

Toy Industry Association Statement for the Record: “U.S. – EU Free Trade Agreement: Tipping Over the Regulatory Barriers”

House Energy and Commerce Committee Subcommittee on Commerce, Manufacturing and Trade July 23, 2013

The Toy Industry Association (TIA) is generally supportive of efforts to pursue a comprehensive U.S.-EU transatlantic trade and investment partnership (TTIP). 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 the EU, enhance both economies and create jobs on both sides of the Atlantic. Moreover, a bilateral agreement that reduces trade barriers and fosters greater regulatory coherence would set a strong example for future trade agreements and help cement the U.S. and EU positions as leaders in the global economy.

As background, TIA has a membership of more than 600 businesses – from toy manufacturers, retailers and importers to inventors, designers and testing labs – all involved in creating and bringing safe toys and games to children. Our members account for 85% of the \$22 billion U.S. toy market. The U.S. toy industry supports an estimated 533,177 jobs (FTE) generating \$25.8 billion in wages for U.S. workers, with a total annual economic impact in the U.S. of nearly \$81 billion.

Thank you for the opportunity to submit a statement for the record on TTIP and regulatory cooperation. The regulatory cooperation objectives highlighted in the Final Report of the High Level Working Group on Jobs and Growth could have a significant impact on the U.S. and EU toy industries. Our specific comments on regulatory cooperation are below.

Regulatory Cooperation

The toy industry in both the U.S. and EU has espoused the goal of greater regulatory cooperation for a number of years. Our experience, however, has shown that there are very significant political and other barriers to this very worthwhile goal. These challenges notwithstanding, we believe the process of seeking greater regulatory cooperation has the potential to yield positive results for the EU and U.S. economies, which are the largest toy markets in the world.

While toys are regulated differently in the U.S. and EU markets, both regulatory systems provide strong and effective consumer protection. Another way to state this is that toys are safe in both markets, but the regulatory approaches to achieving this end differ between the two markets. Given the differences in regulatory approach, in order to sell in both markets, companies often have to make design and/or manufacturing changes to meet both sets of requirements and must at a minimum perform redundant testing in order to demonstrate compliance to both sets of requirements. These costs to the toy industry add up to an estimated US\$3 billion annually – unnecessary and redundant costs of demonstrating compliance – and costs ultimately shared by consumers – without improving the safety of toys. As a result of our ongoing work to promote greater standards alignment, there already exists significant congruence between many of the over 100 separate tests and design specifications in the ASTM F963 and EN 71 toy safety standards. In fact, we estimate that standards are currently about 80% “aligned.”

Achieving the current level of alignment has taken a tremendous amount of time and effort from all involved. In fact, within the 80% of those standards that are “aligned,” only a small handful (about 10% of the EU and US physical and mechanical standards) are word-for-word identical. The other standards that are “aligned,” though not identical, are fundamentally the same or functionally equivalent. In these situations, companies often still have to test to both standards to demonstrate compliance with ASTM F963 and to secure a presumption of conformity to the TSD by testing the identical parts to EN71.

Significant barriers to further alignment, namely politics and differences in regulatory approach, remain on both sides of the Atlantic. Our experience has also shown that politics and differences in regulatory philosophy are the root causes of differences in toy safety standards. Therefore, approaching regulatory cooperation as strictly a technical alignment effort will result in marginal benefits – *especially* considering the short time frame set to complete negotiations. While we recognize that addressing the political barriers to alignment will also be challenging, with support and commitment from senior officials and regulators on both sides of the Atlantic, we are optimistic that the TTIP negotiations may result in meaningful progress.¹

The toy industry is not alone in pursuing and recognizing the benefits of greater regulatory cooperation. The European Commission’s Directorate General for Enterprise

¹As an example of politics resulting in a difference in U.S. and EU standards, the Consumer Product Safety Improvement Act (CPSIA) of 2008 set a U.S. *total* lead content standard of 100 parts per million (ppm). However, prior to this, the EU toy safety standard had a 90 parts per million (ppm) soluble lead content standard. While the soluble approach is preferable because it more closely correlates with exposure and risk, there is no evidence that either limit is more protective than the other; in fact, products typically meet both standards, but the misalignment results in additional (and totally unnecessary) testing and compliance costs. This example also highlights the need for political support of greater regulatory cooperation as the U.S. would likely not be able to align nor recognize the EU standard without Congressional assent.

and Industry (DG ENTR) and the U.S. Consumer Product Safety Commission (CPSC) signed a Recognition of Mutual Interest (RMI) Agreement last year with the purpose to, “memorialize DG ENTR’s and the CPSC’s common understanding of the benefits of continuing and enhancing our cooperation on toy safety issues.” The RMI further states, “Both sides are confident that pursuing such initiatives will ensure that the safety of toys sold on the EU and U.S. markets will be further enhanced.” In fact, DG Enterprise and CPSC note that regulatory cooperation in the toy industry can inspire greater regulatory cooperation in other industries like electrical appliances and fireworks.

