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Re: Request for Comments on Promoting US EC Regulatory Compatibility (Docket ID USTR-2012-0028)

These comments are provided on behalf of the Toy Industry Association (TIA), its members and the U.S. toy industry in regards to the European Commission and U.S. Government's request for comments on how to promote greater transatlantic regulatory compatibility.

By way of background, TIA has a membership of more than 550 businesses – from inventors and designers to toy manufacturers and importers to retailers and testing labs – who are all involved in creating and bringing toys and games to children. Our members account for approximately 85% of the three billion toys sold in the United States each year; the annual U.S. toy market is \$21.87 billion. The industry supports an estimated 533,177 jobs (FTE) generating \$25.8 billion in wages for U.S. workers and the toy industry's annual economic impact in the U.S. is nearly \$80.9 billion. Since the 1930s, TIA has been a leader in the development of toy safety standards, and toy safety has long been the top priority for TIA and its members.

U.S. toymakers have a long history of leadership in global toy safety initiatives. TIA and several U.S. toy company experts created the first comprehensive toy safety standard nearly four decades ago. Congress and the President recognized this industry leadership by adopting the ASTM F963 U.S. toy safety standard as a mandatory consumer product rule under the Consumer Product Safety Improvement Act (CPSIA) of 2008. This standard is frequently used as a model – or adopted outright – by other countries that are developing or improving their own safety measures.

TIA is generally very supportive of efforts between the U.S. and European Union (EU) to launch comprehensive free trade agreement negotiations. The U.S. and EU already have the world's largest commercial relationship. Increasing trade, investment and cooperation between the two markets will strengthen the relationship between the U.S. and EU, strengthen the respective economies and create jobs on both sides of the Atlantic. Moreover, a bilateral, liberalizing trade agreement that eliminates tariff and non-tariff barriers and fosters greater regulatory coherence would set a strong example for future trade agreements and help strengthen the U.S. and EU's positions as leaders in the global economy.

In developing a transatlantic economic agreement, a key objective for TIA is a regulatory component that addresses existing regulatory divergences and promotes future regulatory cooperation. TIA has long worked with both the U.S. and EU governments to promote greater

standards realignment – particularly relating to the U.S. toy safety standard, ASTM F963 and the European toy safety standard, EN 71. In order to sell in both markets, companies often have to make design and/or manufacturing changes in order to meet both sets of requirements, or forego trade. These costs to the toy industry add up to an estimated US\$3 billion annually – costs incurred by consumers *without improving safety as toys are highly regulated on both sides of the Atlantic, and are safe in both markets.*

Greater alignment of toy safety standards reduces the costs of compliance – like production, administrative and testing costs – which helps to keep product prices low for consumers, without negatively impacting safety. Standards alignment assures open markets between nations maximizing product availability and choice. Most importantly, standards alignment enhances product safety: greater coordination, simplification and understanding of science and risk-based standards provide for consistency in the interpretation and comparison of results, closer cooperation and enforcement across borders, and the reduced potential for confusion and mistakes.

The toy industry supports full alignment of standards in both markets but recognizes that this is no small task. On both sides of the Atlantic, there exist several limitations (discussed further below) that make 100% alignment extremely unlikely. Therefore, in the interim, we ask that both governments seek to fully align toy safety standards wherever possible and pursue ***mutual recognition*** where alignment is currently not achievable. This would mean that each jurisdiction would agree to accept declaration of conformance to the other's standards as evidence of an adequate level of safety and acceptability for importation and sale.

Below are suggested approaches to promoting greater regulatory cooperation in both existing toy safety regulations and future new and/or updated toy safety regulations.

Promoting Greater Alignment between Existing Regulations

In promoting greater cooperation among existing regulations, it is important to establish that a unified objective already exists between markets: to ensure that toys are safe. So whether in the U.S. or in the EU, regulators set *effective* toy safety standards with the same intention and consumers in *both* markets expect the same high level of regulatory protection. Consequently, toys in both markets are very safe. Moreover, any divergences between regulations are simply differences in approach – neither approach being consistently “better” than the other. In fact, differences in methodology are due largely to political considerations, not technical ones, and do not advance safety. Since current regulatory divergences are superficial, when addressing regulatory cooperation between *existing* standards, it is important to focus on the regulatory outcomes and not the process used to get there.

As a result of the common objective, there already exists significant alignment among the over 100 separate tests and design specifications between the ASTM F963 and EN 71 toy safety standards. In fact, we estimate that standards are currently already about 80% aligned. Approaches towards greater regulatory cooperation will vary depending on the level of divergences between the standards and the types of divergences. For example, some of the provisions in the standards are exactly the same, some requirements may be the same but apply to different age categories of children, some requirements are more or less stringent than those in their counterpart and then there are some requirements that are the same but have different test methods. In addition, there are cases where testing for one standard can demonstrate compliance with another standard. Overall, the first and easiest step in the process is to establish which requirements and test methods are identical between the standards and clearly state that testing and certifying compliance for one standard satisfies any testing and certification requirements for

the corresponding standard in the other jurisdiction.¹ This would also apply to any aligned regulations developed in the future.

