag). The testing described in the SP Method exercises each component of the product independently, like the shock absorbance, triggering system, and inflation system. The SP Method does not account for the incremental complexity and does not include a singular test that evaluates all the product's sub-systems in unison. Such discrete testing may not capture interdependencies between the device's sub-systems, and may not represent how the product will perform for consumers. In contrast, the impact attenuation testing in part 1203 tests a helmet as a full system. Without a full system test, staff cannot assess the product's performance in dynamic crash events, like those seen in the real world.[28]

5. The SP Method Is Not A Standard and Was Not Developed Through A Consensus Process

CPSC developed part 1203 through an official federal rule making process based on incident data, research, voluntary standards, and stakeholder input. In contrast, the SP Method was developed internally by a lone testing laboratory to meet a particular company's direction. It did not consider the current U.S. regulation.

6. The SP Method requirement for Pre-Test Sample Modifications may enable manufacturers to supply non-representative, "Golden Samples"

As previously described, the SP Method requires samples to be modified for specific tests (*i.e*., the samples are not off-the-shelf) and, therefore, may not adequately represent the products sold to consumers. In contrast, part 1203 requires that samples be in the same condition as those offered for sale to consumers, ensuring that the samples are representative of the wider consumer market. According to the SP Method, 18 of the 22 samples collected for testing must be modified prior to testing (the remaining

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[28] CPSC staff notes that the SP Method, the Stanford Study, and the Folksam Study all appear to test with a pre-inflated airbag. In contrast, the petition stated that the impact attenuation test is not applicable to the Hövding product, because "the airbag is not inflated until it is deployed in an accident." Therefore, CPSC staff is not convinced that a pre-inflated Hövding device could not be tested to part 1203 section 17.

4 may also be modified depending on the test methodology chosen by the test lab). For example, SP Method section 5.1, *Sampling*, states: "Samples 1-8 shall be head protectors without [a] gas generator but with means of inflating the head protector manually and the possibility to measure the pressure."[29] Staff also notes that without significant training by the firm, laboratory staff may not be able to complete some product modifications without damaging the product, altering the product's performance, or risking employee health and safety. Therefore, testing laboratories may need to request modified samples directly from the manufacturer. If all test labs must request modified samples directly from the manufacturer, CPSC staff would not be able to test samples independently, and staff may not be able to test specific manufacturing lots. In summary, staff is concerned that samples tested that do not represent off-the-shelf units bought by consumers, and that are potentially supplied directly from the manufacturer, may significantly affect the results of a performance test, and the results may not be representative of the product's performance in the real world.

7. The SP Method May Introduce Unacceptable Variability In Test Results

CPSC technical staff is concerned that the SP Method test methods are not described with sufficient specificity and may introduce unacceptable variability to the results. For example, SP Method section 5.9, *Evaluation of the function of the triggering system*, allows test labs to use a test dummy or a human subject to complete the test. According to section 5.9.1.2, the criteria for a human subject states, "The test persons shall have a height, weight, head circumference, and any other limitations in accordance with the manufacturer's instructions for use. Any test person(s) shall be selected by the test laboratory."[30] Results from the SP Method test methods are entirely dependent on several variables specific to the subject chosen, such as size, weight, anthropometry, cycling experience, movements, *etc*. Size, weight, and anthropometry, could determine how far the subject is thrown, or how hard of a fall the subject experiences. The subject's cycling experience could lead to better or worse instinctive responses, skewing the reproducibility from subject to subject. The reaction speed of the subject bracing themselves, to fall could produce variability that cannot be reproduced from one test lab to another. Variability in human subject testing plays a role, and possibly yields different testing results, introducing an unacceptable level of variability that would preclude validating results between test laboratories.

Such a lack of specificity in the test protocol introduces an unacceptable level of variability, especially in terms of reproducing and validating results between test laboratories.

IV. ANALYSIS OF THE STANFORD AND FOLKSAM STUDIES

The petition included two studies evaluating performance of an airbag helmet: a Stanford University Study titled *Modeling and optimization of airbag helmets for preventing head injuries* (Stanford Study); and a study funded by the Swedish insurance company Folksam, titled *Bicycle Helmet Test 2015* (Folksam Study).

A. Review of Petition Appendix A: Stanford Study *"Modeling and optimization of airbag helmets for preventing head injuries"*

The petition references the Stanford Study as evidence that the Hövding product provides a greater level of head protection than helmets that comply with part 1203. The petition quotes the Stanford researchers,

[29] (SP Technical Research Institute of Sweden, 2014, p. 11)
[30] (SP Technical Research Institute of Sweden, 2014, p. 17)

"This airbag helmet design almost completely eliminates the risks of severe head injury and fatality ...."[31] [32] Although, the petition does not directly claim equivalency between the testing done in the Stanford Study and part 1203, the petitioner does use the resultant data from the study to further substantiate their claims.

The Stanford Study focuses on optimizing the performance of an airbag helmet when dropped on a flat surface.[33] The Stanford Study begins by developing a mathematical model of an airbag contacting a flat rigid surface to show that it is theoretically possible for an airbag product to provide more protection than current helmet technology for specific boundary conditions (*i.e*., a crown and side head impact to a flat rigid surface at ambient temperatures). The Stanford Study validates the model with post mortem human subject testing and additional headform impacts.[34] Then, the researchers optimized the performance of the airbag system by changing the internal pressure and by varying the thickness of the airbag in their mathematical model.[35]

CPSC staff is encouraged by the theoretical safety improvements identified in the Stanford Study's mathematical model, but CPSC staff notes one methodological issue. Although the Stanford Study's researchers validated the mathematical model initially, the researchers did not confirm the results of their mathematical model through physical testing. Without validation of the model through actual testing of the product, CPSC staff cannot have high confidence that the mathematical model will truly predict the product's performance in real world crash scenarios.

The Stanford Study, as the researchers stated, is a "first attempt to optimize the design of expandable helmets," and may not be representative of real-world performance.[36] For example, the Stanford Study focuses on flat impacts to the crown (top) and side of the head but does not consider impacts to other locations on the head or on other impact surfaces. Furthermore, the Stanford researchers noted that airbag helmets may not perform well under certain environmental conditions, like the hot, cold, and water submersion tests required in part 1203. In addition, the researchers questioned how the airbag helmet would perform against sharper impact anvils - like the hemispherical, curbstone anvils listed in part 1203, or possibly surfaces that could result in puncture of the airbag.

The Stanford Study also notes that such a system is completely dependent upon the sensors and algorithm.[37] CPSC staff is concerned that if the sensor system mischaracterizes a crash event or is unable to sense a particular type of crash event quickly enough to deploy the airbag, the user will be left completely unprotected. Therefore, while CPSC staff is encouraged by the theoretical safety improvements identified in the Stanford Study, due to the limitations of the methodology, CPSC staff can only conclude that the Stanford Study provides a starting point for additional research on air bag helmets. Staff notes that the SP Method does not test whether the Hövding product achieves the pressure and thickness required to take advantage of the theoretical benefits identified in the Stanford Study.

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31 (Petition of Hövding Sweden AB, 2017, p. 3)
32 (Mehmet Kurt, 2017, p. 1)
33 The Stanford Study refers to the Hövding product as an "airbag helmet."
34 A headform is a standardized anthropomorphic device meant to emulate a human head of a specified weight and size for testing purposes.
35

Study refers to the amount of inflatable space in an airbag helmet as "material thickness."
36 (Mehmet Kurt, 2017, p. 7).
37 (Mehmet Kurt, 2017, p. 7).

Accordingly, the Stanford Study does not demonstrate that the protection afforded by the Hövding product is comparable to a bicycle helmet that meets part 1203.

B. Review of Petition Appendix B: Folksam Study – "*Bicycle Helmet Test 2015*"

The petition states that the Hövding product "reduce[s] the risk of concussions and severe head injuries"[38] and that the Folksam Study concludes that the Hövding product "showed the overall best result."[39] [40]

During the Folksam Study, Folksam tested 18 bicycle helmets, including various traditional bicycle helmets as well as the Hövding product, under four distinct impact conditions: a direct flat anvil impact and three impacts against an inclined (oblique) surface anvil designed to produce rotation about each axis of the helmet. During each of the drop tests, Folksam recorded the motion of the simulated human head inside each helmet. After completing the physical tests, Folksam sent the simulated head motion profiles to the Royal Institute of Technology (KTH), where KTH researchers used the simulated head motion profiles and a Finite Element brain injury model to estimate brain injury and concussion risk. The Folksam Study then ranked the helmets in order of safety. The results of the study indicate that, for the physical modes studied, the Hövding product produced the best results in terms of translational acceleration. In particular, the Hövding 2.0 airbag generated only 48g in the flat anvil test, approximately 70 percent to 80 percent less than the other helmets. A translational acceleration of only 48g is consistent with a skull fracture risk of less than 0.1 percent.[41] Additionally, the KTH brain injury simulation showed significantly lower brain injury metrics for the Hövding product, yielding less than a 50 percent risk of a concussion.

Although CPSC staff believes the results from the Folksam Study indicate the performance potential of inflated head protective devices in certain crash scenarios, staff has two main concerns with the testing methodology and its relevance to the petition request. First, the Folksam study only simulated a subset of potential real-world crash events. In particular, the Folksam Study included only flat and inclined impact surfaces. The Folksam Study did not include the hemispherical or curbstone anvils, which are included in part 1203 and according to CPSC historical data, can result in the most severe impacts. The Folksam Study researchers themselves noted that if the Hövding product were tested on a curbstone anvil, the product would need a hard outer shell to distribute the force across a larger area in order to provide similar levels of protection. In addition to testing on flat and angled anvil surfaces only, the Folksam Study helmets were tested at velocities substantially lower than what is required in part 1203 (*i.e.* the flat anvil impact speed required by part 1203 is 6.2 m/s, while the Folksam Study used 5.42 m/s). This means that the kinetic energy absorbed by the helmet in the Folksam study is significantly lower than part 1203, showing that the Folksam study testing is not equivalent. This also means that there could exist a range of injuries (moderate to severe) that are not covered by the Folksam study testing because of the reduced speed delivering less energy.

Second, the Folksam Study test method and preparation photos indicate that the Hövding product was pre-inflated prior to testing. CPSC staff does not have data on the airbag deployment process, and cannot assess the effectiveness of the sensors, the electronic control unit, the sensing algorithm, airbag deployment kinematics, or the performance of all the product's systems integrated together. Therefore,

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38 (Petition of Hövding Sweden AB, 2017, p. 3)
39 (Petition of Hövding Sweden AB, 2017, p. 3)
40 (Folksam, 2015, p. 1)
41 Nahum, A. M., & Nahum, A. M. (1993). Accidental injury biomechanics and prevention (pp. 89-102). New York: Springer.

CPSC staff cannot comment on how the Hövding product would perform in dynamic crash events, like those seen in the real world.

While CPSC staff is encouraged by the Hövding product's translational and rotational performance in flat and oblique anvil impacts, the Folksam Study did not conduct hemispherical or curbstone impacts as required by part 1203. In addition, the Hövding product appears to have been pre-inflated and tested under the assumption that the airbag deployed correctly and covered the consumer's head prior to contact. Therefore, the results of the Folksam Study cannot be considered to be representative of the product's expected real-world performance. CPSC staff concludes that the Folksam Study does not clearly indicate that the Hövding product provides a level of protection comparable to at least that of a bicycle helmet that meets part 1203.

V. CONCLUSION

Although CPSC staff is encouraged that SP developed new testing methods for inflatable head protective devices with electronic triggering systems for pedal cyclists, staff cannot conclude that those tests adequately represent the dynamic and varied crash environments seen in the real world, based on a review of the SP Method and the limited information provided by the petition. The development of the proposed SP Method was intended to specifically target European PPE requirements, and does not take into account the established U.S. bicycle helmet regulation.

CPSC staff concludes that the SP Method is not equivalent to the part 1203, because the methodology does not adequately consider the effects of environmental conditions the product may be used in, hazards addressed in the current CPSC helmet regulation, or currently accepted impact test speeds and anvils, *etc*. Moreover, the petition did not include adequate evidence to substantiate claims that the Hövding product will deliver an equivalent or improved level of safety as compared to bike helmets that meet part 1203.

Although the petition provided two studies showing good performance in a small subset of possible crash events, the petition did not include data demonstrating product performance with other likely crash events that are addressed in part 1203, nor did the petition include data or test provisions that evidence full scale testing of the product as it would be used by consumers.

TAB B: Health Sciences Analysis of Petition CP18-1, Requesting Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: July 26, 2019

TO	:	Brian M. Baker, Project Manager, Petition CP18-1 Division of Mechanical Engineering Directorate for Laboratory Sciences
THROUGH	:	Alice M. Thaler, Associate Executive Director, Directorate for Health Sciences Jacqueline N. Ferrante, Ph.D., Director, Division of Pharmacology and Physiology Assessment Directorate for Health Sciences
FROM	:	Jason R. Goldsmith, Ph.D., Physiologist, Division of Pharmacology and Physiology Assessment Directorate for Health Sciences
SUBJECT	:	Health Sciences Analysis of Petition CP18-1, Requesting Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

This memorandum responds to Petition CP18-1 from Hövding Sweden AB (petitioner), which requests that the Commission exempt "inflatable head protective devices for bicyclists," such as Hövding's product, from the testing requirements of the Safety Standard for Bicycle Helmets, if such product complies with, and is certified to, requirements in another standard that Hövding states is appropriate to test such products.

I. BACKGROUND

A. <u>The Product</u>

The Hövding inflatable head protective device for bicyclists (Hövding product) is designed to offer head protection for bicyclists age 15 years and over who ride in urban environments or on the road. The rechargeable, battery-powered product is worn around the neck, like a collar. Provided that it has been powered on by the user, and has sufficient charge, upon detecting abnormal movements on the part of the bicyclist, the Hövding product will inflate an airbag that covers most of the head once fully inflated, leaving the visual field unobstructed. Hövding states that the airbag inflates in 0.1 seconds and remains inflated for several seconds.

B. Consumer Product Safety Act – Safety Standard for Bicycle Helmets

In 1998, the Commission issued the *Safety Standard for Bicycle Helmets*, 16 CFR part 1203, pursuant to the Children's Bicycle Helmet Safety Act of 1994. The purpose of the Safety Standard for Bicycle Helmets (part 1203) was to reduce the likelihood of serious head injury and death to bicyclists resulting from impacts to the head. Part 1203 defines a bicycle helmet as "any headgear[42] that either is marketed as, or implied through marketing or promotion to be, a product intended to provide protection from head injuries while riding a bicycle." Part 1203 describes the test methods and defines the minimum performance criteria for all bicycle helmets. In brief, all bicycle helmets sold in the U.S. must be capable of meeting the requirements concerning peripheral vision, positional stability, dynamic strength of retention system, and impact-attenuation, as described in part 1203.

C. The Petition

The petitioner states that the Hövding product cannot meet the testing requirements of part 1203 and therefore requests exemption from the testing requirements. Specifically, the petitioner states that four tests (the peripheral vision test (1203.14), the positional stability test (1203.15), the retention system test (1203.16), and the impact attenuation test (1203.17)) cannot be applied to the Hövding product because the product's airbag is not inflated until it is activated in an accident.

The petitioner claims that the Hövding product is superior to bicycle helmets in its ability to prevent serious head injury and fatal injuries, and also reduces the incidence of concussion. Hövding provides two studies in support of these claims, which it maintains demonstrate the superiority of the Hövding product and its ability to provide a reduced risk of concussion, severe head injury, and fatal injury. Further, the petitioner claims that the proposed alternative test method, SP-method 4439[43], ensures that the Hövding product satisfies at least the same performance criteria as conventional bicycle helmets that meet part 1203.

The petitioner states that Hövding is aware of approximately 1600 incidents in which the Hövding product deployed, none of which resulted "in serious, lasting head injury," and only one incident in which the product did not deploy as expected; in this incident, the bicyclist is reported not to have suffered a lasting injury. Hövding did not provide information on incidents for Health Sciences staff to evaluate the validity of these claims regarding injury severity. The petitioner does not indicate whether there have been any fatalities associated with the use of the Hövding product.

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[42] Per Oxford Dictionary, headgear is defined as "Hats, helmets, and other items worn on the head."

[43] Per the petitioner, because the Hövding device is outside the scope of the European Union's standard for shell-type helmets, the SP Technical Research Institute of Sweden developed SP-method 4439 as an alternative standard for inflatable head protective devices so that such devices could be in compliance with the European Union directive for personal protective devices.

II. DISCUSSION

The petitioner states that the Hövding product cannot be tested to the Safety Standard because the product is not inflated, but, at the same time, provides two studies and an alternative test method, all of which inflate the product prior to testing. Also, petitioner asserts superior performance of the Hövding product without testing the product to the same impact attenuation testing as prescribed in part 1203 or using t the same velocities or anvils as used in part 1203. Consequently, CPSC staff cannot determine from the information Hövding provided what protection from impact the Hövding product may actually afford in the urban environment or on other road settings (i.e. suburban), and, specifically, what hazards the Hövding product is capable of protecting against.

Given the many uncertainties associated with the Hövding product, staff focuses this memorandum on what we know about the product with regard to injury protection and the injuries that are likely to occur associated with its use. Staff places special emphasis on those conditions where it appears that the product may be incapable of affording protection against head injury.

A. Known Limitations of the Product

Clearly, the Hövding product cannot afford any head protection in those circumstances where the product fails to deploy its airbag, or does not deploy it fast enough. By design, there *are* certain scenarios wherein the Hövding product's airbag will not deploy; deployment of the device during an accident depends on whether the attributes of the accident align with the device's predetermined potential accident scenarios. This risk of non-deployment contrasts with a properly secured helmet that meets part 1203 — such a helmet will afford much more head protection in all but the most severe accidents, typically those involving impacts with a moving motor vehicle.

Per the Petitioner, the airbag of the Hövding product will only deploy if the conditions match those movements upon which the product's algorithm was written. Those specific conditions (movement patterns that occur during an accident) were accumulated by recording the movements of stunt riders and crash dummies in accidents as they fell from a bicycle while wearing the Hövding product, which Hövding then compared to normal bicycling data that were collected from test cyclists wearing the Hövding product. Hövding provided staff no information on the degree to which the highly choreographed falls (*e.g.,* rolls onto the shoulder) of these stunt riders and inanimate models accurately portrayed accidental falls and the extent to which the captured movements represent all bicycle fall patterns. Online videos of the Hövding product demonstrate incidents where the airbag failed to deploy when one would expect and desire to have it deploy (*e.g.,* Table 1, Videos #1-3) and deploying when unwanted (*e.g.*, Table 1, Videos #3-7). Either scenario could lead to serious injury of the user, and, after deployment, the latter scenario may leave the bicyclist without head protection.

Table 1. Video examples of failed, unwanted, delayed deployments of the Hövding product

Video #	URL*	Source of Video	Description
1	https://www.youtube.com/watch?v=Y7lQaw-VTfY	Dutch Magazine oppad	Delayed deployment at 2:29 Failed deployment at 3:03
2	https://www.youtube.com/watch?v=NxQ5qVfEu3s	Cycle	Failed deployment at 0:14
3	https://www.youtube.com/watch?v=GDNygJnDUes	Ikem Nzeribe	Failed deployment (product not on) at 0:51 Unwanted deployment described at 1:14
4	https://www.youtube.com/watch?v=61Kb53DCeEc	Soenke Strauss	Unwanted deployment at 0:07 and report by commenter of another unwanted deployment
5	https://www.youtube.com/watch?v=nHnzHSLwYRE	Faerge92	Unwanted deployment at 0:09
6	https://www.cyclingweekly.com/news/latest-news/watch-airbag-helmet-inflates-as-cyclist-puts-on-his-jacket-200125	Cycling Weekly Magazine	Unwanted deployment at approximately 5 seconds after start of video
7	https://www.youtube.com/watch?v=vv_llCF5Hqo	Die Fahrrad-Fanatiker	Unwanted deployment at 2:42 Delayed deployment at 4:21
8	https://www.youtube.com/watch?v=JW39_pXW3G4	Insider (includes video from Hövding)	Delayed deployments at 0:02, 0:12, 0:22, 0:23, 0:26, 0:27, and 0:37
9	https://www.youtube.com/watch?v=ZOcQgnNKH30	Bike Bild	Delayed deployments at 3:34 and 4:41
10	https://www.youtube.com/watch?v=f3iK6OeRwr4	Cycling Weekly Magazine	Delayed deployments at 1:14 and 1:41
11	https://www.youtube.com/watch?v=Pr9sNhK4Fyg	MNMbe radio station	Delayed deployment at 0:43 (head contacts “ground” before full inflation)
12	https://www.youtube.com/watch?v=ikYFfxpu3I0	Hövding	Delayed deployment at 1:13 (same as demonstration shown in video 7)
13	https://www.youtube.com/watch?v=gsYxOTmIU_4	Focus Magazine	Delayed deployment at 2:36 (head contacts “ground” before full inflation)
14	https://www.youtube.com/watch?v=hd5ncr091pw	Nikozua	Delayed deployments at 0:11 and 1:05

*Videos were last accessed on February 19, 2019.