TIA views regulatory cooperation as two separate exercises: addressing current regulatory divergences and promoting greater alignment for future regulations.

General Principles

Any regulatory outcomes in the TTIP must adhere to sound principles of science, risk assessment and cost-benefit analysis. As mentioned above, regulatory differences are often politically motivated and these measures add burden to companies without introducing a significant difference in the level of safety. TIA believes this to be a flawed approach. Decisions should be based on sound science, rather than children’s safety being used for political purposes.

Some decision-makers and EU Member States have recently proposed unscientific restrictions in an effort to be seen by citizens as “stricter” than their counterparts, thereby creating a “solution” that does not necessarily fit the situation. Industry is committed to meeting safety requirements, but such rules must be based on sound scientific evidence and risk assessments.

We regret that this approach has resulted in regulatory divergences where standards were once harmonized. As an example, projectiles requirements had to be changed in EN 71-1 some years ago, following a request from one EU national authority. Similarly, hemispheric toy requirements in EN 71-1 were also changed following requests from EU member states; Neither change had any valid scientific rationale, and as a result standards in both areas are no longer aligned with those in the US or elsewhere. In both of these cases, the changes were motivated by a desire to address problems not demonstrated to actually exist.²

² In July 2013, the chemical requirements of the Toy Safety Directive (TSD) go into effect once again moving the U.S. and EU toy safety standards further away from alignment. In 2011, ASTM F963 was updated to bring the U.S. standard’s eight heavy metal limits into alignment with the EU toy safety standard. Unfortunately, the European Commission updated the Toy Safety Directive, effective 2013, making the current heavy metal requirements unnecessarily divergent from the currently aligned limits. The differing limits on the already regulated chemicals do not make the toys safer. CPSC noted in a status report, “Review of Metals in the Toy Safety Standard, ASTM F963” in March, 2012, “that the existing intake limits in ASTM F 963-07 and EN 71-3 are sufficiently protective of children who use toys that conform to the current standard.” Additionally, the TSD added new requirements for 11 additional heavy metals – including metals like aluminum that have been determined safe for use in more sensitive applications such as food contact, like aluminum foil.

Additionally, we caution that the benefits of regulatory cooperation between the U.S. and the EU will be significantly lessened if EU national or sub-national, or U.S. state, local, and/or city governments enact different regulations that address the same risk of harm addressed by EU or U.S. Federal standards.

Addressing Current Regulatory Divergences

Addressing current regulatory divergences will be significantly more challenging than promoting greater future regulatory cooperation. This is because both sides' standards have been set through long-established procedures and each party has significant investment in their own process. However, since differences in methodology are due largely to political considerations, not technical or scientific ones, these differences do not result in differences in the safety of the regulated toy. As current regulatory divergences do not alter the underlying safety of the product, **when addressing regulatory cooperation between *existing* standards, it is important to focus on the regulatory outcomes (ensuring toy safety) and not the specific approaches of the regulations themselves.**

Experience has shown that achieving full regulatory alignment will be extremely difficult and may have some drawbacks (as discussed below) that may result in additional costs to businesses without benefiting consumer safety. Therefore, instead we ask that regulators pursue ***mutual recognition***. This would mean that each jurisdiction would agree to accept suitable demonstration of conformance to the other's standards as presumptive evidence of an adequate level of safety and acceptability for importation and sale.

Seeking mutual recognition depends on the understanding, acknowledgment and acceptance of the fact that regulators on both sides of the Atlantic set *effective* toy safety standards based on a unified objective (to ensure that toys are safe) and consumers in *both* markets enjoy a high level of regulatory protection. *When one recognizes this, it naturally follows then that toys that are compliant with either the U.S. or the EU toy safety standard are safe – regardless of where the toy is sold.* Therefore, mutual recognition would not result in any reduction in toy safety.