Regulators should also look for opportunities to establish a level of equivalency in situations where compliance with one standard can be determined mathematically or scientifically from results of testing for compliance with another. In these situations, testing and certification for one standard should satisfy any testing and certification requirements for the counterpart.² For example, EN71-1 specifies that the sound pressure level of close-to-the-ear toys be measured at a distance of 2.5 cm while ASTM F963 specifies that the sound pressure be measured at a distance of 50 cm. Since it is a law of physics that sound pressure varies inversely to the square of the distance from the source, a simple calculation based on testing for compliance to the European standard would establish compliance with the US standard, and vice versa. Other instances where compliance to one standard can be deduced from testing to another include various abuse tests included in the standards. In those that require a force application, it can be a simple matter to determine which standard is most onerous.

However, *promoting regulatory cooperation does not mean simply adopting the strictest standard*. While establishing equivalency as described above may be the easiest approach to promoting regulatory alignment, it is not the best approach as the strictest standard is not necessarily the best standard. For example, regulatory alignment should not result in EU adoption of the U.S. third party test requirements for toys (as mandated by the CPSIA). Third party testing has taken away a manufacturer's ability to determine a "reasonable testing program" and forced companies to divert resources towards ensuring compliance with extensive paperwork and tracking requirements. The rigid requirements have also disproportionately impacted small businesses. Effective quality control can be done without mandating third party testing and companies should be permitted to design their own quality control programs and means of demonstrating compliance. Similar to those developed in ASTM F963, standards that are based on sound science, address the risk and incorporate multiple stakeholders' input are the most effective standards.

Therefore, whenever regulatory alignment is unachievable, and where standards themselves are different but equally effective in ensuring toy safety, mutual recognition of regulations is a better approach towards promoting greater regulatory cooperation. For example, EN71-1 specifies that toys with self-retracting cords shall have a mechanism recoil force less than 10 N while ASTM F963 mandates that the pull force must be less than 2 lbf (9N). This difference is simply due to conversion to metric from English units. Recognizing that both standards are effective, mutual recognition would limit testing and compliance to only one standard.

¹ This step was also recommended by Consumer Product Safety Commission (CPSC) staff in the [staff briefing package](#) titled, "Consideration of Opportunities to Reduce Third Party Testing Costs Consistent with Assuring the Compliance of Children's Products" (Reduce Testing Costs packet) issued on August 29, 2012. In the packet, staff wrote, "Recognizing other international standards, or test within a standard, as equivalent to a CPSC rule, could allow children's product certifiers to avoid repeating some third party tests for the same product and directly avoid additional costs, while assuring compliance to the applicable children's product safety rules."

It should also be noted that in the U.S., as per the Consumer Product Safety Act (CPSA), testing for children's products must be conducted in accordance with 16 CFR Part 1107 by a third party testing facility that has been accredited by the CPSC. Therefore, as it currently stands, a manufacturer will not be able to certify compliance with an identical international standard unless the test is conducted in a CPSC accredited testing facility.

² This recommendation was also referenced in the "Reduced Testing Costs" packet mentioned above.

Establishing a Framework that Promotes Greater Regulatory Cooperation Going Forward

A significant component of any regulatory cooperation agreement will also need to include a framework for promoting greater alignment for regulations promulgated in the future.

Both the U.S. and the EU have different processes for setting regulations and these different processes have resulted in differences in the regulations themselves. While the goal of regulatory cooperation is to limit these divergences and differences, this agreement does not need to redo current regulatory processes nor undermine either the U.S.'s or EU's regulatory sovereignty. This agreement should maintain both the U.S. and EU's governments' and standard setting and regulatory bodies' ability to carry out their respective regulatory and enforcement mandates. Promoting greater alignment for future standards should simply build on past and ongoing alignment efforts by adding a formal, "international regulatory alignment" consideration on top of domestic priorities of protecting the health safety and welfare of U.S. and EU citizens.

To a certain extent, ASTM already engages in trans-Atlantic and international regulatory alignment. ASTM F15.22 (the Subcommittee on Toy Safety that sets and updates ASTM F963) has an ongoing agenda item to consider opportunities to align with EN-71 and other international standards and propose changes to align where validated and possible. Additionally, when standards to address emerging issues are developed in ASTM, the Subcommittee readily shares this information and rationale with its counterparts in CEN and ISO. CEN also engages in international regulatory alignment (though not specific to ASTM F963) through the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement), which creates a framework for regulatory cooperation between ISO and CEN. The principles within the Vienna Agreement should be strengthened and broadened to include the U.S. in a U.S.-EU regulatory cooperation agreement. Moreover, other preexisting international regulatory alignment efforts must be put into a formal framework for all regulatory bodies to incorporate into the regulation setting process.