As mentioned above, certain circumstances exist where the airbag of the Hövding product will not deploy, or deploy fast enough, and in those circumstances the product will not confer any protection against head injury. Per Hövding’s website, the product cannot protect individuals under age 15, as the movements of that age group have not been built into the algorithm that the product uses to detect hazardous conditions requiring activation of the product. Additionally, many scenarios in the urban environment or on the road exist in which the product would not protect the bicyclist. These scenarios include direct impacts or a direct hit, including from intrusive objects, on the cyclist's head. From the owner's manual[44] of the Hövding product:

> A head impact that occurs before Hövding has reacted and is fully inflated is called a direct hit. Examples of direct hits include an icicle falling onto a cyclist's head or a cyclist riding into a branch at head height. However, direct hits are a *very unusual* [emphasis added by Health Sciences staff] category of cycling accident. No bicycle helmet can protect you against all types of cycling accident. In a collision with a motor vehicle, the speed at impact is always a factor that limits the protection a bicycle helmet can provide. At higher speeds, the risk of direct hits increases, and of the cyclist suffering internal injuries against which a bicycle helmet offers no protection.

Echoing the language from the owner's manual cited above, the SP Method states:

> The head protector does not offer protection in direct hit accidents and offers limited protection when the head protector has only partially reached inflated status prior to head impact. Also, the head protector offers limited protection against pointed objects.

B. Urban and On the Road Hazards and Injury Assessment

Health Sciences staff believes that Hövding's characterization of "direct hits" may omit several real-world situations that could pose a hazard to bicyclists. Bus, truck, and SUV mirrors and open doors; bridge abutments; telephone, light, and other poles; trees and tree limbs; structures, such as mail boxes, sculptures, and bus stop shelters; pedestrians and bicyclists; vendor carts; and traffic control, parking, and advertising signs are just a few of the many hazards in these environments that have the potential to result in a direct hit and/or possess pointed features that may lead to failure of the Hövding product. Health Sciences staff concludes that a headfirst direct hit into any of these objects would be unlikely to activate the Hövding product (or deploy its airbag fast enough) and would have a high likelihood of producing skull fractures and/or severe brain injuries (*i.e.*, an intracranial injury or hemorrhage, including cerebral lacerations and contusions, and subarachnoid, subdural, and extradural hemorrhages) of the unprotected bicyclist involved.

Additionally, during a fall from a bicycle that may or may not trigger the deployment of the Hövding product's airbag, numerous hazards in an urban environment and on the road exist that the bicyclist's head is more likely to impact *before* the product's airbag could fully deploy. This statement is based, in part, on examples of deployments of the Hövding product that staff have viewed in online videos (*e.g.*, see Table 1, Videos #1, 7-14), some of which include video produced by Hövding.

Each of these video graphic examples illustrates that the product's airbag inflates fully only as the head approximates contact with the ground; it appears that any object that the head may collide with before striking the ground would result in an unprotected impact. Such objects may include the following (in descending order by height)[45]: parking meters; vehicles and open vehicle doors; refuse and recycling bins; drinking and water fountains; railings and fencing; shopping carts; bollards, barricades, and jersey walls; newspaper and signalized intersection control boxes; crosswalk call boxes; benches, tables and chairs; bicycle locking products and racks; window ledges; brick, stone, or cement short walls; posters and signs; fire hydrants; open cellar doors; planters; fire department standpipe connections; gutter downspouts; steps; and curbs. The greater the velocity of the bicyclist at the time of the fall, the less likely it is that the Hövding

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[44] See https://hovding.se/app/uploads/2019/03/3296_revB03_Manual_WEBB_NEW.pdf

[45] Lower aspects of the objects listed above in the discussion of direct hits would also be of concern.

product will deploy its airbag in time to offer protection. Head impact with any of these hard and/or sharp objects prior to the airbag of the Hövding product fully deploying is likely to result in skull fractures and/or severe brain injuries of the unprotected fallen bicyclist.

Because the Hövding product is not available in the U.S., Health Sciences staff has no injury data associated with use in the U.S. that can be examined and discussed. However, staff does have information on the accident scenarios involving bicyclists in the United States, from which the effectiveness of the Hövding product in injury prevention can be surmised. A cursory review by Health Sciences staff of the 10,847 NEISS bicycle-related head injuries that were reported between 2013 and 2017 provided many examples in urban environments, and on the road, of both direct hits and head impacts subsequent to falls from bicycles onto objects at above street/ground level. In most cases, staff could not determine from the incident details whether a helmet was worn at the time of the accident.

Staff found 617 NEISS incidents that provided details about the object with which the bicyclist directly collided (*i.e.,* a direct hit, often with their head) while bicycling. The objects directly collided with in the incidents are listed in Table 2. In all of these direct hit incidents, the airbag of the Hövding product would not likely have deployed, or deployed fast enough, to offer protection; consequently, there would be an increased potential for skull fractures and/or severe brain injuries to be sustained were the Hövding product in use in these incidents at the time the head impacted the listed objects.

Table 2. Objects that bicyclists directly collided with while bicycling as detailed in NEISS incidents (listed in descending order of frequency)

Object	**Frequency**
Parked vehicle or vehicle at a standstill[46]	196
Pole/post/lamp post	89
Tree/branch	71
Another bicyclist	69
Wall	50
Fence/gate	34
Mailbox	25
Pedestrian	15
Sign	15
House/shack/garage door/door	12
Trash can/dumpster	8
Barrier/guardrail	7
Person, where unclear if also a bicyclist	7
Bridge abutment/tunnel	4
Cable/telephone pole support wire	3
Railing	3
Bike rack	2
Beam	1
Bleachers	1
Fire hydrant	1
Porch	1
Suspended ladder	1
Pole-mounted utility panel	1
Window	1

Additionally, 161 NEISS incidents provided details about the object that the bicyclist impacted (often with their head) *after* falling from their bicycle. The objects that were impacted in the incidents are listed in Table 3. In these incidents, staff states that were the Hövding product in use, it is unlikely that it would have deployed its airbag fast enough to prevent injury; consequently, skull fractures and/or severe brain injuries would likely have resulted when the head impacted the named objects.

[46] Collisions with moving motor vehicles were excluded.

Table 3. Objects that bicyclists impacted (often with their head) after falling from their bicycle as detailed in NEISS incidents (listed in descending order of frequency)

Object	**Frequency**
Curb	45
Handlebars of bicycle	22
Vehicle	15
Pole/post	15
Wall	13
Barrier/guardrail	8
Stairs/steps/porch	8
Mailbox/metal box/transformer	6
Fence	4
Railing	4
Trash can/dumpster	3
Table/chair	3
Tree	3
Pipe/faucet	2
Planter	2
Bicycle	1
Bicycle rack	1
Edge of pool	1
Fire hydrant	1
Lawn mower	1
Park bench	1
Ramp	1
Sewer drain	1

In addition to the many common scenarios reported in NEISS where it seems likely to staff that the Hövding product would not have protected the bicyclist, staff further notes that the product also would not protect the wearer in *any* type of circumstance, including those movements/falls specifically modeled into the algorithm, if: (1) the user had failed to turn on the product, as is described by the consumer in Table 1, Video #3, (2) the user had accidentally switched the product off, or (3) the product lacked adequate charge to detect an accident and/or deploy its airbag. Per the owner's manual for the Hövding product, the on/off button contains a magnet that activates the product. Hövding warns the user to avoid bringing other magnets (magnetic locks, loudspeakers, etc.) into contact with the activation button on the right side of the collar. Staff does not know

whether bicyclists are likely to have other items containing magnets that could accidently cause the product to be powered off, but this is a concern worth consideration.
Direct impacts, impacts subsequent to a fall from a bicycle with objects that are at or above ground level, other scenarios not covered by the product's algorithm, and impacts that occur when the product is electrically incapable of activating, all represent potentially unprotected scenarios; in contrast, no such "*if then*" caveats exist for a bicyclist who is wearing a properly secured traditional helmet meeting part 1203. Staff critically emphasizes that each of these unprotected scenarios is the equivalent of riding without protective headgear.

Hövding states that it is not aware of any "serious, lasting head injuries" resulting from approximately 1600 incidents where the Hövding product's airbag deployed, but staff is unclear what serious, lasting head injuries means to the petitioner, as no injury information was provided for staff to evaluate. Furthermore, staff is unclear whether serious head injuries actually may have occurred when a Hövding product in use failed to deploy, did not deploy fast enough, or deployed in inappropriate circumstances. Staff is not able to determine whether the petitioner does not consider skull fractures that have healed or intracranial bleeds that have been treated and controlled, as serious, *lasting* head injuries, and has thus discounted them. Because the petitioner does not mention fatalities, staff is also unclear if the petitioner's notion of serious, lasting head injuries would exclude those individuals who were fatally injured (*i.e.,* fatally injured individual do not have a *lasting* injury). In the countries where its use is permitted, fatalities may have occurred to bicyclists wearing a Hövding product, which either Hövding is unaware of or has not shared with CPSC.

Given the proximity of the product to the wearer's ears, an additional health concern is the potential for hearing damage as a result of the Hövding product's airbag deploying. Several of the videos listed in Table 1 indicate that the percussive deployment of the airbag is extremely loud. Health Sciences staff notes that in the stunt falls shown in Table 1, Video #10, which were attended by the CEO of Hövding, the stunt rider was wearing hearing protection.

III. CONCLUSION

Based on the many scenarios in which the Hövding product is unlikely to afford head protection when worn in an urban environment or on the road (*e.g.,* direct hits, impacts with objects subsequent to a fall, other scenarios not covered by the product's algorithm, and non-powered conditions), Health Sciences staff considers the Hövding product to be an unsuitable alternative to a helmet that meets part 1203. Staff concludes that use of the Hövding product could lead to injuries that include skull fractures; severe brain injuries, including intracranial injury or hemorrhage, such as cerebral lacerations and contusions, and subarachnoid, subdural, and extradural hemorrhages; and fatalities, that otherwise could have been avoided by wearing a helmet that meets part 1203.

TAB C: Human Factors Analysis of Petition CP-18-1, Requesting Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: July 26, 2019

TO	:	Brian Baker, Mechanical Engineer, Project Manager Division of Mechanical Engineering, Directorate for Laboratory Sciences
THROUGH	:	Joel Recht, Associate Executive Director, Engineering Sciences Rana Balci-Sinha, Director - Division of Human Factors, Directorate for Engineering Sciences
FROM	:	Zachary Foster, Industrial Engineer Division of Human Factors, Directorate for Engineering Sciences Brian M. Baker, Mechanical Engineer, Project Manager Division of Mechanical Engineering, Directorate for Laboratory Sciences
SUBJECT	:	Human Factors Analysis of Petition CP-18-1, Requesting Exemption from the Testing Requirements of the Bicycle Helmet Standard for Certain Head Protection Devices

I. INTRODUCTION

Human Factors (HF) staff prepared this memorandum to summarize an assessment of Petition CP-18-1, submitted by Hövding Sweden AB (petitioner), requesting that the Commission exempt “inflatable head protective devices for bicyclists,” such as Hövding’s product, from the testing requirements of the Safety Standard for Bicycle Helmets, if such product complies with, and is certified to, requirements in another standard that Hövding states is appropriate to test such products.

II. PRODUCT BACKGROUND

The Petitioner describes the Hövding product as “an airbag for urban cyclists” and “the world’s safest bicycle helmet.” The Hövding product is worn around the user’s neck and contains an airbag that deploys to surround the head and provide protection from impact during a crash. The Petitioner designed the product to determine when a crash is occurring using accelerometers within a pre-determined algorithm. The Petitioner developed the algorithm using data from bicycle crash re-enactments performed by stuntmen, as well as crash data from real-life users. The Hövding product is powered by a rechargeable battery with a reported life of approximately 9 hours and must be activated before each use.

III. DISCUSSION

A. Anthropometry and Fit

To accommodate different neck circumferences, the Hövding product is available in three different sizes: Small (<36 cm), Medium (34-42 cm), and Large (38-45 cm). Petitioner states that all three sizes can accommodate head circumferences of 52-59 cm. Petitioner also states that the product is intended only for ages 15 and older. Hövding does not specify a lower bound for the Small size. Based on the ranges for the Medium and Large sizes (8 cm and 7 cm, respectively), HF staff identifies 28 cm as the lower bound for the Small size. However, consumers may not make this assumption, and the Hövding product in a Small size may accommodate neck circumferences smaller than 28 cm. Based on the materials reviewed, HF staff cannot discern where on the neck Hövding intends the measurement is meant to be taken when determining the proper product size for each user.

Subjects in Snyder's 1977 anthropometric study of U.S. children ages 2-19 years were found to have neck circumferences exceeding 28 cm as early as age 7.5-8.5 years (95th percentile). Subjects' mean neck circumference consistently exceeded 28 cm starting from ages 10.5-11.5 years. Starting from ages 13.5-14.5 years, subject neck circumference exceeded 28 cm in 95 percent of the test subjects. In the same study, subjects as young as 2-3.5 years were found to have head circumferences exceeding 52 cm (95th percentile). Subjects in the study had a mean head circumference that consistently exceeded 52 cm for ages 7.5-8.5 years and older. For ages 14.5-15.5 and older, subject head circumference exceeded 52 cm in 95 percent of the test subjects.

According to anthropometric data of U.S. adults taken from ADULTDATA[47], 5% of male subjects had a head circumference of 60.49 cm or greater and a neck circumference (measured just below the Adam's apple) of 46.27 cm or greater. Five percent of female subjects had a neck circumference (measured just below the Adam's apple) of 46.04 cm or greater. When subject neck circumference was measured at the base of the neck, the mean neck circumference for male subjects was 45.61 cm, 5 percent of male subjects had neck circumferences of 52.55 cm or greater, and 5 percent of female subjects had neck circumferences of 49.74 cm or greater.

An article from the National Institute of Diabetes and Digestive and Kidney Diseases[48] shows significant increases in obesity rates among the U.S. population since the 1960s for both adults and children. In addition, an article from the *Washington Post*[49] states that between 1960 and 2010, the average weight for adults in the U.S. has risen by 18.5 percent among women and 17.6 percent among men. A study published in the North American Journal of Medical Sciences[50] found that neck circumference displayed a strong positive correlation with Body Mass Index (BMI) and other indicators of obesity. Therefore, HF staff believes that increases in obesity rates and average body weights have likely resulted in neck circumferences significantly larger than those measured in the referenced anthropometric data, specifically Snyder's 1977 study. HF staff was not able to find any information regarding the relationship between head circumference and obesity.

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[47] Peebles, L., Norris, B. (1998), *ADULTDATA.* Nottingham, UK: Department of Trade and Industry
[48] Overweight & Obesity Statistics. (2017, August 01). Retrieved from https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.
[49] Ingraham, C. (2015, June 12). The average American woman now weighs as much as the average 1960s man. Retrieved from https://www.washingtonpost.com/news/wonk/wp/2015/06/12/look-at-how-much-weight-weve-gained-since-the-1960s/?noredirect=on&utm_term=.410bf7742901.
[50] Aswathappa, J., Garg, S., Kutty, K., & Shankar, V. (2013). Neck circumference as an anthropometric measure of obesity in diabetics. *North American Journal of Medical Sciences*, *5*(1), 28. doi:10.4103/1947-2714.106188.

The anthropometric data discussed above showed that children in 1977 as young as 7.5-8.5 years met the Petitioner's minimum head and neck circumference requirements. In addition, given increases in obesity rates and average body weight in both children and adults in the U.S., as well as the strong correlation between neck circumference and other indicators of obesity, HF staff opines that children are more likely to reach neck circumferences of 28cm or greater at younger ages than the children from Snyder's 1977 study. Additionally, HF staff concludes that the percentage of children with neck sizes of 28 cm or greater has likely increased for any given age range. HF staff also considers that increases in obesity rates in the U.S. have likely resulted in a larger portion of the adult population, particularly males, having neck circumferences exceeding 45 cm, which is too large for the product, even in its largest size. HF staff is concerned that the product may not be appropriately sized for a significant portion of the U.S. adult population.

B. Potential for Use by Children

The Petitioner states that the product is designed for cyclists 15 years and older. However, the appropriate age range is not communicated to the consumer on the Hövding home page nor on the "shop" page of the product website. Instead, the user must navigate to the FAQ page on the Hövding website and click on two drop-down tabs to find information on the appropriate age range for the Hövding product. The product user manual, which can also be found on the FAQ page, also contains information on the appropriate age range. The Petitioner did not provide a physical manual; staff is unclear if the manual included with the product, if any, is the same manual found on the FAQ page. The Petitioner claims in the FAQ page and user manual that the 15+ age requirement was chosen because the crash detection algorithm was designed based on the movement patterns of adults, and children move differently than adults, both when cycling and when on foot. Additionally, the Petitioner expresses concern that children may have difficulty with activating and deactivating the product because they are "more spontaneous in their movements."

HF staff opines that it is reasonably foreseeable that consumers will not consult the FAQ page or may otherwise miss the age requirement section when purchasing a Hövding product online. As HF staff was not able to examine the product or the product packaging, staff is unclear if age requirement information appears on the product or product packaging. Thus, HF staff finds it foreseeable that some consumers may believe the product to be appropriate for their children if neck and head size requirements are met (a size chart can be found on the Hövding shop page). Given the relatively high price of the product (approximately 338.89 USD at the time of writing), HF staff concludes that children are unlikely to possess the means to purchase the product for themselves and will instead rely on a parent to purchase the product on their behalf. Assuming that some parents will be unaware of the age requirement, the Petitioner's claim that the Hövding offers 8 times better protection than traditional bicycle helmets may convince parents who wish to provide the highest level of protection for their children to purchase the product for them. Given that the product is marketed as a helmet for urban cycling and on-road use only, HF staff opines that parents' perception of their child's riding conditions and behaviors may also influence the decision to purchase the product.

Aside from the understanding that gross and fine motor control develops throughout childhood, HF staff is unaware of literature that substantiates the Petitioner's claim that children move differently than adults. Additionally, HF staff concludes that many children will be able to activate and deactivate the product with relative ease, as the actions involved (zipping the collar, snapping the magnetic button into place) are quite simple and can already be performed by children. For example, school-aged children often uses zippers and snapping buttons on such items as jackets or pants.

C. Helmet Use in the United States

The CDC analyzed a 2012 survey by Consumer Styles in which adult cyclists were asked about cycling in the last 30 days and helmet use for themselves and their children.[51] The study found that 29% of adults reported always wearing helmets. Respondents stated that, of the 61% of children who had cycled in the past 30 days, 42% always wore helmets. The study found that children whose parents always wore helmets were more likely to wear helmets than children whose parents did not always wear helmets. The study also found that helmet use among children was higher in areas with child bicycle helmet laws. In the study, adult respondents living in Metropolitan Statistical Areas (MSAs) or having annual household incomes of $85,000+ reported higher rates of helmet use than adults not living in MSAs or earning less than $40,000 per year. Daily and weekly riders in the study also reported higher rates of helmet use than monthly riders.