Mutual recognition is ultimately a better and more realistic alternative than full regulatory alignment, at least for toys. Mutual recognition would not undermine either side's regulatory sovereignty nor should it mandate that one adopt the other's regulatory approach. Moreover, regulatory alignment could result in significant costs to businesses especially if regulators decide to simply adopt the most onerous standard regardless of effectiveness, or the risk of hazard. However, the most stringent standard is not necessarily a better or more protective standard, and is not necessarily one based on any underlying science. Frequently, standards that are stricter than their international counterparts are promulgated due to political influence or the (often

unstated) desire to erect technical barriers to trade, and not predicated by science or risk factors.³

Establishing a Framework that Promotes Greater Regulatory Cooperation for Future Regulations and Emerging Hazards

A significant deliverable that the TTIP can produce for EU-U.S. trade is to promote greater regulatory alignment for new standards and emerging issues. We believe this area is the most promising as there are already frameworks that exist that can be used as a basis for future regulatory cooperation between the U.S. and the EU.

As mentioned above, the U.S. and the EU have different processes for setting regulations which 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 rework current regulatory processes or undermine either the U.S.'s or EU's regulatory sovereignty. A mutual recognition agreement should respect both the U.S. and EU governments' respective standard setting and regulatory powers. Promoting greater alignment for future standards should simply build on past and ongoing alignment efforts by adding a formal, "international regulatory alignment" mandate in addition to domestic priorities of protecting the health safety and welfare of consumers. We envision such a framework as mandating alignment with an existing standard (or recognizing compliance with that standard) in the other counterpart market unless it can be demonstrated by evidence that it is inadequate to address the hazard concerned or is not evidence-based.

To a certain extent, ASTM International already engages in trans-Atlantic and international regulatory alignment. ASTM F15.22 (the Subcommittee on Toy Safety that is responsible for ASTM F963) regularly considers, as part of its standard operating process, opportunities to align with EN-71 and other international standards. The Subcommittee then proposes revisions to ASTM F963 to align the standard with its international counterparts where valid and possible. Additionally, as emerging issues are identified (something at which the ASTM Subcommittee has become particularly adept, given the nimbleness of the ASTM process and the access to CPSC data), the Subcommittee readily shares new standards and supporting information 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

³ As an example, U.S. Consumer Product Safety Commission (CPSC) commissioned extensive academic study of anthropometry and strength characteristics of children and these data have been used to set various U.S. standards including the U.S. tension test at 15lbf. In contrast, the EU requirement of 90N (20.2lbf) is an historical artifact, incorporated from a predecessor standard with no valid underlying rationale, and requiring additional testing above that required for the U.S. market.

and CEN. The principles within the Vienna Agreement should be broadened to include other international standards development organizations, such as ASTM International. In addition, other preexisting international regulatory alignment efforts must be subject to the above presumptive mandate.

Whenever a standard setting body begins to consider a new regulation, it is important that 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, it should demonstrate a compelling need for divergence from that requirement, and demonstrate convincingly that the costs of that divergence do not outweigh the manifest benefits of alignment. The standard setting body must also consider whether the divergent regulation achieves the same regulatory outcome as the preexisting standard. If both standards adequately protect human health and safety, then the respective regulatory bodies should grant "mutual recognition" of regulations.

Finally, in order to implement, promote and enforce regulatory cooperation, an agreement should create a committee consisting of stakeholders from standard setting bodies on both sides of the Atlantic to mediate any disagreements. Enforcement of a regulatory cooperation agreement will be an important element as an agreement will not be useful if these bodies do not observe their obligation to follow its international alignment mandate.

Conclusion

Toy Industry Association is supportive of overall efforts to facilitate trade between the United States and the European Union. Mutual recognition could address most of the divergences in regulations that unnecessarily burden companies who sell to both markets while reinforcing consumer confidence that toys compliant with either standard can be trusted as safe for children. 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 help provide a benchmark for third country standards development efforts.

Some economic facts on the toy markets in the EU and the US:

EU	US
<ul style="list-style-type: none"> ▪ Significant differences in average price of toys in each country ▪ Estimated 1.4 billion units sold each year (2009) ▪ 73% of sales in France, Germany, Italy, Spain and UK (2010) ▪ US\$21 billion in toy sales (2012) ▪ EU Toy Industry provides 220.000 EU jobs ▪ 25% of the global toy market (2010) ▪ 5000 companies (2012) ▪ 99% of producers are SMEs (2012) 	<ul style="list-style-type: none"> ▪ Average price of a toy is under US\$8.00 ▪ Estimated 3 billion units sold each year (2012) ▪ US\$22 billion in toy sales (2011) ▪ US Toy Industry provides 500,000+ US jobs ▪ Total annual economic impact of US\$81 billion ▪ 27% of the global toy market (2011) ▪ 80%+ of producers are SMEs (2011)