Similar to the WTO Technical Barriers to Trade (TBT) and the Vienna Agreements, we propose that the additional "international regulatory alignment" component be based on the following principles:

- International alignment of standards is ideal for citizens, regulators and businesses and must be a priority consideration when setting domestic standards.
- Both the domestic and the international standard setting processes must be open to representatives of all countries and to producers, consumers, and government, represent a consensus, be inclusive and based on science.
- International or preexisting standards should be used as the basis for new regulations whenever possible. Moreover, whenever a regulatory body is developing a standard, in the absence of incident data indicating that the preexisting standard is insufficient, the body should defer to an existing standard without change.
- A regulatory body has the right to pursue another regulatory direction if the party disagrees with the direction of an international standard.
- All standard setting bodies must engage in constant communication, review, and information sharing.

Whenever a standard setting body begins to consider a new regulation, it is important its international standard setting counterpart is not only alerted but is continuously updated throughout the process. An 'open' standards process should allow active participation and input.

Should the standards setting body diverge from a preexisting regulation, the standards setting body must demonstrate a significant need for diverging from the preexisting regulation and that the costs of divergence do not outweigh the manifest benefits of alignment. The standard setting body must also consider whether the new regulation achieves the same regulatory outcome as the preexisting standard. If both regulations adequately protect human health and safety, then the respective regulatory bodies must grant “mutual recognition” of regulations. These considerations must be open to public comment and participation and fully involve the Trans-Atlantic Regulatory Cooperation Committee (described below).

Trans-Atlantic Regulatory Cooperation Committee

In order to implement, promote and enforce regulatory cooperation, an agreement should create a Trans-Atlantic Regulatory Cooperation Committee consisting of stakeholders from regulatory standard setting bodies on both sides of the Atlantic. Enforcement of a regulatory cooperation agreement will be an important element as an agreement will not be useful if the regulatory bodies do not feel any obligation to follow its mandates. Currently, a similar committee exists to enforce the Vienna Agreement. Broadly, the Committee will:

- Coordinate communications between the respective standard setting, regulatory, and governmental bodies. To ensure transparency, all members on each Committee will need to be able to participate in any regulatory development activity on either side of the Atlantic.
- Be engaged during any regulatory development process to ensure trans-Atlantic alignment to the greatest extent possible.
- Meet regularly to track progress of regulatory cooperation and set realistic goals for future alignment.
- Aid in any regulatory alignment cost benefit analysis and determine mutual recognition.
- Communicate and solicit comments from the public and industry about regulatory alignment objectives.
- Hold meetings, as necessary, with all appropriate regulatory bodies to update members on regulatory alignment objectives, present goals and work through challenges.

Barriers to Greater Regulatory Alignment and Mutual Recognition

As mentioned above, promoting greater regulatory alignment has been a longstanding objective of TIA and the toy industry. While there has been some progress, this progress has been limited due to several barriers. The biggest barrier has been and will continue to be the role politics plays in regulations. It is our belief that standards should be strictly based on science and should be tailored to address the risk of hazard. Unfortunately, oftentimes, whenever politics plays a role in setting standards, science becomes a subordinate factor. For example, in the EU, any member state can object to a proposed regulation. Frequently, member states object for reasons other than those relating to the adequacy of the regulation.

Moreover, there are several cases where any alignment of regulations or determining mutual recognition of standards will require Congressional action. For example, the U.S. lead content standard, which was set by Congress, is set at 100 parts per million (ppm) *total* content while the EU lead content standard is at 90ppm *leachable*. While both standards *adequately protect children's health and safety*, the U.S. would likely not be able to align nor recognize the EU standard without Congressional action.

Additionally, the CEN process for setting and updating EN-71 is far from open and does not allow U.S. participation. A bedrock provision of U.S. Free Trade Agreements has been the requirement that the regulation development and setting process be open to all interested stakeholders. This principle should not be compromised. The ASTM model has successfully included public participation and stakeholders from the U.S. and other countries and regions are welcome to participate. This inclusion has resulted in stronger standards while maintaining a nimble and effective standard setting process. In fact, ASTM's standard setting process allows for faster development of standards than the CEN process, with fewer administrative steps, yet allowing for thoughtful consideration of input.

Finally, each jurisdiction must operate as a single market-EU member states should not be allowed to "layer on" requirements, and CPSC must firmly assert preemption over state requirements where they address the same risk of injury.

Conclusion

The Toy Industry Association is very supportive of overall efforts to develop greater economic ties between the United States and the European Union. Including a regulatory cooperation component within the trade agreement will be particularly beneficial to the toy industry as divergences in regulations unnecessary burden toy companies who sell to both markets. Moreover, establishing a strong regulatory cooperation agreement will assure a joint U.S.-EU leadership role in international regulations, provide a basis for future trade agreements and will help provide a benchmark for third-countries' standards development efforts.

On behalf of the Toy Industry Association, thank you for the opportunity to comment on how to increase regulatory cooperation between the United States and the European Union. The toy industry is committed to working with legislators and regulators in the U.S. and EU to achieve the alignment and mutual recognition of risk-based standards that will provide a new level of confidence that toys from any source can be trusted as safe for use by children.

Should you have any questions, please contact Rebecca Mond, Director of Federal Government Affairs at rmond@toyassociation.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Carter Keithley". The signature is written in a cursive style with a large initial "C".

Carter Keithley
President of TIA