According to an article from Bicycle Universe,[52] factors that may discourage consumers from wearing helmets include: cost, comfort, appearance, and ignorance regarding helmet effectiveness or hazards associated with not wearing a helmet. The Hövding product will likely appeal to some consumers as a more fashionable or comfortable alternative to traditional helmets. Professionals who cycle to and from work may be particularly attracted to this product, as they may wish to avoid the "helmet hair" often associated with traditional helmets. However, the relatively high cost of the Hövding product will likely deter some consumers. HF concludes that the Petitioner's claim that the Hövding product offers eight times better protection than traditional bicycle helmets will also likely influence consumers.

D. Volume and Noise

The Hövding product uses both lights and audio signals to indicate its status. Because the lights are located on the collar (*i.e*. below the head), users will likely have difficulty checking these lights while cycling and must instead rely on audio signals.

For any product that uses audio signals to indicate its status, HF staff places import on the user being able to reliably distinguish these signals. According to the product user manual, Hövding uses distinct signals for the following alerts:

- Power on: Ascending tone in three steps
- Power off: Descending tone in three steps
- Low battery: Two short beeps, recurring every five minutes until critical battery level is reached
- Critical battery: Low battery signal ten consecutive times, followed by power off signal to indicate that product is off
- Product fault: Loud, long signal that Petitioner states "is hard to mistake for other sounds," followed by power off signal to indicate that product is off

Use of distinct audio signals for different alerts is common in other consumer products, such as wireless headphones. Absent a product sample, HF staff has not been able to evaluate these audio signals.

[51] Jewett, A., Beck, L. F., Taylor, C., & Baldwin, G. (2016). Bicycle helmet use among persons 5 years and older in the United States, 2012. *Journal of Safety Research, 59*, 1-7. doi:10.1016/j.jsr.2016.09.001
[52] Taylor, P. (2019, January 18). The Stats behind the Bicycle Helmet. Retrieved from https://bicycleuniverse.com/stats-behind-bicycle-helmet/

Because the product is intended for urban cycling and on road use, HF staff also notes the import that these signals are loud enough to hear over the noise associated with urban environments. Results of a study of street noise levels in New York City showed that noise levels ranged between 55.8 and 95.0 dBA, with a mean noise level of 73.4 dBA.[53] Results of this study also showed a strong positive correlation between noise levels and density of vehicular traffic. Consensus from four U.S. standards for audible alarms and warnings suggests that the signal level should be about 15dB above the noise level.[54] Hövding has not provided any information regarding the volume level of the Hövding product's audio signals; HF staff has not found any readily available information, nor is there any performance requirement in SP-method 4439. Staff is unclear what considerations Hövding made regarding the noise levels of areas with population and vehicular traffic density.

With regard to the charge state of the Hövding product, staff notes that the owner's manual directs the consumer to check the state of the battery charge in a *low noise area*, preferably indoors, so that they can hear the tones associated with a low battery condition. This raises the question whether the wearer will be able to hear the tones in a noisy urban environment (*i.e.*, outdoors) prior to bicycling, or, while bicycling, hear them at such time that the product warns of a low battery condition. If the tones *are* heard while bicycling, staff questions whether the user would dismount their bicycle and walk the remaining distance to their destination; to not do so would mean riding without head protection. Given the shortcomings of this product, staff is troubled that a safety product designed for head protection could be functional only part of the time, and also that the onset of its lack of functionality may go unrecognized or ignored by the user. The electrical-based requirements of the Hövding product are another critical difference between it and an "*always on*" traditional helmet that meets part 1203. Under any of the above conditions (*i.e.*, powered off or insufficient power), a direct hit or fall onto a hard object, *including the ground*, could result in serious injury to the head of an unprotected cyclist.

Conversely, HF staff notes that it is also important that volume levels for the product do not reach hazardous levels, which applies to the audio signals as well as airbag deployment. Regarding airbag deployment, SP-method 4439 states "When deployed, the noise level measured at the test dummy's ear shall not exceed 135 dB."[55] OSHA and NIOSH each have formulas to determine the maximum time a person should be exposed to a given noise level.[56] Using OSHA's formula, HF staff calculated that exposure to noise of 135 dBA should not exceed 56.25 seconds. However, using NIOSH's formula, HF staff calculated that exposure to noise of 135 dBA should not exceed 0.2762 seconds. OSHA's regulations and NIOSH's recommendations allow impulse noises with a sharp rise and rapid decay in level that are ≤1seconds in duration and, if repeated, occur at intervals >1s up to 140dB.[57] Given that the airbag can only deploy once and appears to do so quickly, HF staff believes that airbag deployment likely meets the criteria for classification as impulse noise. HF staff is concerned that an airbag deployment with a noise level at or near 135 dB may still cause momentary pain or discomfort for the user, as the pain threshold of the human ear ranges from approximately 120 to 140 dB[58]. Additionally, in the event of a false deployment while riding, HF staff is concerned that a noise that loud may startle the user and

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[53] Mcalexander, T. P., Gershon, R. R., & Neitzel, R. L. (2015). Street-level noise in an urban setting: Assessment and contribution to personal exposure. *Environmental Health, 14*(1). doi:10.1186/s12940-015-0006-y
[54] Berger et al., (2003). *The Noise Manual*. Fairfax, VA: American Industrial Hygiene Association, 583.
[55] (SP Technical Research Institute of Sweden, 2014, p. 9)
[56] *OSHA Fact Sheet: Laboratory Safety Noise*. (2011). Washington, D.C. United States Dept. of Labor, Occupational Safety and Health Administration
[57] Berger et al., (2003). *The Noise Manual*. Fairfax, VA: American Industrial Hygiene Association, 648.
[58] Table 1: Examples of sound pressure levels in relation to hearing threshold and pain threshold (in dB SPL). (n.d.). Retrieved from http://ec.europa.eu/health/scientific_committees/opinions_layman/en/hearing-loss-personal-music-player-mp3/figtableboxes/table-1.htm

possibly lead to a crash. From customer reviews and product demonstrations, HF staff found multiple instances of false deployment, both during cycling and on foot.[59]

E. Additional Concerns

In addition to the issues discussed above, HF staff expresses the following concerns:

- The product is powered by a rechargeable battery and includes a USB cable. However, the product does not appear to include a USB wall adapter. Thus, consumers must already have an extra wall adapter, purchase one separately, or charge the product via other means, such as a computer.
- While the manual states that the zipper must be fully closed before activating the Hövding product, HF staff cannot determine whether the product can be activated without fully zipping the collar.
- The user manual states that the product is intended for use with two-wheeled standard bikes, e-bikes, and bikes with small wheels. HF staff cannot determine whether mountain bikes or hybrids would be considered "standard" by the Petitioner. However, given the popularity of mountain bikes and hybrids in both urban and rural settings, HF staff finds it foreseeable that a U.S. consumer may use the Hövding product with a mountain or hybrid bike.
- The user manual states that the Hövding product is not intended for use with cargo bikes, though HF staff is unclear what the Petitioner considers a cargo bike. Bicycles with a rack system or a basket may be used for such tasks as holding a laptop or briefcase for a work commute, carrying groceries, and transporting items for deliveries. In an urban setting where cycling is seen as a viable means of transportation, HF staff concludes that such bicycles would likely appeal to consumers.
- The user manual states that the product must be deactivated when not cycling, otherwise it may deploy accidentally. HF staff concludes that it is foreseeable that a user may forget to deactivate the product, or the user may simply choose not to deactivate the product if he or she is stopping cycling for a brief period.
- Because the airbag only deploys when the algorithm detects a crash (*i.e*. a rider falling from his or her bicycle), the Hövding product offers no head protection from falling objects or objects that a rider may hit while upright, such as a street sign or light pole.

IV. CONCLUSION

Given the concerns discussed above, Human Factors does not believe that Hövding has provided sufficient information in its petition request for CPSC staff to adequately assess the safety and efficacy of the Hövding product compared to traditional bicycle helmets.

[59] Video example of false deployment: https://www.youtube.com/watch?v=vv_llCF5Hqo

TAB D: Estimated Number of Injuries and Reported Deaths Associated with Bicycle Rider Head Injuries, 2013 – 2017*, for Petition CP-18-1

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum Date: February 25, 2019

TO	:	Brian Baker, Mechanical Engineer, Project Manager Division of Mechanical Engineering, Directorate for Laboratory Sciences
THROUGH	:	Stephen Hanway, M.S., Associate Executive Director Directorate for Epidemiology Risana Chowdhury, M.S., Director Division of Hazard Analysis
FROM	:	Qian Zhang, M.S., Mathematical Statistician Division of Hazard Analysis
SUBJECT	:	Estimated Number of Injuries and Reported Deaths Associated with Bicycle Rider Head Injuries, 2013 – 2017*, for Petition CP-18-1

I. OVERVIEW

Staff from the Division of Hazard Analysis at the Consumer Product Safety Commission (CPSC) prepared this memorandum in response to a petition by Hövding Sweden AB (the petitioner or Hövding), requesting that the Commission exempt "inflatable head protective devices for bicyclists" like Hövding's product (the Hövding product) from the testing requirements of the Safety Standard for Bicycle Helmets, 16 CFR part 1203, if such product complies with, and is certified to, requirements in a standard developed by SP Technical Research Institute of Sweden, SP-method 4439, *Inflatable head protective devices with electronic triggering system for pedal cyclists* (SP-Method 4439) (Petition CP-18-1). The Hövding product is designed to protect the heads of riders ages 15 years and older, who are bicycling in an urban environment or on the road. Because the Hövding product, or a similar airbag product for cyclists, is not available in the U.S. market, staff found no data associated with this product in the CPSC databases Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS). The multidisciplinary team working on this petition considered collecting the information on bicycle helmets, a similar product in the U.S. market. However, staff is aware that the traditional hard-shell-type bike helmet has a different design from the Hövding product; as such, available injury data associated with traditional hard-shell-type bicycle helmets may not be fully representative of scenarios involving the Hövding product.

The petition team decided to review the data associated with bicycle (product code 5040) incidents involving head injuries as a reference, because no specific product code exists for bicycle helmets in CPSC's databases, and because the Hövding product is intended to protect riders from a head injury during a bicycle incident.

II. ANNUAL INJURY ESTIMATES

From 2013 through 2017, CPSC staff estimates a total of 380,500 emergency department-treated head injuries associated with bicycles. The 95% confidence interval (C.I.) for staff's estimate is 275,000 - 485,900, based on a coefficient of variance (C.V.) of 0.1414. Table 1 displays yearly estimates for head injuries related to bicycles.

Table 1: Estimated Emergency Department-Treated Head Injuries
Associated with Bicycles, 2013 – 2017

Year	Observations	Estimate	95% C.I.	C.V.
2017	1,988	67,800	52,600-83,100	0.1144
2016	2,037	71,800	52,500-91,000	0.1368
2015	2,178	80,000	50,500-109,500	0.1884
2014	2,250	78,400	55,500-101,300	0.1491
2013	2,394	82,500	59,100-105,800	0.1443
Total	10,847	380,500	275,000-485,900	0.1414

Source: National Electronic Injury Surveillance System (NEISS). The estimates are rounded to the nearest 100.

Staff analyzed the yearly estimates for head injuries associated with bicycles for the existence of a trend. Staff found no statistically significant increasing or decreasing linear trend. The p-value is 0.168.

Table 2 displays staff's estimates for emergency department-treated head injuries for bicycles by age. Staff found that most of the estimated injuries (67%) are in the 15 years and older group.

Table 2: Estimated Emergency Department-Treated Head Injuries
Associated with Bicycles by Age Category, 2013 – 2017

Age	Estimate	% Total
15 and older	254,300	66.84%
Younger than 15	126,000	33.13%
Unknown Age	Not Reportable*	Not Reportable*
Total	380,500	100.00%

Source: National Electronic Injury Surveillance System (NEISS). The estimates are rounded to the nearest 100.
*Estimates under 1,200 are not reportable.

The NEISS is a probability sample of approximately 100 U.S. hospitals having 24-hour emergency departments (EDs) and more than six beds. NEISS collects injury data from these hospitals. Coders in each hospital code the data from the ED record and the data is then transmitted electronically to CPSC. Because NEISS is a probability sample, each case collected represents a number of cases (the case's weight) of the total estimate of injuries in the U.S. Different hospitals carry different weights, based on stratification by their annual number of emergency department visits[60].

A coefficient of variation is the ratio of the standard error of the estimate, *i.e*., the measure of variability, to the estimate itself. This is generally expressed as a percentage. A C.V. of 10% means the standard error of the estimate equals 0.1 times the estimate. A large C.V., which is often due to small sample size, alerts the reader that the estimate has considerable variability. Estimates and confidence intervals are usually not reported unless the number of cases is 20 or more, the estimate is greater than 1,200, and the C.V. is less than 33%.

III. Reported Deaths

CPSC staff is aware of 925 fatalities involving bicycle head injuries that were reported to have occurred from 2013 through 2017. The majority of victims were in the age group 15 years and older. Table 3 lists the counts of the reported victims by age category.

Table 3: Number of Fatalities Involving Bicycle Head Injuries by Age Category, 2013- 2017

Year	15 and older	Younger than 15	Unknown Age	Yearly Total
2017	134	11	0	145
2016	168	16	1	185
2015	186	20	1	207
2014	206	11	0	217
2013	155	16	0	171
Total	849	74	2	925

Source: Consumer Product Safety Risk Management System (CPSRMS). Reporting is ongoing for all of these years, especially for 2016 and later.

Notably, staff's summary of information in these fatalities is based on anecdotal data (CPSRMS) collected from reports of incidents received by the CPSC. CPSRMS data collection is based on information reported to the CPSC through various sources. The data are not a complete set of all incidents that have occurred; although the data do not constitute a statistical sample representing all fatalities with head injuries for bicyclists, they represent at least a minimum count for the number of deaths from bicycle-related head injuries. Also, for a given year, incidents are included on an ongoing basis for CPSRMS. CPSRMS combines Death certificates (DTHS), In-Depth Investigations (INDP), and Injury and Potential Injury Incidents (IPII) from newspaper clippings, consumer complaints, state/local government referrals, and medical examiners/coroners, among others. In addition, reports generally continue to be received for the most recent years. CPSC staff extracted information from these cases into

[60] Schroeder T, Ault K. *The NEISS Sample (Design and Implementation)*. U.S. Consumer Product Safety Commission. 2001.

an Excel spreadsheet and sorted the information by incident state and date to eliminate duplicate incident reports.

IV. LIMITATIONS

This report covers the time frame from 2013 through 2017. Staff extracted data on November 9, 2018, from the CPSRMS and the NEISS databases for the product code 5040 (bicycles or accessories (excluding mountain or all-terrain bicycles)), with "body part affected" code 75 (head), in NEISS or "bodypartname" code 10 (head), in CPSRMS.

Staff's report is a summary of bicycle head injuries (fatal and nonfatal) based on CPSC databases. Staff did not consider helmet usage as a screening factor because the current databases do not have a product code for helmet, and thus do not allow for such analysis. In order to collect enough information about bicycle helmet usage in the U.S. and the hazard pattern for the population, staff would need to perform a follow-up special study. In order to conduct a risk analysis, staff would also need the number in the population using bicycle helmets in the U.S. Moreover, to analyze the hazard pattern and risk for *airbag* products, staff would need data from markets where people use this product for both survey and population data. Lacking this information, CPSC staff looked at the available data on bicycle use-related head injuries to understand the severity and magnitude of the hazard of head injuries to bicyclists. However, the incident data do not provide any insight into the performance of helmets (traditional or airbag helmets).

TAB E: Market Information and Other Economic Issues Related to the Hövding Sweden AB Petition, CP-18-1

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: July 26, 2019

TO: Brian Baker, Project Manager
Directorate for Engineering Sciences

THROUGH: Gregory B. Rodgers, Ph.D., Associate Executive Director
Directorate for Economic Analysis

Robert L. Franklin, Senior Staff Coordinator
Directorate for Economic Analysis

FROM: Charu S. Krishnan, Economist
Directorate for Economic Analysis

SUBJECT: Market Information and Other Economic Issues Related to the Hövding Sweden AB Petition, CP-18-1

I. Background

On December 15, 2017, Hövding Sweden AB submitted a petition to the Consumer Product Safety Commission (CPSC) requesting that the Commission exempt "inflatable head protective devices for bicyclists" (the Hövding product) from the requirements of the safety standard for bicycle helmets (16 CFR part 1203) "if those devices meet the requirements of SP-method 4439" (Petition CP-18-1). Hövding is a Swedish manufacturer of inflatable head protective devices, and SP-method 4439 is a Swedish safety standard to assess the performance of inflatable head protective devices. This memorandum discusses economic issues related to the Hövding petition, to the extent possible, with readily available information.

II. Hövding Market Information

The Hövding product differs from standard bicycle helmets in that it is not a rigid head protection device. The Hövding product is instead an inflatable protective device that is worn around the neck. The Hövding product monitors the bicyclist's movement and if it detects an abnormal pattern of movement or rapid acceleration of the head it rapidly fills with helium to protect the head.

The Hövding petition states that the product is sold in 16 European markets and in Japan. The Hövding website identifies the following markets: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Great Britain, Ireland, Japan, Netherlands, Norway, Slovakia, Spain, Sweden, Switzerland, and Turkey. The petition states that the company sold more than 60,000 units since Hövding's inception in 2005. The Hövding website states that Hövding has sold 130,000 units since inception. If accurate, the discrepancy implies that more than half of Hövding's sales occurred in 2018, and suggests a significant increase in sales in the last year. CPSC staff would find it useful to compare sales and use of the Hövding product to the sales or use of rigid helmets in Europe, which could provide some insight on the use of bicycle helmets in Europe and the percentage of the market that consists of inflatable protective devices. Staff would also find it useful to compare sales and use data of the Hövding product to the sales and use of bicycle helmets of all types in the United States. However, we do not have data on the sales or use of bicycle helmets of all types in Europe or the United States. If the Commission directed staff to conduct additional work on this issue, staff is aware of some market research reports that could provide additional market information in the United States and Europe on bicycle helmets that are available for purchase at a cost of around $3,000 each.

The Hövding product retails for 299 EUR on their website, which on February 4, 2019 was equivalent to approximately 340 USD. However, some retailers were offering lower prices for the Hövding product, such as 219 EUR, or approximately 250 USD.[61,62] If the Hövding product inflates or deploys, whether due to the bicyclist being involved in a crash or in error (there are instances of the helmet inflating when a user puts on a jacket or makes other quick movements), the product must be replaced. In most European countries, Hövding offers a Crash Replacement Program that offers a discount for a new Hövding product. The replacement cost is quoted as being 99 EUR on some websites, or approximately 110 USD.[63,64]

The unique features of the Hövding product mentioned in the petition and in comments to the petition include a reduced risk of concussion, reduced risk of severe head injury and death, and the ability to look more presentable because the Hövding product does not ruin the rider's hair. Some commenters noted that traditional helmets deter them from wearing a helmet because they find they are not presentable when they reach their destination.

III. U.S. Helmet Market

An internet search found that the retail price of standard or rigid bicycle helmets in the United States is, on average, significantly lower than the cost of the Hövding product. Staff's search of 24 of the most popular helmet brands in the U.S. market found that the average price of a helmet was approximately $116. This value would likely be lower if we knew the number of units sold by model or brand, because it is plausible that a greater number of lower cost helmets are sold in the U.S. market. The lowest cost helmet found was $25 and the highest was $400. The majority of helmets staff found online were under $200. Thus, the Hövding product would be more expensive than most helmets in the U.S.

61 http://www.cloud9cycles.com/hovding/
62 https://voltbikes.co.uk/electric-bike-helmet.php
63 http://www.cloud9cycles.com/hovding/
64 https://www.theguardian.com/technology/2015/jun/15/hovding-inflatable-bicycle-helmet,

market, but may provide some unique features that might appeal to some consumers who are willing to pay the higher price.