Leading regulatory agencies in charge of toy safety:

EU	US
<ul style="list-style-type: none"> ▪ European Commission, DG Enterprise, Unit C/1 Internal Market and its International Dimension (lead within the Commission) ▪ National and regional Governments (implementation, market surveillance) <ul style="list-style-type: none"> • CEN/CENELEC (standards) 	<ul style="list-style-type: none"> ▪ Consumer Product Safety Commission (CPSC) ▪ Food and Drug Administration (FDA) ▪ Federal Trade Commission (FTC) ▪ Customs and Border Protection (CBP) ▪ ASTM International (standards)

Main legislation on toy safety

EU	US
<ul style="list-style-type: none"> ▪ Toy safety Directive 2009/48 <p>Other relevant legislation includes:</p> <ul style="list-style-type: none"> ▪ General product safety directive 2001/95 ▪ Regulation 765/2008 on requirements for accreditation and market surveillance ▪ Decision 768/2008 on the marketing of products ▪ Regulation 1907/2006 REACH (Registration, Evaluation and Authorisation of Chemicals) ▪ Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) ▪ Directive 2011/65 RoHS (Restriction on the use of certain Hazardous Substances in electric and electronic products) ▪ Directive 2012/19 WEEE (Waste Electrical and Electronic Equipment) ▪ Regulation 1223/2009 on Cosmetics ▪ Directive 2008/98 on waste ▪ Directive 94/62 on packaging and packaging waste ▪ Directive 87/357 concerning products which, appearing to be other than they are, endanger the health or safety of consumers ▪ Regulation 1935/2004 on materials and articles intended to come into contact with food ▪ Regulation 10/2011 on Food contact plastic materials and articles ▪ Directive 1999/5 Radio- and tele-terminal equipment (R&TTE) ▪ Directive 2004/108 Electromagnetic Compatibility (EMC) ▪ Directive 2006/66 Batteries ▪ Directive 2006/95 Low voltage 	<ul style="list-style-type: none"> ▪ Consumer Product Safety Improvement Act ▪ Federal Hazardous Substances Act ▪ Flammable Fabrics Act ▪ Child Safety Protection Act ▪ Consumer Product Safety Act ▪ Food, Drug and Cosmetic Act ▪ Fair Packaging and Labeling Act ▪ Country of Origin Marking <p>Various State Requirements (Stuffed toy labeling, California Proposition 65, Illinois LPPA, Washington CSPA, Maine KSPA, etc.)</p>

<p>Plus a number of national restrictions applying only in some Member States.</p>	
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Standards on toy safety

EU	US
<ul style="list-style-type: none"> ▪ EN71-1 Mechanical and physical properties ▪ EN71-2 Flammability ▪ EN71-3 Migration of certain elements ▪ EN71-4 Chemical experimental sets ▪ EN71-5 Chemical toys ▪ EN71-7 Finger paints ▪ EN71-8 Activity toys ▪ EN71-9 to 11 Organic chemical compounds ▪ EN71-12 N-Nitrosamines and N-Nitrosatable substances* ▪ EN71-13 Olfactory board games, cosmetic kits and gustative games* ▪ EN71-14 Trampolines* ▪ EN62115 Electric toys <p>* under development</p>	<ul style="list-style-type: none"> ▪ ASTM F963 series under ASTM International

A concrete example

Below is an example of the rules with which a simple plastic toy is required to comply for both EU and US markets. All these requirements aim to ensure children’s safety. However, due to legislative differences, however, these requirements oblige industry to carry out duplicative tests in order to comply with safety requirements which convey the same goal.

EU	US
	
<ul style="list-style-type: none"> ▪ EN71-1 Mechanical and Physical Properties ▪ EN71-2 Flammability Requirements ▪ EN71-3 Migration of Certain Elements ▪ Total Cadmium Content, REACH Annex XVII ▪ Total Phthalate Content, REACH Annex XVII ▪ Total Benzene Content, REACH Annex XVII 	<ul style="list-style-type: none"> ▪ ASTM F963 / 16 CFR 1500 Physical and Mechanical Requirements ▪ 16 CFR 1500 Flammability Requirements ▪ ASTM F963 Soluble Migrated Elements Requirements ▪ Total Lead Content, Consumer Product Safety Improvement Act of 2008 ▪ Total Phthalate Content, Consumer Product Safety Improvement Act of 2008