IV. Societal Costs of Bicycle-Related Head Injuries and Deaths

Like traditional bicycle helmets, the purpose of the Hövding product is to reduce the risk of bicycle-related head injury and death and hence the societal costs associated with head injuries to bicyclists. This section describes the societal costs of the injury and death estimates reported by the Directorate for Epidemiology (Qian 2019). As discussed below, the societal costs of head injuries associated with bicycles are high. However, as discussed in the *Conclusions* section below, from the available information, staff cannot determine what effect granting an exemption for the Hövding product would have on the societal costs of bicycle-related head injuries and deaths.

Based on estimates from the National Electronic Injury Surveillance System (NEISS), the Directorate for Epidemiology estimated an annual average of about 76,100 non-fatal bicycle-related head injuries treated in U.S. hospital emergency departments (ED) from 2013 through 2017. In addition to the estimated ED-treated injuries, many product-related injuries are initially treated in other medical settings, such as physician's offices, clinics, and ambulatory surgery centers. Some injuries also result in direct hospital admission, bypassing hospital emergency departments entirely. The number of bicycle-related head injuries initially treated outside of hospital EDs is estimated with the CPSC's Injury Cost Model (ICM) (Lawrence et al., 2018). The ICM is fully integrated with NEISS and uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs, and those treated elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs. According to ICM estimates, and based on the characteristics of the ED injuries reported through NEISS, staff estimates that another 48,900 estimated bicycle-related head injuries were treated outside of hospital EDs annually. In total, staff estimates an average of about 125,000 bicycle-related medically attended head injuries occurred annually from 2013 through 2017 (76,100 treated in an ED and 48,900 treated in other medical settings).

Economics staff also uses the ICM to estimate the societal costs of all medically attended non-fatal injuries (Lawrence et al, 2018). Based on ICM estimates, staff estimates that the aggregate societal costs of the 125,000 medically treated bicycle-related head injuries, including both those treated in hospital EDs and those treated elsewhere, amounted to an average of about $19.2 billion annually (in 2016 dollars) during the 2013-2017 time frame. The societal costs include medical costs, work losses, and the intangible costs of pain and suffering. (Lawrence et al., 2018). In the case of bicycle-related non-fatal head injuries, the pain and suffering component accounts for about 70 percent of the societal costs.

In addition to the nonfatal injuries, CPSC staff is aware of 925 fatal bicycle-related head injuries that occurred from 2013 through 2017, or an average of about 185 per year. Because these are only the deaths reported through CPSMRS, they are likely an undercount of the fatal head injuries that occurred during the time period. Staff estimates the societal costs associated with these fatalities by applying the value of a statistical life (VSL) to estimated deaths (OMB, 1993). CPSC staff is following the Environmental Protection Agency's (EPA) recommendation regarding the value of a statistical life, which is based on a number of studies using the "willingness to pay" methodology. EPA recommends the use of a VSL of $7.4 million in 2006 dollars in their analyses. EPA also recommends the VSL be adjusted for price levels using the Consumer Price Index, All Urban Consumers (CPI-U) for all goods and services, or the GDP deflator (EPA, 2014). Using the CPI-U, staff obtains a VSL of $8.8 million in 2016 dollars. Consequently, based only on the known deaths, staff estimates the societal costs associated with bicycle-related head injuries is at least $1.6 billion annually (185 deaths × $8.8 million). In total, staff estimates the societal costs of fatal and nonfatal bicycle-related head injuries to be about $20.8 billion in recent years.

Conclusions

Staff estimates that the societal cost of head injuries associated with bicycle-related head injuries in the United States is about $20.8 billion annually from 2013-2017, including the intangible pain and suffering costs (about 70 percent of the total) and a societal cost estimate for the known deaths. Staff cannot determine what effect allowing the requested exemption for the Hövding product would have on these societal costs. If the Hövding product is effective in mitigating the severity of some head injuries, and some bicycle riders who reject or resist wearing the standard bicycle helmets now available in the U.S. would wear the Hövding product, then granting the requested exemption could reduce the societal costs associated with bicycle head injuries. On the other hand, if the Hövding product is not as effective as traditional helmets, and some bicyclists who are now wearing the standard helmets switch to using the Hövding product, an increase in societal costs could actually occur. Staff would require more information on the effectiveness of the Hövding product at mitigating head injuries relative to the effectiveness of helmets that meet the CPSC's bicycle helmet standard, as well as the likelihood that people would choose to use the Hövding product, before staff can draw more definitive conclusions regarding the potential impact of granting Hövding's request for exemption on societal costs.

References

Zhang, Qian (2019). CPSC Memorandum to Brian Baker, Project Manager for the Hövding Bicycle Helmet Petition. Estimated Number of Injuries and Reported Deaths Associated with Bicycle Head Injuries, 2013 – 2017, U.S., Consumer Product Safety Commission.

Environmental Protection Agency. (2014). Appendix B: Mortality Risk Valuation Estimates, in *Guidelines for Preparing Economic Analysis*. National Center for Environmental Economics, U.S. Environmental Protection Agency.

Lawrence, B., et al. (2018).*The Consumer Product Safety Commission's Revised Injury Cost Model*. Calverton, MD. Available at: www.cpsc.gov/s3fs-public/ICM-2018-Documentation.pdf?YWuW4Jn0eb2hExeA0z68B64cv6LlUYoE

OMB. (2003). *Circular A-4: Regulatory analysis*. Washington, DC: Office of Management and Budget. Available at: www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf

TAB F: Response to Comments Received on Petition Requesting Rulemaking to Exempt Certain Inflatable Head Protection Devices from the Standard for Bicycle Helmets

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum Date: July 26, 2019

TO	:	Hövding Sweden AB Petition File
THROUGH	:	Andrew Stadnik, Associate Executive Director Directorate for Laboratory Sciences
FROM	:	Brian Baker, Project Manager Directorate for Laboratory Sciences
SUBJECT	:	Response to Comments Received on Petition Requesting Rulemaking to Exempt Certain Inflatable Head Protection Devices from the Standard for Bicycle Helmets

I. Introduction

Hövding requested a rulemaking to exempt certain inflatable head protection devices (the Hövding product) from 16 CFR part 1203, Safety Standard for Bicycle Helmets, if such product meets an alternative standard, SP-Method 4439 (SP Method). CPSC published a request for comments on a petition (petition CP 18-1) submitted by Hövding Sweden AB (Hövding or petitioner) in the *Federal Register* on March 9, 2018. The comment period ended on May 8, 2018. CPSC received 48 comments. Many consumer commenters (36) generally support the petition and the sale of the Hövding product in the U.S. Consumer support appears to be primarily based on the belief that the Hövding product meets the European standard for bicycle helmets. The remaining commenters have a variety of concerns about the Hövding product and the SP Method. CPSC staffs' summary of the comments and staff's responses follow.

II. Comments in Support of the Petition

Comment 1: Many consumer commenters generally support the petition and state that the CSPC should allow the sale of the Hövding product in the U.S. Several commenters state that the Hövding product can help to prevent concussions and save lives, and many commenters state their support because they believe the product provides greater head protection than conventional bicycle helmets, citing European certification of the product and independent testing. One commenter states that he has used the product for three years, including during two falls, and that the product has "worked perfectly." Other supportive commenters state that the Commission needs to allow for novel and innovative methods of protection, as long as the product provides equivalent protection to hard shell bicycle helmets.

Response 1: CPSC staff recognizes that product innovation is important, especially when such innovation results in improved consumer safety. CPSC staff reviewed the information provided by Hövding and concludes that (1) the SP Method is not equivalent to part 1203, and (2) the Hövding product, tested to the SP Method, does not provide overall equal or superior head protection, compared with traditional hard-shell bicycle helmets.

The SP method is not equivalent to part 1203, as it does not require the same impact attenuation tests, nor does it require sample selection, sample conditioning, or impact speeds equivalent to part 1203. See

Appendix III. Moreover, despite consumer belief, the Hövding product is not certified to the European standard for bicycle helmets, EN-1078. The Hövding product carries a "CE" mark, demonstrating that it was tested using an accredited method for testing the requirements for protective headgear under a European safety directive. Even if the Hövding product were tested to EN 1078, the European standard is not equivalent to part 1203. *See* Appendix I.

The SP Method to which the Hövding product is tested was developed specifically for the Hövding product by SP Technical Institute of Sweden (SP), now the Research Institute of Sweden (RISE). RISE also tests the Hövding product to the SP Method. RISE developed the SP Method without using an open, consensus process, such as EN-1078, the U.S. mandatory standard 16 CFR part 1203, or the U.S. voluntary standard, ASTM F1447. Creating a standard or test method through voluntary standards organizations is beneficial because the final product is one that considers all stakeholders, manufacturers, designers, as well as safety experts. CPSC staff has a number of concerns related to the development of the test method and the manner of sample selection.

Comment 2: Several commenters state that use of the Hövding product should be considered not just in relation to hard shell bike helmets, but to adults who chose not to wear a helmet, or not to ride a bike at all, because of the drawbacks of wearing a hard shell helmet. These commenters support sale of the Hövding product in the U.S. because "most" adult bike riders do not wear helmets for a variety of reasons, such as inconvenience, bulkiness, difficulty taking to work, and because it messes up one's hair. A commenter argues that because adults are not required to wear helmets, they should have the option to choose a different head protection device, such as the Hövding product, because such a product is a "huge improvement" over no protection at all and would encourage more adults to choose cycling.

Response 2: CPSC staff has no data regarding whether adults would choose to wear the Hövding product over no helmet at all, or hard shell helmets, and the petition provides none.[65] Because we have no data specifically on this point, staff cannot opine as to whether consumers would choose to wear the Hövding product over a traditional bike helmet, especially given the difference in price between these products. The data cited in the petition is a 2017 report by the Governors Highway Safety Association (GHSA Report) stating that "54 percent of the [adult] cyclists killed in 2015 were not wearing a helmet…"[66] CPSC does not dispute that wearing a helmet decreases the risk of serious injury and death. GHSA Report at 20.

Comment 3: One commenter, a self-styled "avid cyclist" and engineer by training, stated that he suffered a serious head injury from a bicycle accident. According to the commenter, the accident occurred from a low-speed fall in a parking lot, hitting an obstruction, while not wearing a helmet. Based on his own research, the commenter bought a Hövding product and uses it along with traditional helmets. The commenter states that CPSC should establish a second standard that measures the suitability and effectiveness of helmets in preventing traumatic brain injury (TBI) based upon likely accident scenarios. The commenter states that from his research, TBI results from either straight or twisting/torqueing impacts as the result of head strikes, specifically the upper part of the head. The commenter believes that

[65] When the Commission issued part 1203 in 1998, the final rule states: "A Commission study on bicycle and helmet usage patterns found that in 1993 about 18% of bicyclists wore helmets." 63 Fed. Reg. 11,712, 11,713 (March 10, 1998). This data is no longer reliable or relevant, as the study was conducted over 25 years ago, and does not account for the effects of part 1203, nor the changes in state and local laws requiring bike helmet use. In any event, this data does not support the idea that consumers would chose the Hövding product over traditional helmets, but it does support the idea of further research on this issue.

[66] Petition at 3, citing: "A Right to the Road: Understanding and Addressing Bicyclist Safety," Report of the Governors Highway Safety Association, 2017 ("GHSA Report"), p. 20, located at: https://www.ghsa.org/sites/default/files/2017-09/2017BicyclistSafetyReport-FINAL.pdf.

the Hövding product provides better protection in these scenarios than traditional helmets. Additionally, the commenter states that the Hövding product provides secondary impact protection as well or better than traditional helmets. With regard to the need for the Hövding product to be triggered to provide protection, the commenter states that the test protocols should take this in to account, so that the effectiveness of the airbag can be fairly assessed. The commenter states that the goal should be to protect users, not to promote a specific design of helmet, or to quash innovative designs that adults may choose to wear over a traditional helmet.

Response 3: CPSC staff agrees with the commenter that protecting bicycle riders from serious injury and death, versus promoting a specific product design, should be the goal of any bicycle helmet regulation. Commenter 21 mentioned that his injury from a bicycle accident occurred during a low speed fall hitting an obstruction which led to the eventual purchase of the Hövding product. CPSC staff has no information or evidence to support whether the use of the Hövding product in this accident scenario would provide the level of protection of a helmet meeting 16 CFR part 1203. As a comparison, part 1203 allows for multiple strikes on the same helmet, within the same strike zone, using a hemispherical probe while the SP Method has less stringent requirements for each of these factors used to assess the protection provided by helmets meeting part 1203. The hemispherical probe represents a point-loaded impact on the helmet and is typically the most rigorous of the test procedures. The SP Method does not include a hemispherical probe test. Moreover, the studies provided by the petitioner also omit the hemispherical probe test.

With regard to the triggering mechanism in the Hövding product, CPSC staff has not seen test data showing that the Hövding product's algorithm and electronics will sense and deploy the airbag in time to fully protect the users head in a variety of crash scenarios. While the SP Method tests individual sub systems of the product, the SP Method does not include a full systems test of the Hövding product, from sensing a crash through airbag deployment. Accordingly, staff is unclear whether the Hövding airbag deploys with sufficient speed, and with enough pressure, to attenuate impact in all crash scenarios. CPSC staff is concerned that if the system is unable to identify a crash event in a timely manner, the consumer will be left unprotected at the time of head-to-object contact.

Comment 4: One commenter states that she has used, and crashed in, the Hövding product on several occasions. The commenter states that the Hövding product is "super protective," having prevented injury to the commenter in several crashes. The commenter notes that the Hövding product cannot be reused once it deploys, and is therefore currently without one. The commenter states that the Hövding product is carefully and thoroughly tested, and proven to be safe, stating that the product is a "fantastic, worthwhile innovation that should be available to cyclists in the US." The commenter provides pictures of the Hövding product after it deployed and states that the result would not have been the same had she been wearing a traditional helmet.

Response 4: CPSC staff appreciates this example of a successful deployment of the Hövding product. However, without additional incident information, staff cannot comment on whether the consumer would have fared the same or better using the Hövding product or a traditional helmet, and notes that other situations, such as direct hits are not protected by the Hövding product to the extent required in part 1203.

Comment 5: One commenter states support for the sale of the Hövding product in the U.S. after reviewing research conducted by David Camarillo and comments about helmets and concussions.

Response 5: David Camarillo is one of several authors of a study conducted at Stanford University (Stanford Study) that compared the concussion results between standard clamshell helmets and deployable airbag helmets. The study concluded that airbag type helmets that deploy with a specific amount of pressure with a large enough air pocket (0.12 meters or 4.72 inches thick) can reduce concussion risks to less than 10%. The results of the Stanford Study are promising and warrant further research and study on the benefits and complexities of airbag helmets. However, the Stanford Study did not conduct physical testing to validate their model and prove the claim of a reduction in concussions based on the theoretical model. In this case, CSPC staff has no information regarding whether the Hövding product deploys at the pressure indicated in the Stanford Study (70 kilo-Pascal or 10.15 psi) or whether the product has the "thickness" of the air pocket stated in the study. The SP Method does not test whether the Hövding product meets the pressure and thickness requirements in the Stanford Study at the time of a crash.

Comment 6: One commenter, submitted a rebuttal to other commenters who suggest that by asking for an exemption from the bike helmet standard, the Hövding petition seeks to lower safety standards. The commenter states that Hövding does not seek a lower safety standard, but rather seeks alternative requirements that provide at least equivalent head protection for consumers as conventional shell helmets. Petitioner states that the protocol for testing bicycle helmets did not envision an airbag design such as the Hövding product, and is specifically designed to test conventional shell helmets. The commenter states that the SP Method was designed to ensure that the Hövding product satisfies the same performance criteria as conventional shell helmets by reducing the likelihood of serious injury and death from head impacts, by having greater impact protection (acceleration force no greater than 250g versus 300g in the CPSC standard). The commenter states that the SP method includes both a flat anvil and curbstone anvil in its test protocol. The commenter states that the Hövding product provides "far superior head protection" in two crash scenarios that represent the "vast majority" of serious head injuries, those involving impacts with an automobile, and the ground. The commenter also states that the Hövding product offers an alternative to shell helmets that may increase the use of a head protection device. The commenter states that the Hövding product has the potential to save hundreds of cyclists yearly from serious injury or death, and that U.S. consumers should not be prevented from choosing the Hövding product for bicycle head protection.

Response 6: CPSC staff agrees that the current mandatory standard for bicycle helmets in the U.S. does not anticipate an airbag-designed product, and lacks protocols to ensure the safety of batteries, gas inflators, the speed of inflation, and the thickness, and durability of an airbag deployment. However, part 1203 was developed based on a statutory mandate, and with real bicycle crash scenarios in mind. CPSC staff concludes that bicycle helmets sold in the U.S. should provide equal or greater protection to bicyclists as tested in part 1203, regardless of the design. Based on staff's review of the SP Method, it is not comparable to part 1203, as the SP Method does not perform all required tests, does not test impacts against all of the anvils in part 1203, conducts impact testing at slower speeds, does not provide for off-the-shelf testing, does not condition helmets for testing as required in part 1203, and inserts variability into the test design by using stunt riders.

The idea that an airbag product may increase the use of head protective products by adult cyclists is attractive, but this theory is currently anecdotal, because the petition offers no supporting data to demonstrate that bicycle riders will choose a Hövding airbag over not wearing a helmet.

III. Comments that Do Not Support the Petition

Comment 7: Several commenters do not support Hövding's petition. Commenters welcome new helmet designs, but advocate no exception to the existing mandatory rule for bike helmets, as it may result in needless deaths and injuries, and because of unanswered questions about the product's safety profile. Commenters state that the existing testing criteria is based on real world experiences with bicycle crashes and injuries, such as secondary impacts, varying weather conditions, and varying impact surfaces, which is lacking in the proposed alternative. Moreover, the Hövding product has features that raise additional concerns, such as rechargeable batteries and a gas inflator that may create additional hazards.

Commenters state that an alternative standard is not acceptable unless such alternative standard is proven to be comparable to the existing mandatory standard, so that any product passing the alternative standard will be just as safe as those that pass the existing standard. One commenter is concerned that no comparative study was provided to understand whether the limitations of the Hövding product, compared to conventional helmets, is serious or relatively minor. The commenter suggests that approving the sale of the product in the U.S. without such information is unwise. A different commenter states that it is ridiculous to allow a helmet for sale in the U.S. that does not meet the current bicycle helmet standard, and another commenter pleads that the CPSC should not lower standards for bicycle helmets for those who seek to leverage profit from lower safety standards.

A purported expert and a physician state that the protective capacity of the Hövding product is likely inferior to traditional bike helmets, and one commenter is concerned that communicating the limitations of the Hövding product to consumers is likely difficult.

Response 7: CPSC staff agrees with the commenters' statement that new products and innovations meant to replace current technologies should meet or exceed current safety expectations. Hövding has not demonstrated that the SP Method is equivalent to part 1203 or that airbag helmets tested to the SP Method provide the same protection from head injury as traditional helmets.

Comment 8: One commenter states that Hövding's proposed alternative standard, the SP Method, should not be adopted because the standard was not developed in accordance with accepted practices of public standard development, including public input.

Response 8: CPSC staff agrees that the SP Method has not gone through a thorough, public vetting process. In contrast, part 1203 was developed through an official rulemaking process in which the current research, industry standards, and stakeholders were able to provide input.

Petitioner did not provide the CPSC with a comparative study demonstrating that the proposed alternative standard is equivalent or more stringent to the current U.S. mandatory standard. Our own analysis demonstrates that the SP Method is not as stringent as the current mandatory standard. Staff understands that the SP Method was vetted through a Swedish standards organization, but was not developed in an open, consensus environment.

Comment 9: One commenter recommends that the Commission deny Hövding's petition, stating that the product does not provide protection at the same level of the current CPSC standard. The commenter agrees with comments in the Stanford article attached to the petition, that before the Hövding technology is widely available, the product requires more reliable impact triggering technologies and should be evaluated with more realistic bicycle accident simulations. This comment was supported by another commenter.

Response 9: The petition was not accompanied by data or evidence to demonstrate that the Hövding product provides protection equal to or greater than helmets that meet the current mandatory standard, part 1203. CPSC staff's review of the comparative requirements in each standard demonstrate that part 1203 is more stringent.

Although the petitioner briefly addresses the referenced comment from the Stanford Study in the petition, no data or evidence were provided to prove the concerns brought up by this comment and the Stanford Study.

CPSC staff agrees that the product should provide the same or higher level of safety to consumers relative to what is required by the current regulation.

Comment 10: One commenter discusses how the Hövding product could be tested to the existing CPSC standard, stating that an inflated Hövding could be tested for impact management with the CPSC test rig with minor modifications to the headform and anvils.

Response 10: CPSC staff agrees that the test method in part 1203 would only need slight modification to accommodate the methodological differences between part 1203 and the impact tests in the SP Method. CPSC staff notes that all impact testing methods referenced throughout the petition (Stanford Study, Folksam, and SP-Method 4439) are almost identical to the impact tests in part 1203. The petitioner has not explained to the satisfaction of CPSC staff why testing an airbag protective device must exclude basic requirements in part 1203, such as environmental conditions, additional anvils, and meeting the impact tests at higher impact velocities. The Swedish Institute that developed the SP Method stated that they intended to meet the requirements in EN-1078. Staff concludes that impact testing the product to a modified version of part 1203 may be an effective way to determine the level of protection provided at ideal inflation conditions. Staff advises that the Hövding product should be tested to a full system test that is equivalent or superior to part 1203, to accommodate the unique, airbag design of the Hövding product.

Comment 11: One commenter reviewed the Folksam article attached to Hövding's petition, which described how the authors tested the Hövding 2.0 product to the European standard, EN 1078, under section 5.1 for shock absorption. The article states that modified anvils with larger dimensions were used to test the Hövding product in both the shock absorption and three oblique tests, so that the inflated airbag would not come into contact with the sharp edges of the anvil. The commenter contends that, at a minimum, the flat anvil surface dimensions in part 1203 would need to be increased to accommodate the Hövding product. The commenter states that this modification is minor, but raises questions about how the product would hold up if it encountered a sharp object during a crash, such as the teeth on a bicycle chain or other environmental factor, like the edge of a car door.

Response 11: CPSC staff notes that anvil edge effects are not explicitly covered by the current regulation. Because the product is an airbag, staff agrees that the product's response to sharp points commonly found in an urban environment may be a significant concern. The petition did not provide information on the rationale for using larger anvils, or how the SP Method accounts for sharp points in an accident scenario. The Stanford Study attached to the petition listed sharp points in an accident scenario as a concern.

Comment 12: One commenter notes that the test headforms in part 1203 are constant mass, and differ from the SP Method, which relies on the EN 960 variable mass headforms. Headforms used in the U.S. and European standards do not have a neck, which raises questions, as pointed out in the Folksam article attached to the petition. For the article, researchers conducted comparative testing both with and without a neck on the test head, because the neck provides support for the Hövding product in the rotation tests. Researchers found that the Hövding product tested with the neck on the tests head had a slightly higher rotational velocity than testing without a neck. However, testing conventional helmets, which has a very short test scenario, with a neck on the test head had a significant effect on the results. The commenter notes that the Folksam article cites to a 2015 research paper by Fahlsted, and echoes calls for further investigation on the impact the neck has on longer impact durations, such as those for the Hövding product.

Response 12: The petition did not discuss why the SP Method uses variable mass headforms, rather than constant mass, as currently required. Additionally, the petition does not providing information on whether headforms with necks should be used.

Staff agrees with the commenter that this issue should be properly addressed and vetted before the SP Method can be accepted as an alternative to part 1203 for airbag products.

Comment 13: One commenter states that the Hövding petition seeks an exemption from the required CPSC standard for impact protection, based on the SP protocol, which is not equivalent to the mandatory standard. The commenter states that like the CPSC standard, the SP Method contains drop tests on both flat and curbstone anvils. However, the commenter contends that the SP Method does not assure equivalent levels of protection, as the drop protocols are from much lower levels. The SP method requires an impact speed of 3.8 m/s on the curbstone anvil (dropped from a height of about 0.7 meters), compared to a CPSC standard requirement of impact speed of 4.8 m/s (dropped from a height of 1.2 meters). The SP Method drop on the flat anvil is 4.5 to 5.8 m/s (from height of 1.0 to 1.7 meters), well below the CPSC standard requirement of 6.2 m/s (2 meters). The commenter states it has no information as to why the SP Method does not use the CPSC test rig at CPSC drop heights, and that the reported results do not establish Hövding's level of protection.

Response 13: CPSC staff agrees that the SP Method is not equivalent to part 1203, nor was staff provided with a justification to their equivalence or data supporting the theory that the SP Method is more stringent.

An adequate justification for the differences between the SP Method and part 1203 was not provided to staff. Without proper justifications, staff are led to believe that based on the parameters alone the proposed alternative testing method is significantly less stringent than what is currently required by part 1203.

Comment 14: One commenter rejects the Hövding petition's assertion that testing for positional stability is unnecessary. The commenter states that because the Hövding product is worn on the neck, the test and equipment for the CPSC standard should be adjusted to accommodate the Hövding product. The commenter contends that the CPSC test could be modified to add a neck to the head form to assess the ability of the collar to remain on the wearer during various conditions prior to inflation, as well as to keep the inflated airbag on the rider's head during a variety of crash sequences. Additionally, the commenter advises that neck strain would need to be tested to ensure the product does not increase neck injuries during crashes or a "snagging scenario," before and after inflation. The commenter states that the SP Method uses a shoulder dummy rather than a neck test, but that a realistic test would require adding a neck accessory.

Response 14: CPSC staff agrees that further information, which was not provided in the petition, is required to determine whether the product should be exempt from any of the tests included in the current regulation.

Staff currently advises that testing the positional stability of the product is important and should be verified before, during, and after an accident scenario.

Staff also agrees with the commenter that it may be important to address any effects the product may have on the neck during an accident scenario.

Furthermore, the petition did not include any justification for the test methods developed in SP Method, nor did it include any analysis on user neck strain during product use beyond what is required in the SP Method section 5.15 "blocked deployment test."

Comment 15: One commenter states that the immersion test in part 1203 and ASTM standards cannot be used on the Hövding product, as it comes with instructions and exterior graphic warnings not to immerse the product in water. The commenter advises that the purpose of the immersion test is to ensure that a helmet will function while riding in rainy weather. The commenter states that the SP Method suggests use of one of two spray or dribble tests; however, CPSC and ASTM have previously rejected spray tests as inconclusive. The commenter concludes that removing the immersion test raises questions about the Hövding product's ability to function in normal cycling environments. The commenter notes that CPSC would have to waive the immersion requirement to accommodate the Hövding design.

Response 15: CPSC staff agrees that the purpose of the immersion test is to ensure that helmets function properly in rainy weather. Staff notes that during the part 1203 rulemaking process, spray testing as an alternative was reviewed and rejected.

To accept Hövding's alternative environmental conditioning, a scientific and practical justification is required, explaining how spray testing is equivalent or more realistic than the current test method.

Comment 16: One commenter states that the only test to evaluate the fit of a helmet in part 1203 is the positional stability test, which only requires that the helmet not come off the head form. The commenter advises that ASTM F1447 contains a more stringent version of this test, providing a standard which states how far the helmet can move during the test and still pass. The commenter states that neither of these tests is appropriate for an inflatable device, as the hook used under the edge of a helmet could deflate the device, and the test is unlikely to provide a realistic test of whether the Hövding product would stay on the neck before or after inflation. The commenter explains that the introduction to the SP Method states that to achieve maximum performance, and to ensure stability on the head, "it is of great importance that the head protector is of a shape that fits the user's head and neck," but the protocol contains no lab test to assess fit.

Response 16: CPSC staff agrees that the current positional stability test method required in part 1203 cannot be applied to the uninflated device. However, without sufficient explanation why some positional stability test is not applicable to the Hövding product, staff believes that an inflated product should be tested for positional stability before and after the product is triggered. To capture real world use, a test should be developed to gauge the product's dynamic positional stability performance.

Staff also agrees that proper fit of the product may be an extremely important factor for proper functionality, because a product of this nature that is not properly installed could potentially lead to no deployment at all, or could collect movement data incorrectly leading to incorrect deployment.

Comment 17: One commenter states that the worst bike crashes typically involve a collision with a motor vehicle followed by a secondary impact with pavement, stanchions, curbs, or other obstacles. The commenter contends that conventional helmets work well in this scenario, provided that the fit of the helmet is well adjusted.

The commenter states that the Hövding product will not attenuate an impact if the device does not inflate, and that to assess impact attenuation of an inflated Hövding product requires detailed specifications for the pressure in the airbag at the time of initial deployment and the seconds that follow prior to a secondary impact. The commenter reports that a Stanford News article about a research paper attached to the petition states that the deployment device in the Hövding product tested was inadequate to ensure optimal performance. The commenter argues that inadequate inflation "could cause the airbag to bottom out, providing much less protection than a normal helmet. Loss of pressure in an airbag following the first impact might render it ineffective for a second impact, particularly with a curb or stanchion." The commenter opines that developing protocols to assess performance in an inflatable device in a two-impact situation would require extensive modifications to the current data acquisition setups for part 1203. Additionally, the commenter suggests that the speed of deployment of an inflatable device would need to be assessed.

Response 17: CPSC staff agrees that bicycle crashes in the U.S. often involve multiple impact surfaces. As the commenter has pointed out, if the product does not inflate properly the consumer may be left completely unprotected. Staff agrees and is concerned with this "worst case scenario" and others. The petition has provided little evidence to assure staff that the product properly addresses these scenarios as referenced by the Stanford Studies.

Staff acknowledges the commenter's concerns about the effects of the accident on the inflation of the product and how it will change its performance for common multiple impact scenarios. Staff notes that the SP Method includes a "Duration of inflated status" test, but no explanation of the metrics of the test or how duration of inflated status would be applicable to a multiple impact scenario.

Staff believes that in order to understand the real world performance of the product a full scale dynamic test on the product should be required.

Comment 18: One commenter describes published test reports about the Hövding product. The commenter cites a 2014 article in the French consumer magazine, *Que Choisir* and the Swedish affiliate *Rad&Ron*, stating that the Hövding product is reported to fail the European bicycle helmet test when inflated and impacted on the EN 1078 curbstone anvil. The commenter notes that part 1203 uses an additional hemispheric anvil and generally requires more severe impacts. Accordingly, the commenter questions whether the Hövding product can meet anything but a flat anvil test, and notes that testing conducted at other laboratories has only been on flat anvils, including the research attached to the petition. The commenter contends that flat anvil testing alone is insufficient to test against real-world hazards.

Response 18: CPSC staff has not received any data regarding the product's impact attenuation performance to any consensus-based bicycle standard (including CFR, EN, ASTM, or SP). Moreover, CPSC staff has not received any data regarding the product's impact attenuation performance to either the hemispherical or curbstone anvils. CPSC staff has also not received flat anvil test data to any test method that is equivalent or more stringent than the requirements in part 1203. The petition does not provide a justification for the less stringent requirements in the SP Method.

Staff agrees that if the SP Method was accepted as an alternative to part 1203 in its current form, the impact attenuation requirements for the product would be significantly less stringent that what is required for current bicycle helmets on the U.S. market.

Comment 19: One commenter is concerned about the lack of third party testing for the Hövding product, and the limited test protocol purportedly used by SP, and notes that the *Que Choisir / Rad&Ron* article describes the Hövding product's accreditation: "Accreditation, however, consists only in letting the Swedish laboratory SP test the helmet according to criteria considered by SP. No third party in the form of authority or other lab has reviewed the test method." The commenter states that the SP Method has been accepted by the Swedish Board for Accreditation and Conformity Assessment, but only for compliance with the requirements for the CE mark, not for the EN 1078 helmet standard.

Response 19: Staff has not received SP Method test data staff can share, either from SP or a Third Party Lab. Staff notes that the physical testing for the Folksam study was also completed by SP. Staff agrees with the commenter that in order to be a scientifically valid test method, results should be repeatable and reproducible between multiple independent test labs.

Staff acknowledges that the product has not been officially tested to EN 1078, instead the SP Method was developed in order to receive the CE mark and so the product could be sold in Europe.

Comment 20: One commenter quotes the *Que Choisir/Rad&Ron* article explaining that when testing an inflated Hövding product, the Hövding "did not absorb enough energy in the standardized test where the helmet was released against a 130 mm wide steel rod. The result was significantly worse than for regular bicycle helmets. The company Hövding explains the results that instead of testing their helmet against wider metal objects than the 130 mm standard, the results will be much better. But in traffic there are many scenarios where just head protection against narrow, hard objects is crucial. It's far from always that the biker's head hits the wide asphalt, the helmet will also protect against metal posts, sidewalks and the like." The commenter contends that no matter what the helmet design, the product must protect against real-world hazards. The commenter expresses concern that the Hövding petition is really seeking an exemption from the hemispheric and curbstone anvil tests, which is not an exemption based on the product design, but an exemption from the level of head protection required by the U.S. standard.

Response 20: CPSC staff has not received any test data testing the product to any regulatory standard.

Staff notes that part 1203 only contains a 125 mm minimum diameter requirement for the flat anvil, equivalent to the commenter's referenced impact anvil. In accordance with the test method outlined in part 1203, impact anvil edge effects are not intended to be addressed by the standard.

Nevertheless, staff is concerned by the *Que Choisir/Rad&Ron* findings and would welcome any data on the product's performance on currently accepted impact anvils and impact speeds. Furthermore, staff acknowledges that the even though impact anvil edge effects are not addressed, part 1203 does include a curbstone and hemispherical anvils that simulate these effects.

Staff agrees that bicyclists clearly require protection against impacts against a number of different surfaces and obstacles. Therefore, staff is concerned that the petition provides no justification for excluding the hemispherical anvil.

Comment 21: One commenter contends that the inclusion of the Hövding product in the Folksam study, attached to the petition, is misleading. The commenter states that the Folksam study represents that all of the helmets tested passed the EN 1078 standard, but did not attempt to verify the accuracy of this statement. The commenter states that the Hövding product has not passed the EN standard, and has not passed testing at full height on the curbstone anvil, nor has its retention system been tested for strength or stability. The commenter describes that the Folksam study only tested the Hövding product on flat anvils, "again exempting the Hövding from meeting tests for real-world hazards."

Response 21: Staff agrees with the commenter that the statement made in the Folksam report may lead readers to believe the product has met EN 1078. Although staff notes that the report's footnote #3 attempts to clarify this issue.

Nevertheless, staff acknowledges that due to regulatory differences between the EU and the U.S., the fact that the Hövding product has not met any officially recognized helmet standard has been difficult to communicate to consumers.

Staff acknowledges that the petition only includes partial performance data on the product on flat impact anvils, and no data or justification has been provided as to why the petition attempts to exclude the curbstone and hemispherical anvils.

Staff believes helmets offered for sale in the U.S., regardless of design, should definitively meet or exceed the requirements in part 1203 to protect consumers against real world hazards.

Comment 22: One commenter expresses concern that the SP Method advanced by the Hövding petition contains provisions that are "highly subjective judgments of the lab technician," and cannot be replicated by other labs, including the following protocols:

- "The product shall be examined to identify surfaces on or adjacent to the inflatable chamber, which contact the skin, where an excess amount of heat could be transmitted."
- "Inspect the head protector to ascertain whether it is suitable for its intended purpose and fulfils the general requirements in 4.2 (Construction). If no test method is specified in this document the compliance with general requirements have to be checked by visual and/or tactile examination."
- "The head protector shall be placed on a test person representative for the actual head protector size and according to the manufacturer's instructions. The person shall check that, during normal use, i.e. bicycling according to the manufacturer's instructions, normal positions can be reached and movements can be done without any appreciable discomfort."

Response 22: Staff agrees that several sections in the SP Method are dependent on the technician. Staff is concerned with the scientific validity of these tests, and questions whether such subjective test requirements can be scientifically repeatable and independently reproducible.

Comment 23: One commenter points out areas of concern in the SP Method advanced by the petition. For example, one test protocol allows a manufacturer to choose an alternate test procedure if a helmet fails a test: "If head impact occurs before the head protector has reached inflated status, the manufacturer can choose to have the shock absorption test performed at the actual pressure at head impact." The commenter contends that no U.S. helmet standard has allowed a manufacturer to choose an alternative test procedure if their product fails a test.

Response 23: Staff agrees that the option for the manufacturer to decide the test method applied to its product depending on the helmet's results to previous tests is unprecedented. Staff is concerned that manufacturer involvement within the proposed test method can significantly affect the results. Furthermore, if manufacturer involvement is required, such a provision extinguishes CPSC's ability to "secretly" test a regulated product for compliance with the standard.

Comment 24: One commenter points out that the protocol in the SP Method to test the noise level upon airbag deployment which occurs near a rider's head specifies a noise level threshold that "shall not exceed 135 dB," a level that is above the threshold for pain. The commenter contends that although the noise may not do permanent damage to a rider, it will startle the rider and be disruptive, especially if the airbag deploys unnecessarily.

Response 24: Staff discusses this topic in detail in the Human Factors memorandum in TAB C of this briefing package. Using both the discussed NIOSH and OSHA formulas for exposure and duration of a loud noise,[67] staff has approximated that the impulse noise generated by the deployment of the product

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[67] *OSHA Fact Sheet: Laboratory Safety Noise*. (2011). Washington, D.C. United States Dept. of Labor, Occupational Safety and Health Administration

are within both regulations. However, given its proximity to the ear, staff is concerned that 135 dB may cause momentary pain or discomfort, and if falsely deployed, could lead to a crash scenario.

Comment 25: One commenter discusses the importance of the triggering mechanism to inflate the Hövding airbag. The commenter states that it is unaware of other published standards to assess elements of inflatable headgear, but notes that the Stanford Study attached to the petition states the importance of the Hövding product's sensors, and conclude: "…before this technology becomes widely available, airbag helmets need more reliable impact triggering technologies and should be evaluated in more realistic bicycle accident simulations."

Response 25: CPSC staff is also currently unaware of standards that can properly address each of the systems within the product. CPSC staff would urge voluntary standards groups to consider development of such standards prior to such products like inflatable head protective devices with electronic triggering mechanisms enter the market.

Comment 26: One commenter notes inherent issues with airbag technology, stating that unlike a traditional bike helmet, if the airbag fails to inflate for any reason prior to impact, the rider has no head protection. The commenter lists several non-inflation scenarios, such as if the rider fails to turn on the Hövding, the batteries are depleted, or the airbag sensors fail. The commenter also states that impacts that do not involve typical fall motions will fail to inflate the Hövding, such as impacts with an overhanging back of a truck, overhanging tree limbs, low bridges, and impacts with vertical hazards, such as stanchions, utility poles, bridge abutments, motor vehicles, trees, and others, where the first impact to the head occurs before a fall or other change in head direction. The commenter notes that moving hazards, such as car mirrors, can overtake a rider from behind without warning. The commenter explains that a conventional helmet will provide protection in all of these scenarios, while a Hövding will not be inflated in these instances. The commenter links to a video to demonstrate a crash scenario when the Hövding product may fail to inflate in time to protect a rider's head.

Response 26: Staff shares the same concerns as the commenter. A more comprehensive list of intrusions can be found in Tab B of the briefing memorandum. Staff concurs that a standard helmet that meets part 1203 provides a constant shield from these objects, as well as offering relief from incidences that could cause more severe injuries like concussions. Petitioner submitted no evidence that the Hövding product will provide protection in these situations.

Comment 27: One commenter states that a reactive inflatable device such as Hövding's may not be in place when an impact occurs. The commenter points out that this idea is stated in the SP Method attached to the petition, which states: "When an inflatable head protector is used in normal bicycling there is no protection against a direct hit to the head. Also the head protector offers limited protection against pointed objects . . . [and] offers limited protection when the head protector has only partially reached inflated status prior to head impact." The commenter notes that the Folksam Study attached to the petition also discusses the limitation of the Hövding product in that it does not provide direct head impacts, meaning those that occur without falling off of the bike.

Response 27: As discussed throughout the memorandum, obstructions, intrusions, and other objects that enter the head space while riding in an urban environment are of great concern. Staff has asserted that the Hövding product does not provide protection, until and unless, it deploys. Outside of these situations are the intrusions from an overabundance of objects found in the urban environment. These objects are further discussed and detailed in Tab B.

Comment 28: One commenter provides a link to videos taken during the lab tests for the Folksam article attached to the petition. The commenter contends that the videos "show considerable rebound after impacts testing the Hövding." The commenter states that such rebound may increase the velocity of the head (delta V) more than a conventional helmet, and that recent suggestions for helmet testing include measuring delta V, a suspected factor in concussions. The commenter again notes that the Folksam Study calls for additional research on the effect of testing the Hövding with a neck during longer impact sequences.

Response 28: The Folksam Study uses a pre-inflated manufacturer-modified sample of the Hövding product inflated to approximately 8 psi (0.55 bar). Based on the public information provided by the petitioner, staff is unable to determine if this is a normal, under, or over pressurized system. While staff believes that the rebounding velocity is an important aspect of the overall testing of helmets which can lead to additional concussion scenarios, its implications here cannot be assessed due to lack of information and relevance to the current helmet regulation.

Comment 29: One commenter notes that the shape of the Hövding airbag and its extension from the head could complicate injuries, especially if the airbag snags on an object before or after impact.

Response 29: Staff cannot comparatively evaluate the dimensions of the inflated Hövding product to a traditional hard shell helmet based on the information submitted by the petitioner. However it is feasible that the additional difference in volume, whatever that may be, could catch on an object or intrusion during an accident scenario.

Comment 30: One commenter states that the zipper on the Hövding product is complicated and could be difficult for first responders to remove if not familiar with the product. The commenter provides a link to a video to demonstrate this concept. The commenter notes that part 1203 does not contain a test for ease of removal of the product, because traditional helmets are easy for first responders to see and remove without disturbing the rider's head or neck position.

Response 30: Staff shares the concern and discusses this point in detail in the Human Factors memorandum in Tab C. First responders may or may not be able to identify the product, and, in the scenario where an injury resulted in the product not responding – may create an additional accident scenario to first responders and the victim if the product is not properly disarmed.

Comment 31: One commenter states that an inflated Hövding product may not pass peripheral vision requirements in part 1203, which may restrict a rider's ability to manage a crash, "particularly if the Hövding has deployed unnecessarily and no crash has yet occurred."

Response 31: Staff shares the commenter's concern regarding the peripheral vision requirements, however, due to the lack of information provided by the petitioner, staff cannot confirm the concerns. The SP Method does not have any requirement for peripheral vision. Once deployed, the Hövding product could limit peripheral vision, and create a potential hazardous situation after the deployment has occurred, such as, the cyclist walking away from an accident in the middle of the street or intersection.

Comment 32: One commenter is concerned about foreseeable misuse of the Hövding product. The commenter notes that the petition states that the Hövding is not designed for mountain biking, but the commenter believes that riders would use it for this activity if the product is sold in the U.S. The commenter points out that Hövding does not explain why the airbag product cannot be used for mountain biking, or other activities such as scooters, roller skating, or others.

Response 32: Staff discusses the same concern in the Human Factors memorandum in Tab C of this briefing package. The Hövding user manual states that the product is intended for use with certain two-wheeled bikes; however, staff could not rule out the possibility of hybrid bikes or mountain bikes, being used in urban and rural settings (non-mountainous) by consumers. Therefore, staff determined that it was foreseeable for the product to be used in these additional scenarios.

Comment 33: One commenter opines that the nine hour maximum batter recharge may be too short for some riders, as some may start a ride without a fully charged battery, and could complete a ride without an operable airbag. Moreover, the commenter asserts that because batteries lose capacity over time, the issue of riding when the battery runs out could increase over time as the battery ages. The commenter notes that airbags left without use for two or three years could have a dead battery and the inability for use until charged.

Response 33: Staff shares the same concerns in the Human Factors memo found in Tab C. The petitioner has given no details surrounding the maximum number of charges until depletion or maximum capacitance (amp-hours) or rate of dissipation (amperage consumed while active). As such, staff views the 9-hour length of charge as a gross approximation.

Comment 34: One commenter questions Hövding's statement that the company is only aware of one incident where the product did not deploy as expected. The commenter explains that a quick internet search revealed at least 5 videos demonstrating problems with the Hövding product either not deploying as it should in a crash scenario, or deploying in circumstances when it should not. The commenter contends that the product technology requires additional evaluation in more realistic bike accident scenarios before the product becomes widely available. The commenter also queries whether airbags for bike riders are similar to airbags in cars, where the technology is used as a supplementary protection to seatbelts.

Response 34: Staff is aware of several accidental deployments as demonstrated by the online videos detailed in Table 1 of Tab B. Based on the available information provided by the manufacturer, the algorithm is under constant development, learning from previous failures of the device. However, the petition provided no information as to whether the product consistently works as expected.

Comment 35: One commenter states that section 205 of Public Law 103-267, 108 Stat. 722, June 16, 1994, directed the CPSC to adopt a bicycle helmet standard, and that helmets sold in the U.S. must meet this standard. The commenter contends that the law does not grant CPSC the authority to make exceptions to the mandatory helmet standard, stating that it "would be unfortunate and could be illegal for CPSC to grant an exemption from the legally-mandated standard to accommodate one manufacturer whose product cannot meet the required standard. The commenter argues that the Hövding product does not provide equivalent protection to helmets compliant with part 1203, and CPSC has never previously issued waivers for this regulation. The commenter predicts that if CPSC grants a waiver, the agency should expect additional requests, including "folding helmets, recyclable helmets and helmets made from recycled materials." The commenter additionally warns that a second wave of airbag products may include inexpensive competitors with "low-grade design and quality control . . . [and] may have inferior performance." The commenter recommends denying the Hövding petition "on the grounds that it seeks approval of a device with a lower level of protection than conventional helmets certified to 16 CFR 1203."

Response 35: Staff does not recommend granting the petition at this time. However, if a product or standard offers consumers equal or better protection from known hazards, staff could consider options for modifying a regulation under the appropriate statutory and regulatory framework at that time.

Comment 36: One commenter states that it has concerns that the Hövding product will present consumers with a confusing choice between a CPSC-tested and certified bicycle helmet and a new, as yet unproven, alternative. The commenter points out that various state and local laws require the use of bike helmets by cyclists under the age of 18. As an example, the commenter cites California Vehicle code Article 4, Section 21212, which the commenter contends requires the use of a helmet by a person under the age of 18 when operating a bicycle, and prohibits the use or sale of any helmet that does not meet the requirements of either the ASTM or the CPSC helmet standard. Accordingly, the commenter notes that the Hövding product would not be a lawful replacement for a bike helmet in California or in other jurisdictions with mandatory requirements. The commenter advises that use of the Hövding product in California could result in the risk of citation or imposition of liability in a crash scenario.

Response 36: Staff agrees that the Hövding product is an as yet unproven alternative to a traditional bicycle helmet that meets part 1203, but concludes that merit exists in further research for deployable airbag safety devices. If the Commission granted the petition, the Commission would begin a rulemaking proceeding to amend part 1203. Airbag helmets would only be allowed if they met a final rule establishing an appropriate alternative test method for them.

Comment 37: One commenter states that Hövding's choice to market its product as "the new bicycle helmet" creates the potential for consumer confusion about the efficacy of the Hövding product. The commenter quotes statements on Hövding's website regarding aspects of the European helmet standards and the CE mark. The commenter contends that Hövding should not be allowed to promote its product as a "bicycle helmet" and at the same time be exempt from test standards that all other manufacturers of helmets must meet.

Response 37: All products marketed as a bicycle helmet offered for sale in the U.S. must meet the requirements in part 1203. If the Hövding product were allowed to be sold in the U.S. by meeting the SP Method, staff agrees that the term "helmet" could be misleading, because staff concludes that the product would not offer the same protection as a helmet that meets the current part 1203.

Comment 38: One commenter states that he was struck by an SUV driving 25 mph while riding a bike 3 years ago. According to the commenter, his head shattered the SUV's windshield, covering the SUV driver and his CPSC-certified helmet with shards of broken glass. The commenter survived, but purportedly suffered a concussion and numerous spinal fractures, and the SUV was totaled. The commenter doubts that "a plastic bag full of helium would have offered that level of protection."

Response 38: Based on the petition, staff cannot assess the likelihood or survivability of such a scenario. The impact speed test requirements for the Hövding product vary, depending on the zone and surface being used in the scenario, and are typically less than the speeds tested in the current regulation. *See* Appendix III.

IV. Comments that are Neutral Regarding the Petition

Comment 39: One commenter states that the Hövding product is not a helmet, and does not pretend to provide the same level of crash protection as a helmet in the event of a fall or crash. The commenter states that the Hövding product is an unregulated elective product for adults that do not wish to wear a bicycle helmet, which is not required in most cities and states.

Response 39: Part 1203 defines a bicycle helmet as "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." To be allowed under CPSC's standard, the Hövding product would need to provide an equivalent level of safety as a helmet that meets part 1203.

Comment 40: One commenter states that the CPSC should allow for responsible product innovation and adopt an alternative test method that provides for the same level of impact protection for products such as

Hövding's. The commenter states that while the Hövding product uniquely allows a consumer to bike to work without the attendant hair and pressure mark issues of conventional helmets, the CPSC should not rubber-stamp a test method submitted by a potentially biased manufacturer. The commenter advocates that CPSC: (1) evaluate the proposed SP Method, against the mandatory safety standard for bicycle helmets, and look for areas of equivalency and divergence; (2) explore the fundamental differences between hard shell helmets with their inherent safety protections, such as protection against low-speed falls, airborne debris, objects hanging in the path of travel, and work while wearing, with airbag products that bring new safety concerns, such as low batteries, gas canisters, ergonomic issues, user failures, and degradation of ability; and (3) adopt a policy of viewing a manufacturer-submitted standard with skepticism and scrutiny. The commenter states that Hövding should work with the CPSC to develop a new standard for airbag products that is equivalent to the existing standard.

Response 40: Staff agrees with the commenter. CPSC strives to provide fair and unbiased evaluation of unique and emerging products. Staff has evaluated the current mandatory standard for bicycle helmets against the SP Method, as shown in Appendix III, and has shown that in overlapping areas, the SP Method is not as stringent as the current regulation. In addition, staff has weighed the differences between hard shell helmets against the developing technology for airbag deployables. While the submitted studies show promise from some threats to cyclists, the studies raise new issues for further study. Staff encourages any and all manufacturers to conduct "round robin" styled testing of any proposed alternative, as well as reaching out to voluntary standards committees to improve and develop any potential new performance requirements.

TAB G: EXC - Petition CP-18-1; Summary of Product Safety Recalls and Associated Injuries for Bicycle Helmets from January 1, 2013 to December 31, 2017

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: July 26, 2019

TO	:	Brian Baker, Mechanical Engineer, Project Manager Division of Mechanical Engineering, Directorate for Laboratory Sciences
THROUGH	:	Robert Kaye, Assistant Executive Director, EXC Jennifer Timian, Director of Regulatory Enforcement, CRE Shaun Keller, Supervisory Compliance Officer, Mechanical/Chemical Hazards Team
FROM	:	Julio Alvarado, Compliance Office, Mechanical/Chemical Hazards Team
SUBJECT	:	Petition CP-18-1; Summary of Product Safety Recalls and Associated Injuries for Bicycle Helmets from January 1, 2013 to December 31, 2017

I. INTRODUCTION

Staff for the Office of Compliance prepared this memorandum in response to Petition CP-18-1, submitted by Hövding Sweden AB (petitioner), requesting that the Commission exempt "inflatable head protective devices for bicyclists," such as Hövding's product, from the testing requirements of the Safety Standard for Bicycle Helmets, if such product complies with, and is certified to, requirements in another standard that Hövding states is appropriate to test such products. This memorandum summarizes the product safety recalls conducted by the Office of Compliance and Field Operations (Compliance) and the reported injuries involving bicycle helmets.

II. BACKGROUND

The existing mandatory standard for bicycle helmets is codified at 16 CFR part 1203. Section 1203.4(b) defines a *bicycle helmet* as "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." Furthermore, a footnote makes clear that multi-purpose "helmets" would fall within the standard if a reasonable consumer would conclude the helmet can be used for bicycling. Accordingly, unless a helmet is specifically marketed for another activity, such as skateboarding, a helmet sold for use in the U.S. must comply with the mandatory standard for bicycle helmets.

Hövding clearly intends its product to be used by bicyclists. Hövding's petition seeks to exempt "inflatable head protective devices for bicyclists" from the requirements of part 1203. The Hövding product is marketed and sold as a "helmet," indicating that it would be covered by the mandatory standard for bicycle helmets if the product is sold in the United States.

III. COMPLIANCE INVESTIGATIONS

Compliance staff reviewed the recalls and press releases on bicycle helmets from January 1, 2013 to December 31, 2017, and found a total of seven consumer level recalls involving 187,530 bicycle helmets.

On March 28, 2013, Bell Sports initiated a recall involving about 2,500 Bell Full Throttle Bike Helmets, sold from July 2012 through January 2013. As documented, the buckle on the helmet's safety strap can release in an accident and allow the helmet to fall off the rider, posing a risk of head injury. No injuries or incidents were reported. Consumers were told to immediately stop using the recalled helmets and contact Bell Sports for instructions on receiving a full refund.

On October 10, 2014, Louis Garneau recalled about 1,180 of their P-09 aerodynamic bicycle helmets. The helmets were sold from January 2014 through September 2014. In cold temperatures, the helmet can fail to protect the wearer from impact injuries. No incidents or injuries were reported. Consumers were instructed to immediately stop using the recalled helmets and return them to Louis Garneau USA for a full refund or replacement with a similar helmet.

On December 12, 2014, UVEX initiated a recall involving about 46,800 of seven models of UVEX helmets, sold from September 2009 through June 2014. The anchor for the helmet's chinstrap can fail, causing the helmets to slide off the head, posing a head injury hazard. The bicycle helmets also do not comply with the impact requirements of the CPSC safety standards for bicycle helmets. Consumers were instructed to stop using the helmets and contact UVEX for a free compliant helmet or a refund of the purchase price.

On February 13, 2015, SCOTT conducted a recall involving about 1,450 of the 2015 SCOTT® Vanish Evo Bicycle Helmets, sold from July 2014 through December 2014. The bicycle helmets do not comply with the impact requirements of the CPSC safety standards for bicycle helmets. No incidents or injuries were reported. Consumers were instructed to immediately stop using the recalled bicycle helmet and to take it to an authorized SCOTT dealer for a refund of the purchase price.

On May 17, 2016, Pacific Cycle recalled about 129,000 infant bicycle helmets with magnetic no-pinch buckle chin straps, sold from January 2014 through April 2016. The magnetic buckle on the helmet's chin strap contains small plastic covers and magnets that can come loose, posing a risk of choking and magnet ingestion to young children. Pacific Cycle received three reports of the plastic cover coming loose. No injuries have been reported. Consumers were instructed to immediately take the helmets away from children and contact Pacific Cycle for instructions on how to receive a free replacement helmet**.**

On September 01, 2016, SAHN Designs recalled about 2,000 of the Classic SH523 adult bicycle helmets, sold from May 2013 through December 2015. The bicycle helmets do not comply with the impact requirements of the federal safety standard for bicycle helmets, posing a risk of head injury. No incidents or injuries were reported. Consumers were instructed to immediately stop using the recalled bicycle helmets and contact SAHN Designs for a free replacement helmet.

On September 25, 2017, Pro-Tec recalled about 4,600 of the City Lite and Pro-Tec Street Lite adult multisport helmets, sold from February 2016 through January 2017. The buckle on the helmet fails to meet current federal safety standards, posing a risk of head injury. No incidents or injuries were reported. Consumers were instructed to immediately stop using the recalled helmets and return them to Pro-Tec for a full refund.

APPENDIX I: Bicycle Helmet Safety Standard Comparison – Section By Section

Bicycle Helmet Safety Standard Comparison - Section by Section

On the next page, Table 1 contains an in-depth comparison between part 1203, the SP Method, and EN 1078. The purpose of this comparison is to demonstrate which sections in each standard are considered relatively “equivalent”. Table 1 is organized by (in order): A product description describing what is meant to be covered by the scope of each standard; sections included in part 1203; sections specifically included to meet EU Directive 89/686/EC included to allow the product to have the “CE” mark; and sections specifically designed for inflatable head protective devices with electronic triggering mechanisms.

Table 1: Bicycle Helmet Safety Standard Comparison - Section by Section

Bicycle Helmet Safety Standard Comparison

CFR 1203 : The current U.S. helmet regulation. **- vs. -** **SP-method 4439 :** The proposed alternative standard. **- vs. -** **EN 1078 :** The current European helmet standard.

Add.info.	Section	CFR 1203	Section	SP - method 4439	Section	EN 1078
Product Definition	1203.4	Bicycle helmet: 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	3.2.1	Inflatable head protector - Head protector: Device intended to reduce the risk of head injury to pedal cyclists and including: a) the outer covering and shock attenuating system, b) all associated software	3.1	protective helmet: item to be worn on the head and intended to absorb the energy of an impact, thus reducing the risk of injury to the head.
CFR 1203 Subsection A - The Standard: Background Information	1203.1 1203.2 1203.3 1203.4	Scope, general requirements, and effective date Purpose and basis Referenced documents Definitions	0 1 2 3	Foreword/Introduction Scope References Terms and definitions	0 1 2 3	Foreword/Introduction Scope Normative references Terms and definitions
Visual Inspection Tests	1203.5	Construction requirements	4.1 4.2 5.2	Materials Construction Visual and tactile inspection and wearer trial	4.1 4.2 4.6 5.2	Materials Construction Retention System Inspection and determination of mass
	1203.6	Labeling and instructions	6 7	Marking Information to be supplied by the manufacturer	6 7	Marking Information supplied by the manufacturer
Physical Test Preparation & Background	1203.7	Samples for testing	5.1	Sampling	5.3	Number of samples and sequence of tests
	1203.8	Conditioning environments	5.1 5.3	Sampling Conditioning	5.4.2	Conditioning
	1203.9	Test headforms	5.5.2	Headforms	5.1	Headforms
	1203.10	Selecting the test headform	5.5.4.1	Testing parameters	5.1	Headforms: Table 1 Sizes of headforms
	1203.11	Marking the impact test line	5.4	Determination of area to be protected	5.4.1	Test Area
	1203.12	Test requirements	4	Requirements	4	Requirements
	1203.13	Test Schedule	5.1	Sampling	5.3	Number of samples and sequence of tests
Physical Tests	1203.14	Peripheral vision test	N/A		4.3 5.7	Field of vision Determination of field of vision
	1203.15	Positional stability test (roll-off resistance)	N/A		4.6 5.6	Retention System Determination of retention system effectiveness
	1203.16	Dynamic strength of retention system test	N/A		4.6 5.5	Retention system Determination of retention system strength and ease of release
	1203.17	Impact attenuation test	5.5 5.10	Determination of shock absorbing capacity Drop test	4.4 5.4	Shock absorbing capacity Determination of shock absorbing capacity
Additional Subparts in CFR 1203	Subpart B - Certification		N/A		N/A	
	Subpart C - Recordkeeping		N/A		5.8	Test report
	Subpart D - Requirements for Bicycle Helmets Manufactured From March 17,1995, Through March 10, 1999		N/A		Annex B Significant technical changes between this European Standard and EN 1078:1997	
Sections included in SP 4439 to meet EU Directive 89/686/EEC (CE Mark)	N/A		4.16 4.17 4.18 4.9/5.11 4.12/5.15	Pressure equipment EMC Low voltage Acoustic test Wear resistance test	Annex ZA Relationship between this European Standard and the Essential Requirements of EU Directive 89/686/EEC Personal Protective Equipment	
Sections of SP 4439 specifically developed for Inflatable Head Protective Devices with Electronic Triggering Mechanisms	N/A		4.14	Durability	4.5	Durability
			5.6	Determination of activation time	N/A	
			4.5/5.7	Duration of inflated status		
			4.6/5.8	Temperature exposure evaluation (applicable only for hot gas generators)		
			4.7/5.9	Evaluation of the function of the triggering system		
			4.10/5.12	Function test following conditioning		
			4.11/5.13	Resistance to false accident detection during normal bicycling		
			4.13/5.14	Function indicator		
			4.15/5.16	Blocked deployment test		

APPENDIX II: Helmet Standards Comparison – Physical Testing

Physical Testing Comparison by Standard

Table 2 provides a detailed visual comparison of all the physical test sections required by part 1203 which address specific hazards, and their counterparts within the proposed alternative standard, SP-method 4439, and the E.U. helmet standard, EN 1078.

Table 2: Physical Testing Comparison

Physical Testing Comparison By Standard						
* Describes the general performance requirement of the test, comparable to 16 CFR 1203.12 - Test Requirements ** Test determines the functionality of the device after general use (similar to toy testing), not impact attenuation in an accident.						
	CFR 1203		SP - method 4439		EN 1078	
	Section		Section		Section	
Relevant Test Section	1203.14	Peripheral vision test	N/A		*4.3 5.7	Field of vision Determination of field of vision
	1203.15	Positional stability test (roll-off resistance)	N/A		*4.6 5.6	Retention System Determination of retention system effectiveness
	1203.16	Dynamic strength of retention system test	N/A		*4.6 5.5	Retention system Determination of retention system strength and ease of release
	1203.17	Impact attenuation test	*4.4 5.5	Shock absorbing capacity Determination of shock absorbing capacity	*4.4 5.4	Shock absorbing capacity Determination of shock absorbing capacity

APPENDIX III: Impact Testing Breakdown

Impact Testing Breakdown

Beginning on the next page, is an in-depth side-by-side analysis of the impact tests required by part 1203, SP-method 4439, and EN 1078. The analysis is based on the information available and CPSC staff's current interpretations of each standard's test methodology.

Impact testing is often the most prominent test for helmets, it determines if the product absorbs enough of the impact energy to protect the head from skull fractures and death. Due to the importance of the impact attenuation test, CPSC staff has prepared an additional chart for the impact attenuation test itself, to provide a side by side comparison of the specific differences in testing. Table 4 "Impact Zones" and "Impact Speeds" highlight the differences in speed mentioned throughout the briefing package.

Table 3: Impact Attenuation Test Comparison

Impact Attenuation Test Comparison Breakdown

* - The manufacturer may choose to perform up to two impacts on each samples instead of one.
** - Each impact is completed in succession on a single sample in the order deemed as most onerous by the testing lab.

	16 CFR 1203	SP - method 4439	EN 1078
Relevant Impact Test Section & Title	1203.17 - Impact attenuation test	5.5 - Determination of shock absorbing capacity	5.4 - Determination of shock absorbing capacity
Number of Samples Tested	8	3 to 6*	3
Sample Designations	*T1 T2 T3 T4 T5 T6 T7 T8*	*1 2 3 4 5 6*	*1 2 3*
Pre-test Sample Modifications	**16 CFR 1203**	**SP - method 4439**	**EN 1078**
Number of samples modified		6	
Modifications		• Gas generator removed • Manual inflator installed • Pressure measurement installed	
Modified		*1 2 3 4 5 6*	
Pre-environmental conditioning tests	**16 CFR 1203**	**SP - method 4439**	**EN 1078**
Number of samples tested			1
Test 1			Section 5.6 - Determination of retention system effectiveness
Tested			*1*
Environmental Conditioning	**16 CFR 1203**	**SP - method 4439**	**EN 1078**
Exposure Time	4 to 24 hours	4 hour minimum	4 to 6 hours
Samples Per Environment	2	3 to 6*	1
Ambient	Temperature: 17 °C to 27 °C Relative Humidity: 20% to 80%	Temperature: 22 ±5 °C Relative Humidity: 55 ±30%	
Applied to	*T1 T5*	*1 2 3 4 5 6*	
High Temperature	Temperature: 47 °C to 53 °C		Temperature: 50 ±2 °C
Applied to	*T2 T7*		*1*
Low Temperature	Temperature: (-17) °C to (-13) °C		Temperature: (-20) ±2 °C
Applied to	*T3 T6*		*2*
Water Immersion	Temperature: 17 °C to 27 °C Position: "crown" face down Crown Depth: 305 mm ±25 mm		
Applied to	*T4 T8*		
Artificial Aging			UV Irradiation 48 hours, under a 125 W xenon-filled quartz lamp, at a range of 250 mm. Water Spraying: 4 to 6 hours, with water at ambient temperature, at a rate of 1 L/min.
Applied to			*3*
Post-environmental conditioning tests on samples (Pre-impact testing)	**16 CFR 1203**	**SP - method 4439**	**EN 1078**
Number of Samples Pre-tested	5		
Test 1	Section 1203.14 - Peripheral vision test		
Tested	*T1*		
Test 2	Section 1203.16 - Dynamic strength of retention system test		
Tested	*T1 T2 T3 T4*		
Test 3	Section 1203.15 - Positional stability test		
Tested	*T5*		

Table 4: Impact Attenuation Test Comparison (Continued)

Impact Attenuation Test Comparison Breakdown (cont.)

* - The manufacturer may choose to perform up to two impacts on each samples instead of one.
** - Each impact is completed in succession on a single sample in the order deemed as most onerous by the testing lab.

Impact Number per Sample		16 CFR 1203				SP - method 4439						EN 1078		
Unaltered Test Method	1 Impact per Sample	T5	T6	T7	T8	1	2	3	4	5	6			
Unaltered Test Method	2 Impacts per Sample											1	2	3
Unaltered Test Method	4 Impacts per Sample**	T1	T2	T3	T4									
Manufacturer Alternative Test Request*	Scenario 1: 2 Impacts per Sample					1		2		3				
Manufacturer Alternative Test Request*	Scenario 2					Any combination of the options above								

Impact Anvils		16 CFR 1203				SP - method 4439			EN 1078		
Unaltered Test Method	Hemispherical Anvil Impact Samples	T1	T2	T3	T4						
Unaltered Test Method	Flat Anvil Impact Samples	T1	T2	T3	T4	2	3	6	1	2	3
Unaltered Test Method	Curbstone (Kerbstone) Anvil Impact Samples	T5	T6	T7	T8	1	4	5	1	2	3
Manufacturer Alternative Test Request*	Scenario 1: Flat Anvil Impact Samples					1	2	3			
Manufacturer Alternative Test Request*	Scenario 1: Curbstone (Kerbstone) Anvil Impact Samples					1	2	3			
Manufacturer Alternative Test Request*	Scenario 2					Any combination of the options above					

Impact Zones	16 CFR 1203								SP - method 4439		EN 1078		
Number of Impact Zones	1								3		2		
Impact Zone Determination Factors	• Headform Size • Fit Location								• Headform Size • Impact Location		• Headform Size • Fit Location • Impact Anvil Type		
Impact Zone 1 Description	Entire required coverage zone								The front section of the coverage zone		Kerbstone Impact Zone - Partial rear coverage zone excluded		
Samples Tested in Zone	T1	T2	T3	T4	T5	T6	T7	T8	1	2*	1	2	3
Impact Zone 2 Description									The top section of the coverage zone		Flat Impact Zone - Entire required coverage zone		
Samples Tested in Zone									3	4*	1	2	3
Impact Zone 3 Description									The rear section of the coverage zone				
Samples Tested in Zone									5	6*			

Impact Speeds	16 CFR 1203	SP - method 4439			EN 1078	
Number of Impact Speeds	2	5			2	
Speed Determination Factors	Impact Anvil Type	Impact Anvil Type Impact Zone			Impact Anvil Type	
Impact Zone	Zone 1	Zone 1	Zone 2	Zone 3	Zone 1	Zone 2
Hemispherical Anvil Speed	4.8 m/s					
Flat Anvil Speed	6.2 m/s	4.53 m/s	5.42 m/s	5.81 m/s		5.42 m/s
Curbstone/Kerbstone Anvil Speed	4.8 m/s	3.68 m/s	4.57 m/s	4.57 m/s	4.57 m/s	

Impact Acceleration	16 CFR 1203	SP - method 4439	EN 1078
Acceleration Limit	300 g	250 g	250 g

Table 3: Impact Attenuation Test Comparison

Impact Attenuation Test Comparison Breakdown

* - The manufacturer may choose to perform up to two impacts on each samples instead of one.
** - Each impact is completed in succession on a single sample in the order deemed as most onerous by the testing lab.

	16 CFR 1203	SP - method 4439	EN 1078
Relevant Impact Test Section & Title	1203.17 - Impact attenuation test	5.5 - Determination of shock absorbing capacity	5.4 - Determination of shock absorbing capacity
Number of Samples Tested	8	3 to 6*	3
Sample Designations	*T1*, *T2*, *T3*, *T4*, *T5*, *T6*, *T7*, *T8*	*1*, *2*, *3*, *4*, *5*, *6*	*1*, *2*, *3*

Pre-test Sample Modifications	16 CFR 1203	SP - method 4439	EN 1078
Number of samples modified		6	
Modifications		• Gas generator removed • Manual inflator installed • Pressure measurement installed	
Modified		*1*, *2*, *3*, *4*, *5*, *6*	

Pre-environmental conditioning tests	16 CFR 1203	SP - method 4439	EN 1078
Number of samples tested			1
Test 1			Section 5.6 - Determination of retention system effectiveness
Tested			*1*

Environmental Conditioning	16 CFR 1203	SP - method 4439	EN 1078
Exposure Time	4 to 24 hours	4 hour minimum	4 to 6 hours
Samples Per Environment	2	3 to 6*	1
Ambient	Temperature: 17 °C to 27 °C Relative Humidity: 20% to 80%	Temperature: 22 ±5 °C Relative Humidity: 55 ±30%	
Applied to	*T1*, *T5*	*1*, *2*, *3*, *4*, *5*, *6*	
High Temperature	Temperature: 47 °C to 53 °C		Temperature: 50 ±2 °C
Applied to	*T2*, *T7*		*1*
Low Temperature	Temperature: (-17) °C to (-13) °C		Temperature: (-20) ±2 °C
Applied to	*T3*, *T6*		*2*
Water Immersion	Temperature: 17 °C to 27 °C Position: "crown" face down Crown Depth: 305 mm ±25 mm		
Applied to	*T4*, *T8*		
Artificial Aging			UV Irradiation 48 hours, under a 125 W xenon-filled quartz lamp, at a range of 250 mm. Water Spraying: 4 to 6 hours, with water at ambient temperature, at a rate of 1 L/min.
Applied to			*3*

Post-environmental conditioning tests on samples (Pre-impact testing)	16 CFR 1203	SP - method 4439	EN 1078
Number of Samples Pre-tested	5		
Test 1	Section 1203.14 - Peripheral vision test		
Tested	*T1*		
Test 2	Section 1203.16 - Dynamic strength of retention system test		
Tested	*T1*, *T2*, *T3*, *T4*		
Test 3	Section 1203.15 - Positional stability test		
Tested	*T5*		

Table 4: Impact Attenuation Test Comparison (Continued)

Impact Attenuation Test Comparison Breakdown (cont.)

* - The manufacturer may choose to perform up to two impacts on each samples instead of one.
** - Each impact is completed in succession on a single sample in the order deemed as most onerous by the testing lab.

Impact Number per Sample		16 CFR 1203				SP - method 4439						EN 1078		
Unaltered Test Method	1 Impact per Sample	T5	T6	T7	T8	1	2	3	4	5	6			
	2 Impacts per Sample											1	2	3
	4 Impacts per Sample**	T1	T2	T3	T4									
Manufacturer Alternative Test Request*	Scenario 1: 2 Impacts per Sample					1		2		3				
	Scenario 2					Any combination of the options above								

Impact Anvils		16 CFR 1203				SP - method 4439			EN 1078		
Unaltered Test Method	Hemispherical Anvil Impact Samples	T1	T2	T3	T4						
	Flat Anvil Impact Samples	T1	T2	T3	T4	2	3	6	1	2	3
	Curbstone (Kerbstone) Anvil Impact Samples	T5	T6	T7	T8	1	4	5	1	2	3
Manufacturer Alternative Test Request*	Scenario 1: Flat Anvil Impact Samples					1	2	3			
	Scenario 1: Curbstone (Kerbstone) Anvil Impact Samples					1	2	3			
	Scenario 2					Any combination of the options above					

Impact Zones	16 CFR 1203								SP - method 4439		EN 1078		
Number of Impact Zones	1								3		2		
Impact Zone Determination Factors	• Headform Size • Fit Location								• Headform Size • Impact Location		• Headform Size • Fit Location • Impact Anvil Type		
Impact Zone 1 Description	Entire required coverage zone								The front section of the coverage zone		Kerbstone Impact Zone - Partial rear coverage zone excluded		
Samples Tested in Zone	T1	T2	T3	T4	T5	T6	T7	T8	1	2*	1	2	3
Impact Zone 2 Description									The top section of the coverage zone		Flat Impact Zone - Entire required coverage zone		
Samples Tested in Zone									3	4*	1	2	3
Impact Zone 3 Description									The rear section of the coverage zone				
Samples Tested in Zone									5	6*			

Impact Speeds	16 CFR 1203	SP - method 4439			EN 1078	
Number of Impact Speeds	2	5			2	
Speed Determination Factors	Impact Anvil Type	Impact Anvil Type Impact Zone			Impact Anvil Type	
Impact Zone	Zone 1	Zone 1	Zone 2	Zone 3	Zone 1	Zone 2
Hemispherical Anvil Speed	4.8 m/s					
Flat Anvil Speed	6.2 m/s	4.53 m/s	5.42 m/s	5.81 m/s		5.42 m/s
Curbstone/Kerbstone Anvil Speed	4.8 m/s	3.68 m/s	4.57 m/s	4.57 m/s	4.57 m/s	

Impact Acceleration	16 CFR 1203	SP - method 4439	EN 1078
Acceleration Limit	300 g	250 g	250 g

APPENDIX IV: CFR 1203 – Test Schedule Flowchart

CFR 1203 – Test Schedule Flowchart

A flowchart generated by CPSC staff explaining the testing schedule of the current U.S. bicycle helmet regulation, 16 C.F.R Part § 1203, is shown in Figure 3 and is described below.

Description of 16 CFR Part § 1203 Testing Schedule

1. 8 samples per helmet size and model are collected in the condition in which they are offered for sale. [§1203.7]
2. Samples are visually inspected for construction and labeling requirements. [§1203.5 and §1203.6]
   Samples are fitted to the proper head form size. [§1203.10 and §1203.11]
3. Samples are labeled as T1 to T8 conditioned in 4 different environments for 4 to 24 hours prior to and physical testing [§1203.8].
   - Ambient - 17° C to 27°C and 20 to 80% relative humidity.
     i. Samples Conditioned – T1 and T5
   - Hot - 47° C to 53°C
     i. Samples Conditioned – T2 and T7
   - Cold – (-17)° C to (-13)°C
     i. Samples Conditioned – T3 and T6
   - Wet – The sample is fully immersed crown down in potable water at 17° C to 27°C and a crown depth of 305 ± 25 mm
     i. Samples Conditioned – T4 and T8
4. Physical testing
   - Peripheral vision. [§1203.13]
     i. Sample Visually Inspected – T1
   - Dynamic strength of retention system test.[§1203.16]
     i. Samples Tested – T1, T2, T3, and T4
        - Sample T1 can only be tested after peripheral vision testing.
   - Positional stability test. [§1203.15]
     i. Sample Tested - T5
   - Impact Attenuation Test [§1203.17]
     i. Samples Tested – T1, T2, T3, and T4
        - Samples receive 4 impacts each – 2 impact on the hemispherical anvil, and 2 on the flat anvil.
        - Samples T1, T2, T3, and T4 can only be tested after Dynamic strength of retention system testing.
     ii. Samples Tested – T5, T6, T7, and T8
        - Samples receive 1 impact each – 1 impact on the curbstone anvil
        - Sample T5 can only be tested after positional stability testing.
5. A report of results is generated.

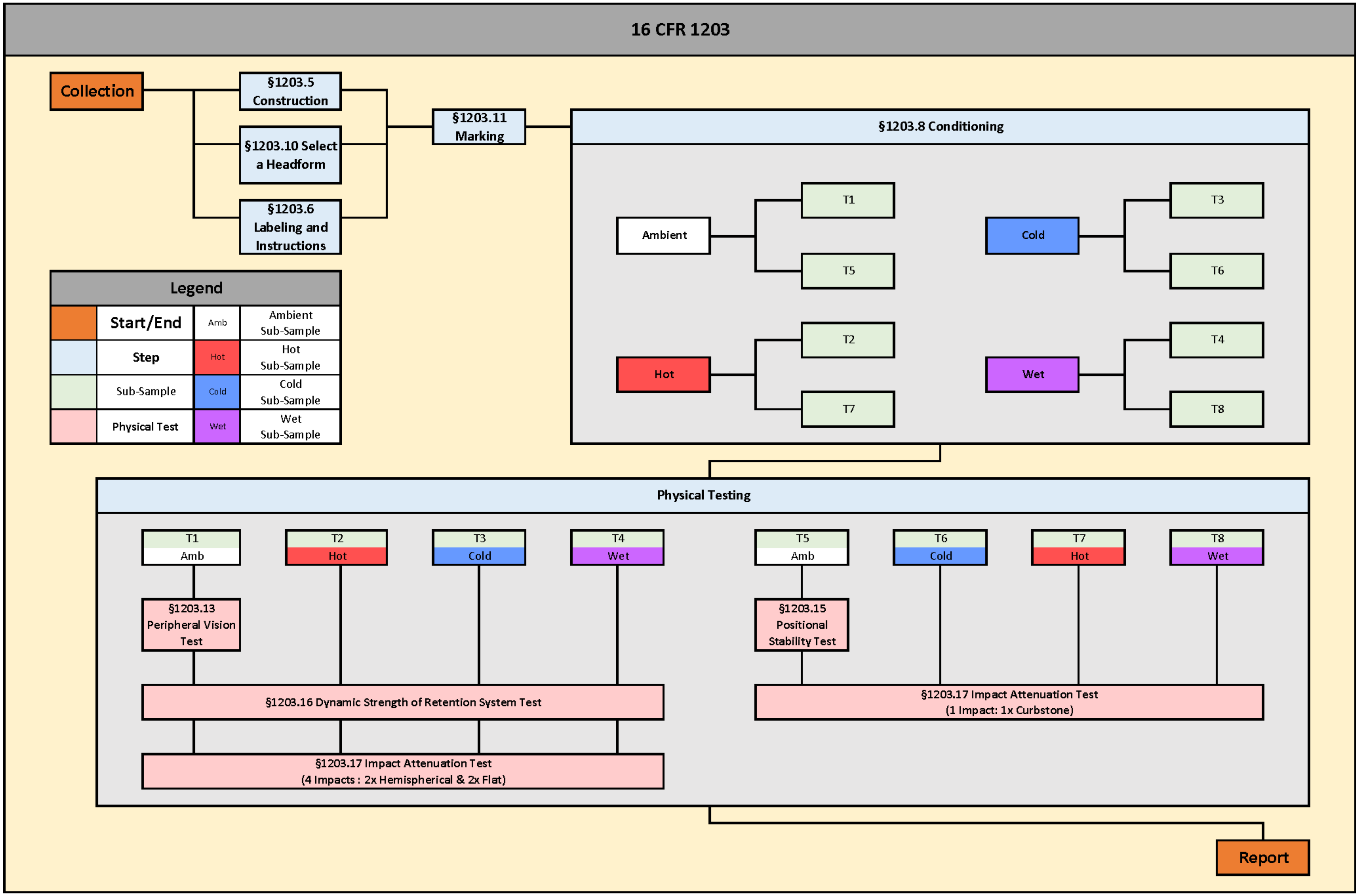

Figure 3: CFR 1203 – Test Schedule Expanded Flowchart

APPENDIX V: SP-method 4439 – Test Schedule Flowchart

SP-method 4439 – Test Schedule Flowchart

A flowchart generated by CPSC staff explaining the testing schedule of the proposed alternative standard is shown in Figure 5 and is described below.

Description of SP-method 4439 Testing Schedule

1. 22 Samples are collected
2. Samples are inspected for Materials, Markings, and Information requirements. [4.1, 6, and 7]
3. Sampling, pre-test modifications are made to the samples prior to any environmental conditioning. [5.1]
    - Modification Group 1
        i. Samples Modified – 1, 2, 3, 4, 5, 6, 7, and 8
            - Gas generators are removed
            - Manual inflation mechanism is installed
            - Pressure measurement device installed
    - Modification Group 2
        i. Samples Modified – 9, 10, 11, and 12
            - Manual triggering mechanism is installed
            - Pressure measurement device is installed
    - Modification Group 3
        i. Samples Modified – 13, 14, 15, and 16
            - Samples are to be new and complete head protectors as offered to for sale. Unless the testing lab uses test persons instead of a test dummy, then they are modified according to Modification Group 4
    - Modification group 4
        i. Samples Modified – 17 and 18
            - Inflators "will be made inert", effectively disabled
            - Inflation status indicator installed to replace inflator
    - Modification Group 5
        i. Samples Modified – 19 ,20, 21, and 22
            - Manual triggering mechanism installed
4. Samples are conditioned to 4 different environmental conditions for at least 4 hours prior to any physical testing.
    - Ambient – 22 ± 5°C and 55 ± 30% relative humidity
        i. Samples Conditioned – 1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 14, 15, 16, 17, 18, 19 20, 21, and 22
    - Hot – 50 ± 2°C
        i. Sample Conditioned – 9
    - Cold – (-20) ± 2°C
        i. Sample Conditioned – 10
    - Aged – 50 ± 2°C, the sample's outer surfaces are successively exposed to: ultraviolet radiation from a xenon-filled quartz lamp at a distance of 250 mm for

48 hours; and sprayed with tap water at a temperature of 27°C or less for 4 to 24 hours.

    i. Sample Conditioned – 11

5. Physical testing
   - Determination of shock absorbing capacity [5.5]
     i. Samples Tested – 1, 2, 3, 4, 5, and 6
        - Samples each receive a single impact
          a. Samples 1 and 2 are impacted within zone 1
             i. Sample 1 is impacted on a kerbstone anvil
             ii. Sample 2 is impacted on a flat anvil
          b. Samples 3 and 4 are impacted within zone 2
             i. Sample 3 is impacted on a flat anvil
             ii. Sample 4 is impacted on a kerbstone anvil
          c. Samples 5 and 6 are impacted within zone 3
             i. Sample 5 is impacted on a kerbstone anvil
             ii. Sample 6 is impacted on a flat anvil
        - Samples 7 and 8 reserved as backup samples
     ii. The manufacturer may choose to allow each sample to receive 2 impacts instead of one impact, to reduce the total number of samples impacted from six to three.
   - Drop Test [5.10]
     i. Sample Tested – 13
   - Function indicator test [5.14]
     i. Sample Tested – 14
   - Evaluation of the function of the mechanism of activation [5.9]
     i. Samples Tested – 13, 14, 15, 16, 17, and 18
     ii. Sample 13 can only be tested after drop testing
     iii. Sample 14 can only be tested after function indicator testing
   - Accidental inflation during bicycling [5.13]
     i. Samples Tested – 17 and 18
     ii. Samples 17 and 18 can only be tested after evaluation of the function of the mechanism of activation testing
   - Acoustic Test
     i. Sample Tested – 19
   - Determination of area to be protected [5.4]
     i. Samples Tested – 9, 10, 11, and 12
     ii. If the test lab chooses, this test may be simultaneously completed with the following tests:
        - Determination of activation time [5.6]
        - Temperature exposure evaluation [5.8]
        - Function test following conditioning [5.12]
   - Determination of activation time [5.6]
     i. Samples Tested – 9, 10, 11, and 12

   ii. If the test lab chooses, this test may be simultaneously completed with the following tests:
      - Determination of area to be protected [5.4]
      - Temperature exposure evaluation [5.8]
      - Function test following conditioning [5.12]

- Function test following conditioning [5.12]
   i. Samples Tested – 9, 10, 11, and 12
   ii. If the test lab chooses, this test can be simultaneously completed with section 5.4, 5.6, and 5.8.
      - Determination of area to be protected [5.4]
      - Determination of activation time [5.6]
      - Temperature exposure evaluation [5.8]
- Temperature exposure evaluation [5.8]
   i. Sample Tested – 12
   ii. This test is completed only if the product has a hot gas generator
   iii. If the test lab chooses, this test can be simultaneously completed with section 5.4, 5.6, and 5.12.
      - Determination of area to be protected [5.4]
      - Determination of activation time [5.6]
      - Function test following conditioning [5.12]
- Duration of inflated status [5.7]
   i. Samples Tested – 9, 10, 11, and 12
   ii. If the test lab chooses, this test can be completed immediately following 5.4, 5.6, 5.8, and 5.12.
      - Determination of area to be protected [5.4]
      - Determination of activation time [5.6]
      - Temperature exposure evaluation [5.8]
      - Function test following conditioning [5.12]
- Blocked deployment test [5.16]
   i. Samples Tested – 20, 21, and 22
- Wear resistance test [5.15]
   i. Samples Tested – Three unspecified samples

6. A report of results is generated

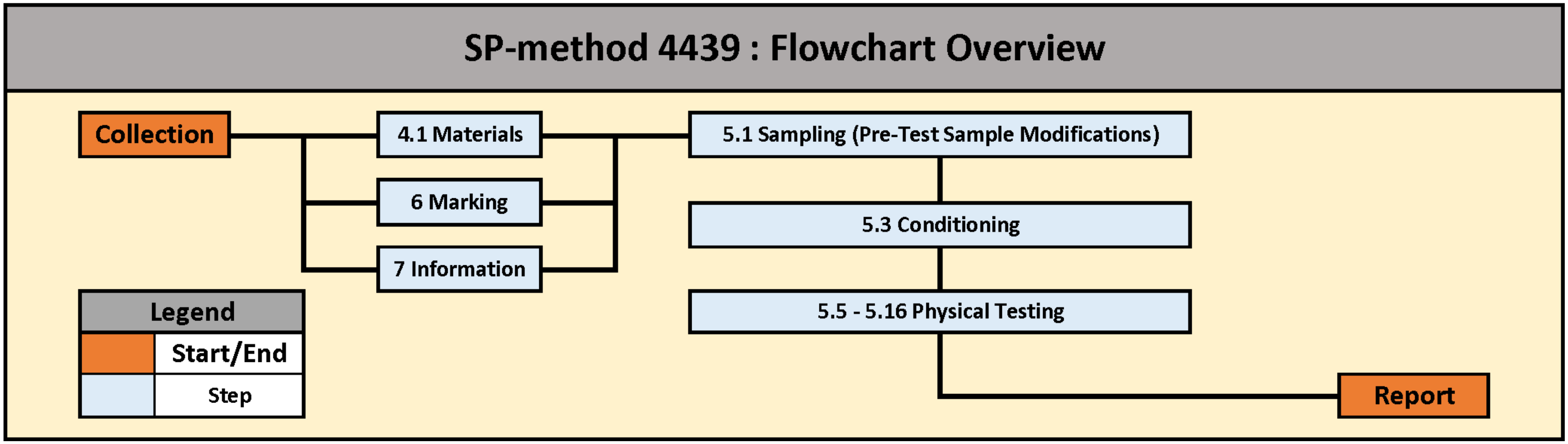

Figure 4: SP-method 4439 – Simplified Overview

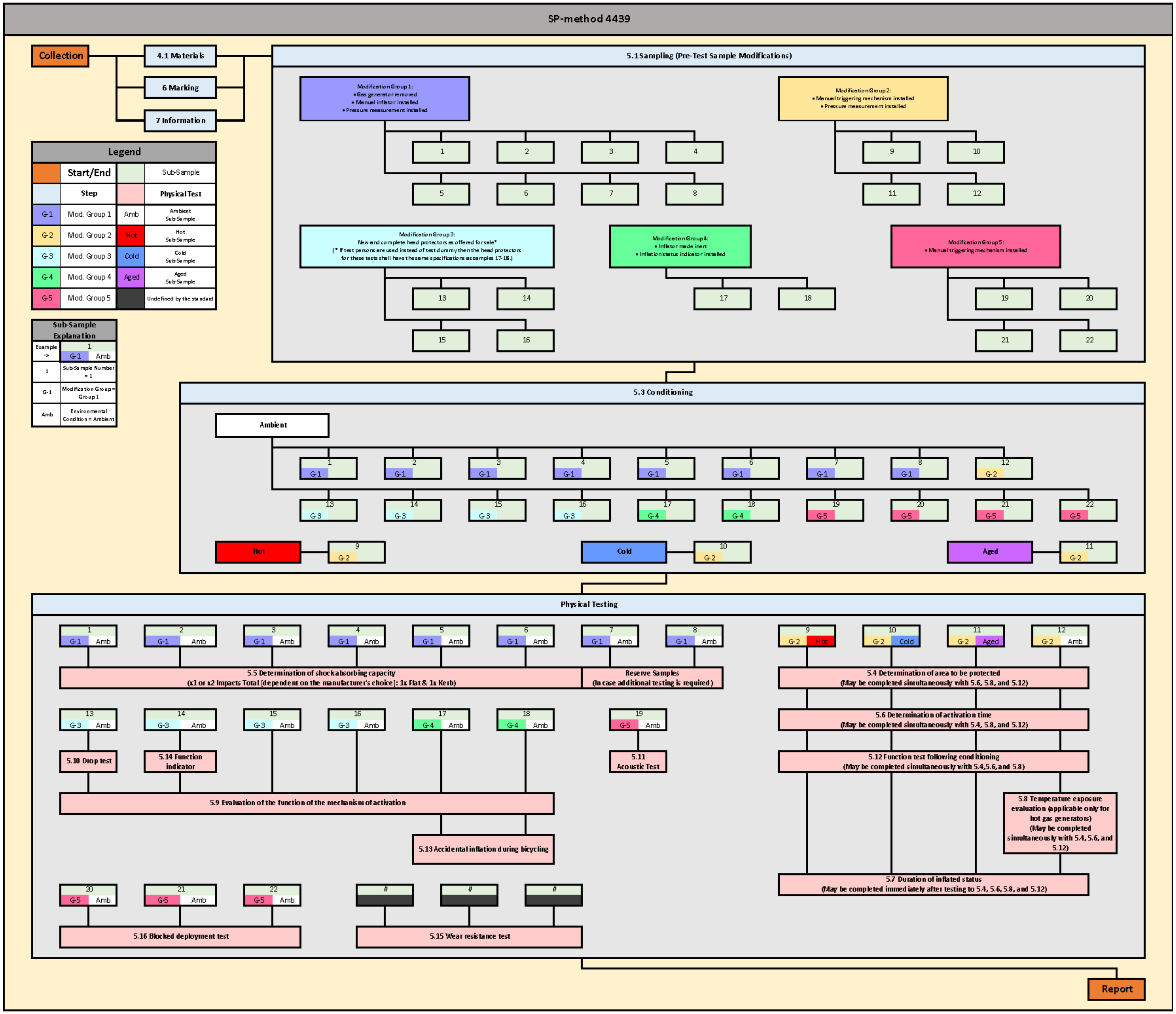

Figure 5: SP-method 4439 – Test Schedule Expanded Flowchart

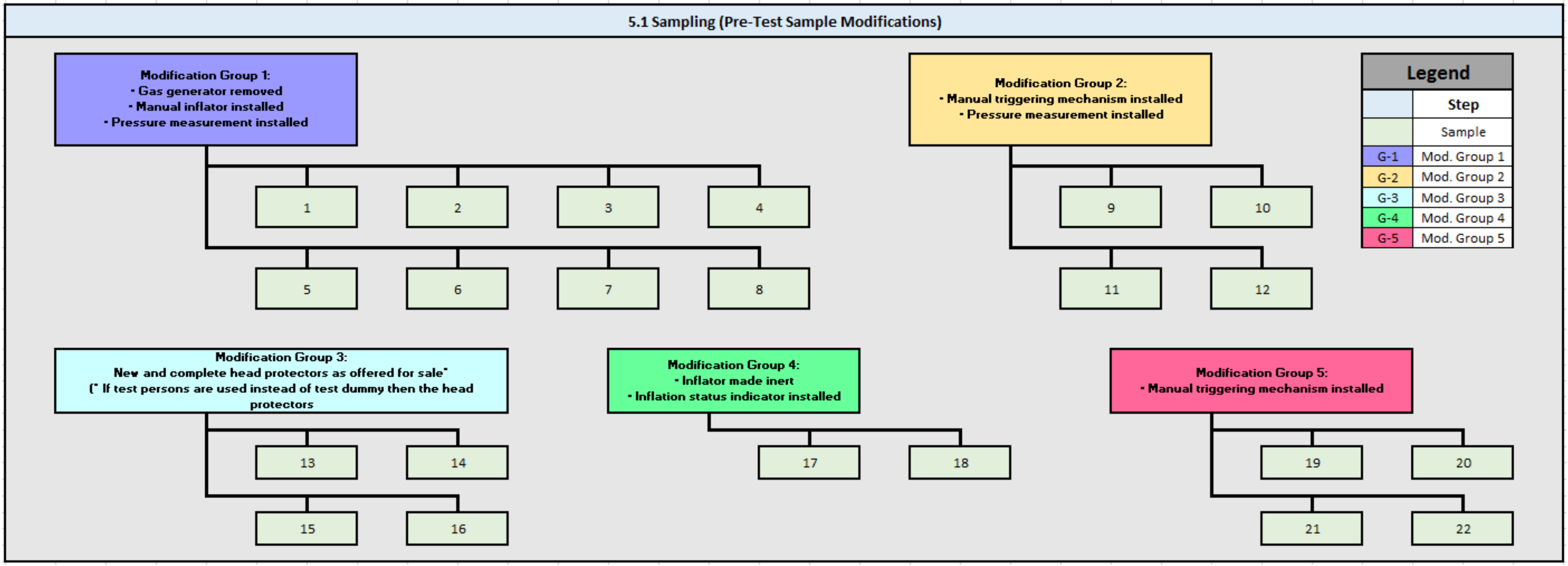

Figure 6: SP-method 4439 – Sampling

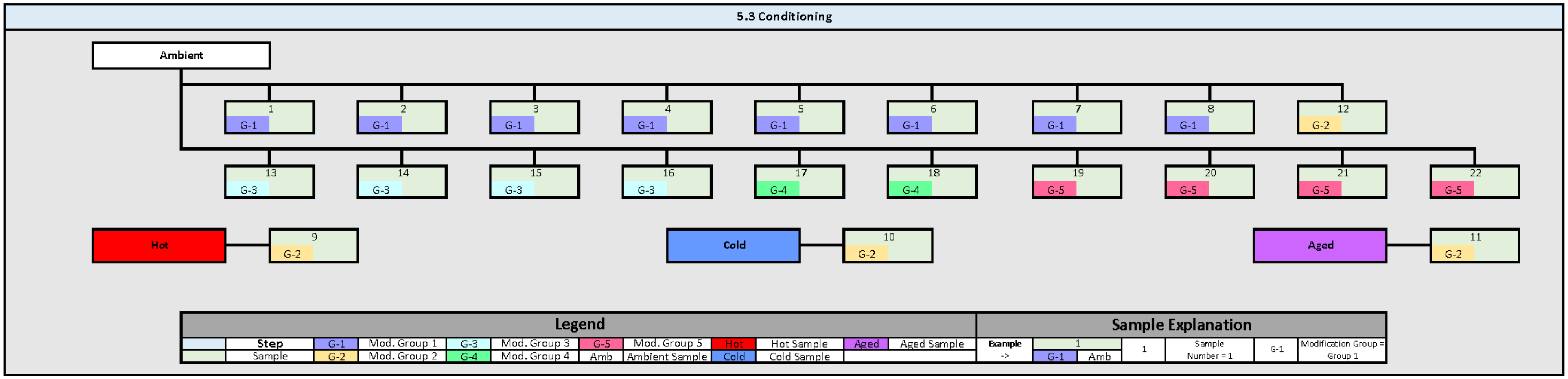

Figure 7: SP-method 4439 - Conditioning

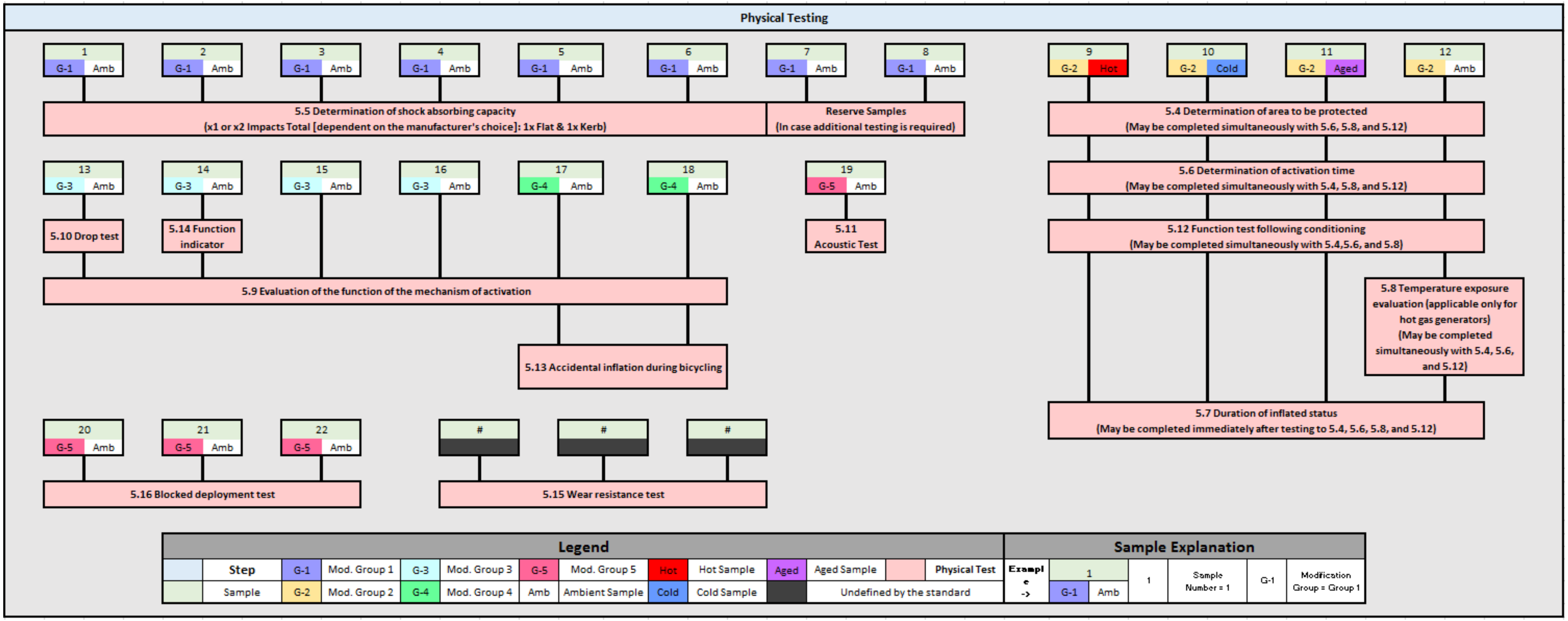

Figure 8: SP-method 4439 - Physical Testing